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Sensemaking of Organizational Rule Systems: Requirements for a Modeling Method

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Abstract. Organizational rule systems, comprising internal rules, external regulations, and contractual obligations, pose significant sensemaking challenges for actors in heavily regulated sectors. For example, actors need to consider conflicts and incoherence among rules, how higher-level rules are refined by complementary rules at lower levels, and how rules are changed over time. This study aims to elicit requirements for a visual modeling method that supports practitioners who are not rule experts in comprehending and navigating such rule systems. Within the framework of design science research, the study uses a case study of the Swedish regulatory system for health data innovation. Data were collected through both semi-structured interviews and documents, and analyzed using theory-driven thematic analysis based on complex adaptive systems theory. The results include a thematic map and a structured set of requirements for the proposed modeling method. In summary, the requirements specify a method that allows the user to move up and down multi-level hierarchies, sometimes drilling deep into details, sometimes looking at high-level emerging patterns. These requirements lay the groundwork for designing and evaluating the modeling method.

Keywords: Organizational Rule System, Complex Adaptive System, Case Study, Thematic Analysis, Legal Design, Requirements Engineering.

1 Introduction

Organizations operate through a dense and evolving set of rules that include legislation, regulations, standards, contractual obligations, policies, and guidelines. Such rule systems are not only external constraints on organizational action; they constitute information that must be interpreted, negotiated, and then operationalized by organizational actors in everyday work. Organizations are expected to identify which rules matter, understand how they relate to one another, and translate them into decisions — often without legal experts. In other words, they must make sense of rule systems that are multilayered, ambiguous, and continuously changing.

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This challenge is amplified in settings where rules originate from multiple institutional levels and domains and where their practical implications are difficult to infer from any single document or expert interpretation. Consequently, organizational rules require continuous *sensemaking*.Sensemaking research has shown that organizational actors construct workable understandings under conditions of interpretive ambiguity rather than simply retrieve fixed meanings [1]. This implies that the problem is not only one of compliance or formal correctness, but also one of human–information interaction: how actors comprehend, navigate, communicate, and use complex rule-related information in order to act.

One way of supporting sensemaking of organizational rules is *enterprise modeling (EM)*, which can provide structured visual representations that support shared understanding, analysis, and communication across heterogeneous stakeholder groups [2], [3]. A structured approach to modeling requires a well-defined *modeling method* [3]. A modeling method is composed of a modeling language, implemented using a modeling procedure [4]. A modeling method may support sensemaking of rules by enabling actors to externalize interpretations, compare viewpoints, identify dependencies and conflicts, and develop a shared language for discussing rule-related issues.

1.1 Study Aim and Approach

Against this background, the aim of this article is to develop a theory-grounded understanding of what a modeling method must support in order to help organizational actors make sense of complex organizational rule systems. Accordingly, the research question is: *What are the requirements for a modeling method that supports sensemaking of organizational rule systems?* It is aimed not at solving one isolated domain problem, but at generating knowledge about the representational and analytical capabilities that such a modeling method should provide.

To address the research question, this study employs a qualitative case study approach based on interviews and document analysis. As an analytical lens, we view organizational rule systems as complex adaptive systems (CAS) [5], in other words, socio-technical and multi-level relations of organizational actors and rules. CAS theory highlights features that are under-represented in conventional modeling approaches: messiness, fuzziness, non-linearity, non-determinism, feedback, emergence, and adaptation — features that complex rule systems exhibit. CAS theory is prominent in describing complex situations, such as in healthcare management [6]. In the same vein, our definition of an organizational rule is wide: an element of guidance that regulates the action space of an organizational unit. This definition includes rules of both internal and external origin. Organizations and regulations are a type of CAS that we denominate *organizational rule systems* [7] and define as a CAS constituted by organizational agents and the organizational rules that regulate their interactions. Based on this CAS perspective, the focus of this research is on the sensemaking of the higher-level rules that require significant human interpretation of their meaning in relation to other rules in the organizational context.

Firstly, this study contributes to providing a theory-grounded set of requirements for modeling organizational rule systems. Secondly, it offers empirically grounded insights into how organizational actors engage in sensemaking in complex information environments characterized by ambiguity, overlap, and change. In doing so, the article extends the study of rules from a primarily legal or compliance-oriented concern to a broader view of understanding, representation, and interpretation in complex settings.

