



Managing Standards for mCHP on Company Level

Abstract micro Combined Heat and Power (mCHP) technology was developed by several established companies and start-ups in parallel. This chapter provides detailed insights into the different companies' innovation management approaches. Based on in-depth interviews, it compares how these firms managed standards and regulation while developing their mCHP products. It shows the types of awareness, expertise, and resources needed to provide a solid foundation for addressing standards and regulation that affect an innovation. Building on this, the chapter shows how these factors enable managers to introduce their innovations into highly regulated markets.

Keywords Innovation management · New product development
Regulatory compliance · Standards · Regulation

The findings outlined in Chapter 3 show the importance of standards for developing the technology of mCHP and bringing the appliances to the market in Europe, thus making standards a key issue to manage as part of this development. Processes to manage these standards occurred on two levels: (1) Each of the involved companies had its own internal NPD process, as part of which standards were addressed. (2) In parallel to these company-internal activities, the industry collaborated on developing new and adapting existing standards to allow mCHP's development, where needed. Both levels interacted throughout the process, i.e. work

within the companies reflected the industry-level developments, and the activities to adapt standards were driven by the individual actors in line with their internal activities.

In this chapter, we focus on the company-level activities related to managing standards for mCHP (see Chapter 5 for a description of the collaboration between actors in the industry). There was a variety in approaches to managing standards and regulation and the degrees to which they were seen as important, as the following quote from an interviewee at a notified body illustrates:

You see differences. Some manufacturers, they – I mean if we have this pre-assessment we push them to really read standards and then you see that some of them, they even haven't bought one.¹ And others, they already read it three times. So there is a difference in experience and seeing the need of using these standards.

We summarise these different approaches in Table 4.1² and outline them in more detail below. In Sect. 4.1, we focus on the companies' general approaches to standards and regulation. This includes aspects such as their awareness of the topic and the degrees to which it is handled strategically, as well as how standards and regulation are embedded into the companies' structures. Section 4.2 then shows how the interviewed companies incorporated standards and regulation into the mCHP development process, covering aspects like the timing of their management, how the companies identified relevant standards and how they incorporated input from the industry level into their development activities.

¹Actors wishing to access the contents of standards developed by the ESOs and their national member bodies must buy the documents from the publishing arms of the standardisation organisations.

²We omit component suppliers from this table because all three interviewed component suppliers' activities related to regulation and standards were tightly linked to those of the appliance manufacturers, rather than standing on their own.

Table 4.1 Overview over appliance manufacturers' activities

	<i>Company A</i>	<i>Company B</i>	<i>Company C</i>	<i>Company D</i>	<i>Company E</i>	<i>Company F</i>
<i>Type of company</i>	<i>Established company</i>	<i>Established company</i>	<i>Established company</i>	<i>Established company</i>	<i>New entrant</i>	<i>New entrant</i>
Awareness of standards' and regulation's importance	High	High	High	High	High, focussing on certification-related issues	Medium on certification-related issues, low on other issues
Technological expertise	High	High	High	High	High	High
Standardisation and regulation expertise	High	High	High	High	Low	Low
Available resources for influencing standards and regulation	Sufficient	Sufficient	Sufficient	Sufficient	Insufficient	Insufficient
Organisational structures for managing standards and regulation	No dedicated staff, the topic is coordinated by a senior engineer	Dedicated staff; additional company internal database of experts to support activities	Dedicated staff	No dedicated staff, the topic is coordinated by the head of the product certification department	Absent	Absent
Degree of strategic orientation for managing standards and regulation	High	High	High	Medium	Low	Low

(continued)

Table 4.1 (continued)

	<i>Company A</i>	<i>Company B</i>	<i>Company C</i>	<i>Company D</i>	<i>Company E</i>	<i>Company F</i>
<i>Type of company</i>	<i>Established company</i>	<i>Established company</i>	<i>Established company</i>	<i>Established company</i>	<i>New entrant</i>	<i>New entrant</i>
Core actors in identifying standards and regulation for mCHP	Company's own engineers	Company's own engineers	Company's own engineers	Company's own engineers	Notified bodies and consultants	Notified bodies and consultants
Conformity evaluation during development process	Important elements carried out in-house	Heavy reliance on notified bodies	Heavy reliance on notified bodies			
Timing of addressing standards and regulation in NPd process	In initial investment decision and at subsequent stages of process	In initial investment decision and at subsequent stages of process	In initial investment decision and at subsequent stages of process	In initial investment decision and at subsequent stages of process	Throughout process	Only in late stages of process
Participation in technology development collaboration	Yes	Yes	Yes	Yes	Yes	Yes
Participation in standardisation and regulation processes	Yes, in a leading role	Yes	Yes	Yes	No	No

4.1 COMPANIES' APPROACHES TO MANAGING STANDARDS AND REGULATION

As the quote in the introduction to this chapter shows, companies in the industry differ substantially on their fundamental approaches towards standards and regulation. Their awareness of the topic's importance varies (Sect. 4.1.1) and they are able to devote different amounts of the required expertise and resources to managing the subject (Sect. 4.1.2). As we outline in Sect. 4.1.3, these different foundations affect the grounding of managing standards and regulation, both in terms of strategic focus and integration into the organisation.