The remainder of this article is organized as follows. Section 1.2 presents the context through a case study in which the data collection was conducted. Section 2 expands on the research background. Section 3 presents the research methodology. This includes the case study research strategy described in Section 3.1, data collection from interviews and documents described in Section 3.2, and thematic analysis described in Section 3.3. Section 4 presents the results of the thematic analysis and identified requirements, including a map of the themes. Section 5 discusses

strengths and weaknesses of the study and revisits the research question. Section 6 concludes the article.

1.2 Context of the Study

The present study was undertaken in the context of the Health Data Sweden (HDS) project[†], in which the first author is involved. The overall goal of HDS is to stimulate innovation using health data to contribute to improved healthcare. HDS is, in turn, a member of the umbrella project DIGIfor1healthSE[‡], which gathers other projects in Sweden working towards the same goal as HDS, although from different angles. One of the deliverables of the HDS project is to develop a legal toolbox[§] for small and medium-sized enterprises (SMEs): an easy-to-use guide for understanding regulations in the healthcare area.

The study is part of a *design science research* (DSR) PhD project related to HDS. The overall research aim of the project is to design a visual modeling method that supports practitioners in heavily regulated fields who are not experts in rules and regulations in their sensemaking of organizational rule systems.

A modeling method, as any artifact, can be constructed within the DSR paradigm [8]. A full DSR cycle includes the following six phases: explicate problem, elicit requirements, design artifact, demonstrate artifact, evaluate artifact, and communicate it [9], [10].In previous studies, we have explicated the problem by analyzing what CAS theory means for enterprise modeling (EM) [11] and completed a systematic mapping review of existing EM efforts on organizational rules in complex settings, analyzed with a framework of CAS theory concepts [7]. In this study, we define the requirements through a case study informed by practitioner interviews and documents, preparing for the artifact design.

2 Background

Rule modeling has a rich history that, from several angles, informs this project. It spans efforts to express detailed, computable rules, approaches to modeling business rules, and more abstract ontological frameworks for the analysis of legislation. This section provides a brief overview, while also explaining why yet another method is needed.

Starting with business logic [12], there are decision tables that specify what to do under certain circumstances. There are also standards such as Business Process Model and Notation (BPMN) that make it possible to represent the rules that control a process. However, these rules are on a rather detailed level and usually of the determinate kind, such as “if the value of an order exceeds 1,000 EUR, it must be signed by a manager”. While standards such as BPMN are imperative, representing how to do something, other standards are declarative, stating what should be done and what is allowed. One example is the Case Management Model and Notation (CMMN), which complements BPMN for more unstructured and knowledge-intensive work. This is closer to our need, but not sufficient, since we are interested in an even higher-level understanding of complex issues. Our interest is not in modeling process cases, but entire systems. It is therefore unfeasible to model what the rules exactly imply in a specific situation.

While standards such as BPMN and CMMN are used to represent rules, other standards focus on metadata of rule descriptions, for example, the European Legislation Identifier (ELI) [13], which “is a framework to make legislation metadata available online in a standardized format”. These standards for metadata align with our approach insofar as they can be used to model a high-level, interconnected system. For instance, they can express how legislation is interconnected. However,

[†] https://www.healthdatasweden.eu/
[‡] https://digifor1health.se/
[§] https://legaltoolbox.healthdatasweden.eu/

they do not express the behaviors that occur when agents interpret, implement, and enforce (or ignore, circumvent, or violate) the rules.

Business modeling standards such as Semantics of Business Vocabulary and Business Rules (SBVR)[¶], together with its sister standard Business Motivation Model (BMM[‖]), offer an extensive number of constructs that align with our purpose of organizational rule modeling. However, these standards also lack sufficient focus on agency and behavior, and provide few mechanisms for viewing a system at different levels of abstraction, which is essential for sensemaking of large, complex networks. Moreover, both SBVR and BMM models are often expressed textually, even though visual meta-models also exist.

There are also legal ontologies. Two of the most prominent are UFO-L [14] and LKIF-Core [15]. Of these two, the most relevant for our work is UFO-L. The main reason is that LKIF-Core, based on legal positivism, assumes clearly applicable norms, which may not be the case in a complex system. UFO-L, on the other hand, allows for the balancing of contradictory principles and can, together with the UFO-B event ontology, also model behavior. On the other hand, UFO-L is detailed in a way that makes it incompatible with our aim of overall sensemaking.

In summary, to the best of our knowledge, there are no visual EM methods for high-level sensemaking of rule systems. What essentially distinguishes our aim is the focus on high-level sensemaking, to contribute to an overall understanding of entire systems of rules that affect an organization.

3 Methodology

This section describes the research strategy as well as data collection and analysis methods.

3.1 Research Strategy: Case Study

The study employs a holistic, single-case study [16] approach. A case study strategy was preferred because the concept of an organizational rule system is still new and needs to be explored in depth, something case studies excel at.

The chosen case is the Swedish regulatory system for health data innovation, and the studied phenomenon is organizational rule systems.

The case was delimited as follows:

1. It includes actors with the goal of substantially contributing to health data innovation in Sweden.
2. It includes organizational rules that affect how these actors can contribute to this goal. This includes indirect effects. For example, a rule that results in healthcare staff not having time for innovation is included.
3. It also includes the actors that make these rules.
4. Other organizational rules and actors are excluded.

The case was primarily selected because of its challenging regulatory complexity. Previous research suggests that the domain of health data, characterized by heavy regulation, intricate collaborative care chains, and goal conflicts between the right to health and the right to personal integrity, provides a complex setting [17]. Second, legislation is usually well-structured and publicly available. As argued by Yin [16], access to the relevant sources is essential in case studies. Third, the main author already had some insights into the case through the HDS project mentioned in Section 1.

[¶] https://www.omg.org/spec/SBVR/1.5/About-SBVR
[‖] https://www.omg.org/spec/BMM/1.3/PDF

3.2 Data Collection: Semi-Structured Interviews and Documents

Two data collection methods were used: semi-structured interviews and document studies. The selection was purposeful, meaning that interviewees and documents were chosen based on their expected ability to provide information relevant to the research question. The intention was to gather sources that describe, from different viewpoints, how the Swedish health data regulatory system is experienced by innovators, and how this system functions on a more general level.

3.2.1 Semi-structured Interviews

The selection of participants, shown in Table 1, was purposeful; the seven participants were selected based on their knowledge and experience of regulatory issues in the Swedish health data field in the area of healthcare innovation. The participants were selected through the HDS project. They have experience of dealing with regulatory issues from different angles: from being innovators themselves, from working in Swedish regions — which are responsible for public healthcare and important collaborators of innovators — and from helping innovators navigate legal issues. Three of the participants were co-founders of medical device start-ups that had previously answered a digital questionnaire distributed by the HDS project, indicating that they had a need for support regarding regulatory issues. The other four participants were in different roles and degrees involved in the HDS project.

Table 1. Overview of interviews

Interview	Participant	Experience	Selection rationale
1	1 and 2	Co-founders of Organization 1, a start-up developing a medical device.	Executives of small innovative companies in health data are among the foreseen end-users of the modeling method to be proposed.
2	3	Co-founder of Organization 2, a start-up developing a medical device.	Same as above
3	4	Mid-level manager in Organization 3, a Swedish Region.	Regions are central actors in the system, both as interpreters and creators of rules.
4	5	Innovation expert in Organization 4, a Swedish Region.	Same as above.
5	6	Innovation expert at a center for innovation in health technology supporting companies in their innovation process, including regulatory issues.	Experts helping companies accumulate knowledge about how these companies experience the system.
6	7	Legal expert supporting clients with health data regulatory issues.	Same as above.

The six interviews were semi-structured, using a script, available in Appendix Appendix B, with questions grounded in themes from the analytical framework. One of the interviews was conducted as a group interview with both co-founders of one of the start-ups. Before the interviews, all participants were given a written presentation of the study, including detailed information about confidentiality, to which they gave their informed consent. The interviews took place during the spring of 2025.

3.2.2 Document Study

Documents were included in the study to provide more details of the complexity of the regulatory system. Three larger documents, shown in Table 2, together comprising 257 pages, were studied systematically. Two of them were practical guides on medical device manufacturing [18]

(Document 1 in Table 2) and health data [19] (Document 2), and the third was an overview [20] (Document 3) of the state of the Swedish health data system.