4.1.1 *Awareness of Standards' and Regulation's Importance*

A first factor driving companies' approaches to managing standards in the context of mCHP were the degrees to which they were aware of the topic's importance for developing the technology. This differed according to functions of standards and regulation, such as certification and providing market access, or acting as information sources.

4.1.1.1 *Awareness of Standards for Certification and Related Issues*

Standards and regulation can have a major impact on the certification, market access, and liability questions related to a technology like mCHP (see Chapter 3). One interviewee described this significance as follows:

Both for the technology and the company – the success and the safety of a company – standardisation is an elementary topic. And companies and start-ups must be aware of this. (translated from German)

Most established companies acted in line with this view on standardisation and regulation. Based on their experience in the industry, they treated managing standards and regulation as a necessary condition for successfully developing new products and bringing them to the market. On the other hand, new entrants to the market sometimes did not understand the importance of standards and the European system, as the following quote from an interview with an engineer from a notified body, who had conducted conformity assessment of many companies' mCHP appliances, shows:

Basically, these boiler manufacturers, they already know standards, they know certification processes, so they were from that perspective better prepared. But on the other hand, the start-ups or the Japanese or the Americans are not familiar with the European situation. They were not that focused yet in standards, although some manufacturers were already (...) prepared but some of them were not prepared. Especially the start-ups – for them it’s new to read and understand these standards, seeing the complete picture is difficult for them. And that’s also the case for all parties outside Europe, they don’t understand our system with directives and standards.

While none of the companies that we interviewed lacked awareness to a degree described in this quote, two of the smaller start-up companies explained that their awareness developed throughout the development of mCHP. When these two companies initiated their activities in the field, they did not yet know about the need for considering standards which caused some duplications of effort in the NPD process (see Sect. 4.2).

4.1.1.2 Awareness of Non-certification-related Functions of Standards

On functions which are unrelated to certification that standards can fulfil, such as providing useful information for the technology’s development or defining interfaces, we observed more variation in the awareness among our interviewees. Interviewees at smaller companies mostly focussed their attention completely on standards which are related to certifying the product. They therefore did not seem to have a high degree of awareness of standards’ other functions.

In established companies, interviewees were aware that standards can also fulfil non-certification-related functions. For example, interviewees brought up standards defining interfaces between a heating boiler and a building’s pipework, standards providing information about characteristics of materials for certain applications, and standards reducing variety in components like control electronics. When these functions were mentioned, this was an aspect ‘on the side’, and interviewees saw them as a given when developing new products. They considered them such a basic element of their companies’ internal innovation processes that they did not warrant much attention as part of managing standards and therefore these functions did not play a major role in the interviews.

Nevertheless, the non-certification-related functions of standards were significant for developing mCHP in the collaboration of parts of

the industry that we describe in Chapter 5. Examples include reducing variety by standardising the Stirling engine component across different companies' products, facilitating collaboration in technology development (see Sect. 5.1.1 for both), and defining interfaces with the electricity grid (see Sect. 5.2.1). In addition, developing a standard to provide information about appliances' energy efficiency was a major focus of the industry's collaboration (see Sect. 5.2.2).

4.1.2 *Expertise and Resources for Managing Standards and Regulation*

In addition to a company's awareness, its available expertise and resources are key to the ability to manage standards and regulation effectively. As outlined below, we found in our interviews that this work requires specific expertise which can only be provided if a company has substantial resources at its disposal.

4.1.2.1 *Required Expertise for Managing Standardisation and Regulation*

Our interviews show two distinct topic areas in managing standards and regulation that require different types of expertise: (1) topics with technical, subject-related focus, and (2) topics on a higher, strategic level. The first area comprises all work that is directly connected to the technical contents of the standards, such as contributing to the development of technical requirements in standards and regulation, assessing their implications for product design, and implementing them in technical development. It therefore often requires in-depth subject knowledge. Tasks related to the second type include, for example, following ongoing developments in standardisation and regulation, assessing their significance for the company, and deciding whether and how the company should engage in standardisation and regulation initiatives. This also aims to coordinate the company's standardisation and regulation initiatives, e.g. in terms of assuring that input into a standard for one technology does not result in issues for another technology in the portfolio. One interviewee described his work in this context as follows:

I am responsible for the strategic association work (...). Strategic association work distinguishes itself from operational association work because it is concerned more with which associations we should be part of: Where do we need to represent our interests and, if we have interests there, what

are our positions in the respective topics which are covered by the associations? (...) In addition to the strategic association work, the area of political lobbying belongs to association work. (translated from German)

In addition to the skill sets required for these distinct activities, interviewees agreed that effective of standardisation and regulation and representing the company in external working groups also necessitates staff with a high level of social skills, as the following quote shows:

It is equally important that one has the appropriate standing in these committees. Social skills in the widest sense. Because otherwise one leaves these committees with a lot of confusion and little results. (translated from German)

4.1.2.2 Required Resources for Managing Standardisation and Regulation

Providing the required expertise for managing standardisation and regulation is resource intensive. Especially in the early phases of a technology's development, many issues related to the topic must be resolved. There was consensus among interviewees that new technologies, such as mCHP, require substantial initial effort until the needed standards and regulation are established and all involved parties (manufacturers, notified bodies, regulators, market surveillance authorities etc.) are familiar with the technology. Once a technology has been established, the effort required for managing standards and regulation (e.g. following ongoing developments and contributing to keeping standards and regulation up-to-date) is much smaller.

Accordingly, interviewees reported using substantial resources for managing standards and regulation in mCHP's development. One interviewee stated that his company invested several man-years of work time into mCHP-related standardisation and regulation questions as part of developing the technology. Another interviewee estimated that the work of one out of approximately 30 full-time-equivalent positions involved in developing mCHP at his company was related to the topic. Overall, all interviewees whose companies participated in standardisation and regulation work estimated the effort to be somewhere between three and ten per cent of the overall time and effort for developing mCHP.

Standardisation—and regulation-related activities therefore comprised a relatively small but still significant share of all work needed to bring

mCHP technology to the market. In larger established companies, these resources were usually available as needed, although one interviewee explained that it could sometimes be difficult to convince direct superiors of the required experts to make their staff available for standardisation work because the benefits may be long-term and/or difficult to measure.

Smaller start-up manufacturers explained that their limited resources sometimes hindered their ability to effectively manage standards and regulation, even if they were aware of the topic's importance. Especially participation in standard development and lobbying for changes to regulation was often unfeasible for them, as the following quotes show:

This [participation in standardisation], especially for a small enterprise, is very difficult. Such a new product development by itself already needs a great deal of resources and providing them in a company of our size is already, in my opinion, a considerable achievement. (translated from German)

Definitively, this [participation in standardisation] is an enormous advantage, clearly. But, as I already said, there always is a balancing act at our company regarding what personal and financial resources are available. If one wants to participate there, participate really constructively, then one also has to invest quite a bit. And for us, this is always a balancing act what can be used for that or whether our means can better be used in another place for the actual development work. (translated from German)

Unfortunately, they [the company's clients] didn't pay you to do that [participating in standardisation] and within [company name] we never had enough people. Again, this is where it's difficult to do a lot of product development and standards development from within a small company because we don't have the people, we don't have the money. Yeah, it would be nice to.

4.1.3 Strategic and Organisational Grounding of Managing Standards and Regulation

The degree of companies' awareness of standards and regulation and/or the available expertise and resources determined how the topic was grounded in the company's organisation. This in turn was linked to which degrees the companies could address the topic strategically. Some companies address these issues in an ad hoc manner whereas others

have very clear structures and procedures for addressing standards and regulation.

The smaller start-ups we interviewed fall on the ‘ad hoc end’ of this spectrum. Their lack of dedicated resources meant that they were only able to address the most pressing standardisation and regulation issues at the point when they occurred and could rarely address the topic in a very strategic way. Other companies spent substantial resources to put clear structures in place that support managing issues related to the topic in a strategic and coherent manner. In between these two extremes, other companies implemented some elements to steer their standardisation efforts while using fewer resources to do so. We outline these observations in detail below, focusing (1) on the organisational structures for the management of standards and regulation, and (2) the intra-company networks to facilitate these activities.

4.1.3.1 Organisational Structures for Managing Standards and Regulation

In order to provide the skills needed to fulfil the tasks outlined in Sect. 4.1.2, the companies attached standardisation and regulation activities to different parts of their organisational structures. The first, subject-specific area of activities was directly linked to the product development activities for mCHP at all interviewed companies. It was often stressed during our interviews that it is essential for effective management of standardisation and regulation that a company’s representatives have in-depth technological knowledge. The following are only a few of many quotes in the interviews which stress this importance:

It is very important that in meetings where these topics [standardisation and regulation] are discussed, the technical expertise is present to talk about these topics, so that one does not just stop and say ‘I am going to discuss this and come back next time’ but that one is immediately in a position to make the required points. (...) Otherwise (...) one has to rework everything back at the company, [then] goes back [to the committee], but they are already further. This really hinders the process. Especially these technical expertise and social skills of those who work there and their internal network in the development departments is very important. One cannot simply send any – I don’t want to say business economist – who is detached from the technology. (translated from German)

He [the company representative in standardisation] was extremely close to the project team [and] was very, very deeply involved in the development activities. This means it was not like we had a separate department which assumed the standardisation activities. Instead, the people who were very close to the project also did this. (translated from German)

It has always been important that one directly implements this experience which one has gained in [product] development in the standard. This is extremely important. This is also why the employees who have contributed to the standardisation committees – they all were employees from the new product development area. (translated from German)

And it can absolutely go so far that developers come along to, for example, the ministry of economic affairs to present a topic, explain a topic, precisely because these relationships are partly not trivial and are also not immediately accessible to civil servants, even if they have been at home in this subject area for a long period. Using development engineers for such communication tasks in our association work is something that we have been doing relatively often in the last years. (translated from German)

All interviewed companies assigned subject-related tasks in managing standards and regulation to the development engineers whose work already addressed these technological questions. In contrast, they differed regarding where in the organisational structure the responsibility for the more strategic questions was located. Specifically, we observed three different ways in which this was addressed: (1) Companies at the very ad hoc end of the spectrum of standardisation approaches did not address strategic questions at all, usually because of lacking awareness and/or resources. (2) In companies falling in the middle of this continuum, the topic was often covered as an additional activity by one or a few employees who were also otherwise involved in managing standardisation in regulation. For example, these tasks were handled in one company by a senior product developer and in another one by the head of the department responsible for product certification:

At [company name], we have a division which mainly occupies itself with certification, conformity declaration and so forth. And the head of this department dealt with the coordination [of standardisation activities] in close consultation with the development projects. (translated from German)

(3) Finally, two companies stand out because they have dedicated teams and can therefore be located at the very strategic and professional end of the continuum. The members of these teams to some extent also had a formal function to guide their companies in choosing where to engage and in defining common positions that should be followed by all staff representing these companies in standardisation and regulation. In the first example, the company established a team that is directly responsible to the head of product development which focuses on the strategic questions related to standardisation. In the second example, a team within the company's department of public relations is charged with these topics.

I am responsible for the strategic association work (...). And we are embedded in public relations. (translated from German)

4.1.3.2 Intra-company Networks for Supporting Standardisation and Regulation Work

The organisational structures outlined above mean that the subject-specific questions are potentially addressed by many different experts. While some of the necessary alignment of their activities is ensured by the staff who address the strategic level of a company's standardisation activities, a consistent approach to standardisation also requires communication among the company's experts. In addition, some of the quotes above also show that there is a need for them to remain connected to other engineers who do not participate in standardisation themselves.

In several companies, we observed informal networks to ensure this communication. For example, we learned that one company's engineers who participate in standardisation keep each other informed about their activities through regular e-mail exchanges and other informal communication. Beyond such an informal approach, interviewees at a company that falls on the professional end of the standard-management-spectrum also explained that they support this intra-company network with a database which keeps track of all of the company's standardisation activities and the experts who are involved in this work:

Interviewee 1: [We were talking] of the integration and transmission of information from mainly standardisation committees or maybe also associations into our company structure. For standardisation, we have a network where we can approach specific people through a matrix if

we have specific topics. (...) And in this network different people are named with different focus topics. And they are simply involved if you have such a topic. They then get the information.

Interviewee 2: This is the same for industry associations. (...)

Interviewer: This means a product development team can say ‘we now have this problem here, we are now searching the database for the relevant person and approach him’?

Interviewee 1: This as well, exactly. [And] you can also share information between, I say, stakeholders who are located in different parts of the company. And they know through this (...) company internal network who has also dealt with this specific topic. (translated from German)

4.2 INCORPORATING STANDARDS AND REGULATION INTO mCHP DEVELOPMENT

Following our outline of the general approaches that the companies in the case took towards standards and regulation, we now describe how they incorporated the topic into their development activities related to mCHP. Because most of the interviewees focussed on standards that are relevant for safety and obtaining certification for their mCHP appliances, we also emphasise these areas in our description.

Our interviews reveal four core themes in this context: (1) identifying applicable regulation and standards (Sect. 4.2.1), (2) using them in specifying the company’s product (Sect. 4.2.2), (3) evaluating the product’s conformity to applicable standards and regulation (Sect. 4.2.3), and (4) the degrees of freedom for technology development afforded by standards and regulation (Sect. 4.2.4).