Table 2. Overview of documents

Doc.	Title (translated)	Description	Selection rationale
1	Handbook for Efficient Development of Medical Devices. [18]	Handbook for manufacturers of medical devices recommended by one of the company interviewees; 164 pages.	A resource of this kind aggregates accumulated experience and describes the concepts that are most relevant for innovators.
2	The Health Data Guide [19]	Website guide for innovators in the health data field presenting a seven-step model for innovation, of which one is about regulatory issues; 17 web pages.	Same as above.
3	DIGIfor1healthSE – a collaboration for sustainable access to and use of health data [20]	An overview of the state of the Swedish health data system, including access to health data, legal analysis (including at the EU level), and recommendations to policy makers. 76 pages.	As a complement to Documents 1 and 2, this source provides a bird's-eye view, explains problematic aspects, and is directed to policy makers.

3.3 Data Analysis

The interviews were recorded and then transcribed non-verbatim using a tool from the Department of Computer and Systems Sciences, Stockholm University. Both interview transcripts and studied documents were subject to thematic analysis, drawing from Braun & Clarke [21], moving from extracts to codes, to subthemes, and themes. The analysis was theory-driven, using a framework of 15 CAS concepts from the systematic mapping study [7] mentioned in Section 1.2 as predefined themes. The concepts were identified through consulting more than 30 articles and book chapters about CAS in organizations. The framework is presented in Table 3.

Table 3. Analytical framework with predefined CAS themes. (Definitions of each subtheme are presented in Section 4).

Theme	Subthemes
Complexity Characteristics	Messiness [22], Fuzziness [23], Non-linearity [24], Non-determinism [25]
Constitutive Components	Constraint [26], Agent [27]
Systemic Structure	Environment [28], Multi-level system [29], Structural Emergence [28]
Short-term Dynamics	Interaction [5], Event [30], Behavior [30], Behavioral emergence [28]
Adaptive Dynamics	Feedback loops [31], Adaptation [27]

The *complexity characteristics* theme relates to the nature of reality in which a CAS exists. The theme's *constitutive components* and *systemic structure* provide a snapshot of the system, i.e. a static view. The theme's *short-term dynamics* and *adaptive dynamics* describe the behavior of the system. The meaning of each concept is briefly defined in Section 4. For a more detailed discussion, we refer to the mentioned systematic mapping study [7].

The subthemes discovered in the data were latent [21] rather than semantic; that is, they were identified through analytical work that went beyond the explicit or surface meaning of the data.

For each of the nine sources (six interview transcripts and three documents), we identified text extracts related to how people perceive and deal with regulations. We were looking for text extracts

of four different types. The first type was about *rule sensemaking issues*, either in how people perceive or deal with regulations in general. The second type was about *how sensemaking is affected* by the rule domain characteristics of the Swedish regulatory system for health data innovation. For instance, an observation that the rules do not give all the answers that an entrepreneur may need, or that it is impossible to know exactly what regulations are applicable at the beginning of the design of a medical device. The third type consists of extracts expressing *domain-specific concepts and relations*, in other words, statements close to what in ontology design is called competency questions. An example is that "a regulation is created by an organization". The fourth type of text extracts contained concrete, *domain-specific facts*, for instance, that "the Swedish Medical Products Agency has a role as competent authority with regard to the EU Medical Device Regulation (MDR)". The fourth type extracts can be considered instances of the third type. The first two types distinguish between general sensemaking challenges and those shaped by domain-specific regulatory characteristics. The third and fourth types align with distinctions common in ontology engineering and conceptual modeling between domain concepts and relations, often articulated through competency questions, and concrete domain instances. Jointly, the four types form a layered analysis, in which the analysis of higher levels benefits from the lower levels.

The tool used for the thematic analysis was Kumu.io, an interactive network diagram tool.

For each identified text extract, the following steps were undertaken:

1. Register the extract with a unique identifier.
2. Connect the extract to a code (new or existing) that very briefly captures the essence of the extract in the light of CAS theory.
3. Connect the code to a theme (new or existing). The theme can either be one of the predefined subthemes or a subtheme created bottom-up based on the codes.
4. If the theme is new, connect it to another, more abstract, theme.
5. Before proceeding to the next extract, ensure that all the nodes in the Kumu map are connected to one single graph.

Specifically, during the analysis, a thematic map, using the Kumu.io tool, was created. As shown in Figure 1, the map initially consisted of the five predefined themes as top-level nodes, connected to the 15 predefined subthemes.

As the thematic analysis proceeded, discovered (second-level) subthemes were added and connected to the predefined subthemes. The thematic map was refined iteratively to ensure logical paths from code to main themes.