4.2.1 *Identifying Applicable Regulation and Standards*

In a first step of managing standards and regulation for mCHP, the companies needed to identify which regulatory texts and standards would be applicable to the technology’s development. Doing so was important because companies entered new areas where they were unfamiliar with the requirements for the technology. In addition, regulation and standards are not static, meaning that the companies needed to stay aware of changing requirements. We observed two fundamentally different approaches to identifying applicable standards and regulation:

(1) an active approach used by the established companies, and (2) a more passive approach used by the smaller appliance and component manufacturers. Following an outline of these two approaches, we explain how companies in the industry anticipated changing and new requirements for mCHP.

4.2.1.1 *Active Approach*

Established companies usually started with an initial identification of areas of requirements that apply to the technology.

At a very early stage when one defines the product specifications, it has to be clear which standards need to be fulfilled. (translated from German)

This involved the question which European directive(s) applied. Although the characteristics of the technology meant that a number of directives were already set for mCHP (see Table 3.2 for an overview), companies had some leeway in deciding which of them should be the “*leading directive*” (translated from German). All of the interviewed companies chose the Gas Appliance Directive for this purpose, due to their experience with previous products that had been certified based on this directive. This primary choice of directive(s) then guided much of the further search for standards. The following quotes from different interviews illustrate this approach:

Before we address standards, one actually has to go a step back. Before one does this at all, one has to say in today’s environment ‘which directive do I even want to comply with?’. (...) And accordingly, I then have to look which standards are available. (translated from German)

For us, it was clear relatively quickly that we want to work according to the Gas Appliance Directive. The Machinery Directive was also being discussed. But since we certify all our other appliances according to the Gas Appliance Directive, it was actually clear quite soon that we want to go in that direction. (translated from German)

It always has been clear that the Gas Appliance Directive plays a role because the appliance will always have a gas connection, that the Low Voltage Directive will play a role because the appliance always will have an electricity connection, that the EMC Directive plays a role because the appliance has electronic components which can emit or receive electro

magnetic interference. These three directive are always a given, they are also always a given for our current heat generators, you always have to go by them. (translated from German)

The companies were already familiar with directives from their previous products and they also knew most applicable standards in that context, e.g. for gas safety. In other areas, e.g. related to the electricity producing aspects of mCHP, a relative lack of knowledge and experience meant that additional applicable regulation and standards had to be identified after the initial search. In an iterative approach, the search for regulation and standards was linked to the NPD process where moving on to new technological topics also led to the discovery of new standards and regulation for mCHP. The following quote illustrates this:

[At the time] we don't have any experience of or knowledge on electricity generation. So there you're treading a kind of 'terra incognita' and we have to find our way. We're discovering things – some from the outset and we see already at the beginning... 'How does that work with the grid?', 'How to connect with the grid?', 'And what are the requirements?'. And some [topics] we are discovering a bit later, for instance domestic wiring. So, it's a mix in fact of thinking ahead and discovering while you're going your way.

4.2.1.2 *Passive Approach*

Smaller companies relied to a large degree on other parties to identify the applicable requirements for their products. For example, the interviewed start-up appliance manufacturers used the support of notified bodies and/or consultants:

Interviewee: At this point [...] it was about standards and which standards we have to comply with. And then we hired two consultants, one in [the country where the company's R&D department was based] and one consulting company in the Netherlands. This consultancy company is [name of a notified body].

Interviewer: And they in essence created a kind of list for you of the standards that were relevant for the topic?

Interviewee: Exactly. And at this point they have accompanied us very well. (translated from German)

Interviewee: We had to find out for ourselves first which standard – if we wanted to have the mCHP appliance tested as a whole with the aim to obtain a CE-mark – which one would apply there at all.

Interviewer: And how did you proceed to determine what applies in this case?

Interviewee: On the one hand we got in touch with the test laboratories which are active in this area and discussed with them according to which standards they would conduct the tests or which standards apply according to their opinion. And then, in parallel, we also conducted our own search based on these insights. (translated from German)

This role of the test laboratories was confirmed by our interviewee at a notified body:

The process starts very often with the, we call it pre-assessment meeting, where we (...) discuss (...) the complete overview of relevant standards.

Component suppliers also used help from external parties. Because component suppliers were mostly not directly involved in the certification process, they largely relied on the appliance manufacturers to inform them about the requirements arising from regulation and standards. The following quote illustrates this approach:

When this specification sheet is created (...) these are on one hand market requirements (...) but of course also legal requirements. Especially for gas and electricity there are clear safety requirements that must be fulfilled. There is no way around this. The thing is that we get this from our cooperation partner – because he is responsible for bringing [the appliance] in circulation – in a relatively nicely condensed way from one source. That makes it easier. (translated from German)

This reliance on appliance manufacturers to provide lists of applicable standards is partly explained by their ultimate responsibility for the entire product's safety but also by their better knowledge of the application area. For example, one fuel cell manufacturer supplied fuel cells to both mCHP and automotive applications. Our interviewee at that company noted that the standards and regulation in these areas differ to a large extent, making it difficult for suppliers to stay up-to-date and understand the specific requirements without their customers' support.

4.2.1.3 *Anticipating Future and Changing Requirements*

In addition to identifying current standards and regulation for mCHP, companies in the industry also needed to anticipate future requirements for the technology:

If suddenly any new requirements, which impact on our development, come out of the standard, then it is extremely important to know this at an early stage. (translated from German)

Because mCHP's development took several years and the products needed to be certified according to the requirements in place at the time when they were released to the market, it was essential to already anticipate these requirements during the design process. Participating in standardisation and other working groups is key for learning about—and influencing—these developments (see Chapter 5). In addition to information about upcoming standards and regulation, this participation also provided the companies with further knowledge. In many cases, participation in standardisation committees brought them in contact with stakeholders outside the heating industry. This provided insights into these stakeholders' needs, their views on mCHP, and implications for the products' design in order to make the technology acceptable for these external stakeholders and even provide additional value for them (e.g. in the context of electricity grid stability, see Sect. 5.2.1).

While much of this information about upcoming requirements and other stakeholders' views was obtained by participating in standardisation, the participation's resource intensiveness sometimes made this unfeasible. Established companies sometimes relied on external consultants who participated in standardisation committees on their behalf whereas the smaller companies again largely relied on notified bodies to obtain information before new standards and regulation were made publicly available:

At this point we have, for example, a consultant who informs us, for example, about technical standards. Through this pipeline, through this consultant we get tips about which new standards are changing for us now and in the future. And as a second channel, [name of notified body] informs us about changes. (translated from German)

Especially for the smaller companies with insufficient resources, this was the only way of accessing advance information about upcoming standards, putting them at a disadvantage compared to established players who could directly participate in the process or hire consultants to do so on their behalf:

Of course, we always got access to this [information about developments in standardisation] a bit later. This is clear. I would say that there have been tips from time to time in which direction this goes or similar things. But this is, as I already said, a process which you have to accompany continuously if you want to be really close to it. And this does not always work when you also have to deal with every-day problems. (translated from German)

4.2.2 *Specifying the Product*

Following the identification of requirements for mCHP, their implications for the product needed to be specified. This specification of the requirements had far reaching consequences for mCHP's further development, the product's viability, and thus eventually also the technology's success. A first step in specifying the requirements was 'translating' them into concrete technical terms and including them into the product's specification sheet, which took substantial effort in itself:

We had requirements from the standards but the process [within the appliance], the appliance, the concept must first undergo a risk analysis from which requirement specifications are derived: 'What do the controls look like? Which sensors are required? What is the performance? Which failure models?' (translated from German)

As part of this activity, the established companies³ also faced the question whether to apply the existing standards and regulation to the technology or whether to attempt influencing the requirements (see Chapter 5 for a description of how they did do so):

³The smaller start-up players did not face this choice due to their limited resources, and had to design their products based on the given standards and regulation.

You have the product and you have the regulations and finally they have to comply, either by changing the product, adapting the product to the regulations or by adapting the regulations and standards to the product.

4.2.2.1 External Support for Specifying Requirements

Because of the importance and complexity of specifying the requirements, most interviewed companies again called on external support, like they did in identifying the requirements. This support came from (1) notified bodies, (2) external consultants, and (3) using pre-specified components.

Again, the smaller start-ups relied on notified bodies' help to understand the contents of relevant standards and regulation. Their consulting activities accompanied these players' development of mCHP products and included an important element of explaining the requirements:

We started with this pre-assessment, then the consultancy phase, to assist them in understanding the requirements and the standards.

Our consultancy is really focussing on the standards, on the content of the standards.

Although the notified bodies performed such consulting activities, these activities were limited in scope and could not cover the full specification process in order to avoid conflicts of interest when eventually certifying an mCHP appliance. The notified bodies could not go as far as proposing design solutions or supporting the companies' risk assessment, which were assessed at a later stage in the certification process. This made some of the notified bodies' consulting work as 'grey area', as our interviewee at a notified body acknowledged, and they needed to be careful not to exceed their role:

Of course, there is a grey area. (...) We cannot do a risk assessment of an appliance because afterwards we have to assess this risk assessment. That's not allowed, so the consultancy we do is advising them on the requirements in the standards. (...) So, we give them some guidance but we cannot say 'you have to change this'. That's not our role.

Because of these limits to the support that the notified bodies could provide, several companies, including all major actors who we interviewed,

also relied on an independent consultant in the field. Several interviewees named him as the leading expert for standards and regulation for mCHP. This consultant described his focus as “*consulting companies during the development of a safety-related concept*” (translated from German). He was involved in various ways in the product development of the different companies to support them in implementing the standards and regulation. Sometimes he was involved only at selected points in the companies’ NPD processes to address specific issues, e.g. when notified bodies pointed out problems during the certification process that the companies could not address without help. In other cases, his input into technology development was much more substantial:

My development work in many of these projects is writing the safety-related specifications of the requirements. There you write in detail: ‘Which standards, which features and how are they implemented?’ In some cases, I also write the safety-related concept for the software. (...) My consulting goes up to successful certification. (translated from German)

In addition to hiring external experts for support in the specification process, companies could also rely on pre-specified components from suppliers for certain safety-critical parts of the appliance. Especially smaller companies made use of this option. This allowed them to meet key requirements from standards and regulation without spending scarce resources on own developments and specifications:

There are certain safety devices. This is, for example, the automatic firing device which we do NOT develop ourselves. This is a purchased part from companies like [company names] which have been established in that area for years. These developments cost a lot of money because they include building failsafe controls and software. They are inspected by a notified body and we then rely on ready-made products. We cannot afford to develop such things ourselves. (translated from German)

4.2.3 *Evaluating Conformity to Regulation and Standards*

In order to make their final products conform to the regulation and standards, companies also needed to evaluate this conformity at different stages in the development process. Below, we outline what we learned about (1) the initial evaluation at the outset of their development

projects, and (2) the review procedures throughout the development process.

4.2.3.1 Initial Evaluation of Regulation and Standards for mCHP

Especially the established companies, with their high awareness of regulation and standardisation and their professional approach to managing the topic, already addressed standards and regulation as an issue in their initial appraisal of mCHP technology's potential. When making the business case for mCHP and deciding whether to invest in its development, an analysis of the degree to which standards and regulation would support or hinder the technology was essential:

A certification capability analysis, doing this is a standard procedure. Is this product even capable of being certified at all? Are there any hurdles from a standard or regulatory point of view? This is something one does very early. (translated from German)

Such evaluations often did not only consider regulation and standards that were directly relevant for certification but also could be wider in scope. The following example shows how important such analyses can be: One interviewed company first assessed the technology's potential in 2000 when it was concluded that the regulation for feeding electricity into the electricity grid was unfavourable, only allowing an insufficient return on investment for buyers of mCHP appliances. Because of this insight, the company decided not to invest in developing mCHP technology at that point in time. The company then re-evaluated mCHP technology in 2004. At that time, the requirements had changed and it was deemed feasible to manage remaining issues during the NPD process so that regulation and standards would no longer hinder mCHP when the technology would be ready for market entry. Following this assessment, the company initiated its development activities.

4.2.3.2 Evaluating Conformity Throughout the NPD Process

Following the decision to initiate the NPD process for mCHP, most interviewees stressed the need to assess regularly whether the developed solutions were in line with requirements from regulation and standards. At most interviewed companies, this was incorporated into the project management tools used to manage mCHP's development, e.g. by including the topic in the progress evaluation at regular milestones or in

the companies' stage-gate processes. Doing so was seen as a way to prevent duplication of effort that would have been caused by not addressing the issue throughout the process and then having to adapt the product in the late stages of development to make it acceptable for certification and market introduction.

In several instances, the ongoing evaluations of conformity throughout the NPD process were also advised by the notified bodies and the independent consultant mentioned in Sect. 4.2.2. Especially the smaller players relied on the advice of notified bodies to identify areas that they needed to address before their products were ready for the certification process, as the following quotes from interviews with a start-up and a notified body show:

We definitely tried to develop the first prototype in 2004 in a standard-compliant way. We also collaborated with a test laboratory which supported us in a consulting manner but we did not really try to get the CE-mark yet for this prototype because it was clear that we still would need fundamental revisions. (translated from German)

And after that [the initial pre-assessment meeting] we dig into the technology itself and we check for what the risks are and where some parts of the system do not meet the standards, so the safety – this is purely focussing on safety. And then what follows is very often a kind of consultancy phase where they are further developing the system.

So they say 'we have this safety concept' (...) and then we say 'OK, it does fit for 90% and this 10% does not fit'.

4.2.4 *Degrees of Freedom for mCHP's Technological Development*

A final theme related to managing standards and regulation in mCHP's development that recurred in our interviews was the degrees of freedom that the requirements left for developing innovative solutions. As we outlined in Sect. 3.2.2, not following standards carries substantial additional effort for the NPD process. Although "*undertaking this effort*" can "*sometimes [be] worthwhile if one has corresponding cost savings*" (translated from German), it became clear during our interviews that companies rarely did so in developing mCHP. Usually, standards were perceived

as leaving sufficient freedom to develop the technology, and notified bodies were flexible in interpreting them, as the following quotes show:

Standards usually leave the latitude to get equivalent solutions accepted – this is often the case. (translated from German)

[Name of notified body] in this context paid attention to the content of the standards and not the wording of the standards. So the content – safety – was more important than narrowly [following the standard word-for-word]. Our engineers enjoyed the product-oriented interpretation of standards. (translated from German)

Despite this generally positive view on standards and regulation across all interviewees, we did observe some disagreement on two aspects related to how they should best be handled in the NPD process to provide optimal freedom for the innovation. This disagreement concerned (1) dealing with the missing standards, and (2) the timing of involving standards in the NPD process.

4.2.4.1 *Handling Missing Standards in the NPD Process*

As outlined in Chapter 3, some important standards for mCHP were missing when the industry started the technology's development and key requirements were therefore unknown at the outset of mCHP's development. Some of the interviewed companies saw the resulting uncertainty as a bigger problem for the whole NPD process. They therefore focused their efforts (see Chapter 5) on creating certainty as quickly as possible by engaging in standard development. However, other companies valued this situation as an additional degree of freedom for the engineers in developing the technology. They took this opportunity to experiment with new approaches to product safety, which they later contributed to the standardisation process:

Interviewee 1: To the contrary, we could shape the standards very well based on our experience and the freedoms which we had [when the standard was still missing]. Especially not being regulated, overregulated and restrained too much in the beginning gave us much space to develop our safety concepts and develop ideas that we might not have had if there had been a relatively fixed standardisation frame. And this was very positive. As this point, we started using HAZOP analysis (...) a very interesting tool which we got to know in the USA and then

brought to Germany (...). And this is now also anchored in the standard. (...) And this has helped us a lot to be certain that we are on a good way with this new technology.

Interviewee 2: In collaborating with the Americans (...) – they had a different safety philosophy. (...) And with the standard as we have it now, there is on one hand clearly the European strategy of prevention but through the risk analysis we now have a bit more free space. (translated from German)

4.2.4.2 *Timing of Handling Standards and Regulation in the NPD Process*

A second aspect related to freedom for product development where the views diverged was the question at what stage in the development to start addressing questions related to standards and regulation. In particular one interviewee stressed that doing so too early would restrict the ability develop novel solutions, and that standards only became helpful at a later stage in the process when the prototype-mCHP-appliances were transformed to production models:

He [the manager of the development process] attached great importance at this point to avoid restricting the innovation through standards. They [the development team] perceived this as hindering in the early stages. (...) At this point in time standards would have hindered the engineers. (...) And then, at this point [later in the process], there is a bridge when the engineers see the need to be standard-compliant and this is helpful to bring the product to the market. (...) At this point, the company is getting used to standardisation and thinking in standards. When you standardise, when you produce in large numbers then you have certification, then you must [adapt] processes (...) and at this point, the freedom of the engineers is limited anyway. (translated from German)

[The development team] always (...) wanted a development strategy which put the innovation, the innovative element first. This is the fundamental thought which brings the product to life. And in this place, they always [aimed] to first find the technical solution and (...) later adapt it to the standards. Because you don't get a working system just like that and it can happen that a new development dies on the workbench in the lab if you already restrict it with standards at this stage. (translated from German)

In contrast to this strong view, all other interviewees advocated addressing standardisation and regulation early in the development process, as demonstrated by the very early first assessment of requirements outlined in Sect. 4.2.3 and shown by the following exemplary quotes:

Interviewee: It's really important that with your first step this pre-assessment [involving the notified body] takes place in a very early stage of the development.

Interviewer: So, is there already a prototype or even before that?

Interviewee: Even before that is better. But in practice, I think, half of the cases, they already have a prototype. And some are very late. But I think about half of the parties, they didn't have a prototype yet, only paperwork.

Interviewer: What would you suggest in general to a company in a similar situation which also develops a product where standards and regulation are relevant?

Interviewee: Deal with this topic early on. (...) Not just developing a product or anything and then we'll see what we have to adhere to. Instead, incorporate this from the outset and say 'this is what I want to develop, what do I have to take into account?'. Not just having the technical specifications in mind but also looking immediately at what [requirements] are coming from the market and what we have to consider to bring it into the market at a later stage. (translated from German)

The interviewees, who favoured this approach of addressing standards early, reasoned that this avoided duplicate effort in developing the technology. According to this reasoning, the limitations in freedom for innovation imposed by standards only restrict the development of solutions that are not suitable for certification and therefore would need to be replaced by other approaches at later stages anyway (or require changing the standards). This is also reflected in the experience of one interviewee whose start-up encountered substantial rework in its early technology development projects because of not considering standards and regulation early enough and changed its development approach based on this experience.

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