After working through all the sources, the analysis was refined top-down. For each of the predefined subthemes, the connecting themes and codes were revised, and if needed, rearranged. The most common change was to add detail to the mapping by grouping similar incoming themes and codes into new subthemes.

We did not have a lower bound for how many codes or extracts were needed to render a theme. This means that a single extract from a participant or document could give rise to a requirement. In the same vein, we do not intend to prioritize the requirements or classify their strength. Rather, we treat them all as tentative, and defer to the design and evaluation phase to decide which will remain. We consider this justified due to the exploratory focus of the study and the concept of organizational rule systems.

Finally, some of the discovered subthemes could be used to deduce requirements for the proposed modeling method. In principle, most discovered subthemes could have each resulted in a requirement, but to avoid many overlapping requirements, only the most relevant were used for this purpose. The resulting Kumu map is available online[**].

This study uses interviews, document analysis, and thematic analysis to elicit requirements. The requirements are documented as a structured list, with each requirement explicitly linked to themes

[**] https://kumu.io/joran/projekt1-thematic-analysis-aggregated

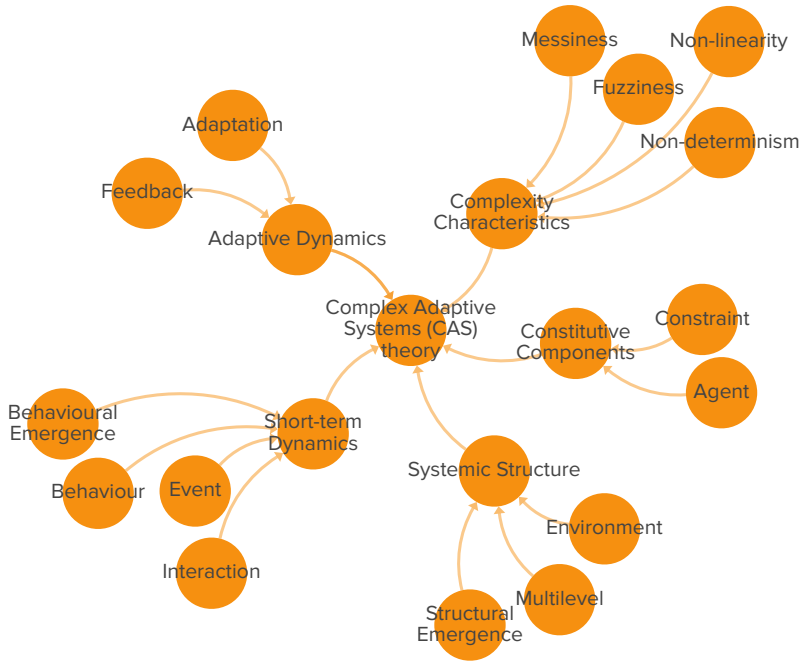

Figure 1. The predefined themes and subthemes of the thematic analysis, derived from the analytical framework in Table 3.

to ensure traceability to source data. Subsequent design work may use these requirements as a basis for formats such as user stories, use cases, or scenarios. Such requirements formats are useful once the problem domain is sufficiently understood. However, as this study examines challenges in sensemaking around organizational rule systems, a theory-driven and interpretive elicitation and documentation approach was prioritized.

4 Results: Thematic Analysis and Elicited Requirements

This section presents the results of the thematic analysis and resulting requirements. This section describes important characteristics of the Swedish health data regulatory system, as well as problems and strategies related to sensemaking in this system.

The presentation of the predefined subthemes is structured as follows. For each predefined subtheme, the discovered (second-level) subtheme is presented with a paragraph, usually followed by an illustrative quote. Since the thematic analysis, as mentioned in Section 3.3, was latent rather than semantic, some themes lack illustrative quotes. Each of the referenced discovered subthemes has an identifier and a title, such as *T1. Rule incoherence*. The quotes have been translated from Swedish to English. Each quote is attributed to both its source and extract identifier. Sources can be interviews (I), such as *Participant 5, I4.2*, and documents (D), such as *Document 1, p. 54, D1.151*. The identifiers correspond to the thematic analysis available in the online Kumu map mentioned in Section 3.3. After the discovered subthemes have been presented, a summary is made, from which the requirements are deduced. The requirements also have identifiers corresponding to the Kumu map, for instance, *R1. Represent incoherence among rules*.

4.1 Complexity Characteristics

The main theme of complexity characteristics is composed of the subthemes messiness, fuzziness, non-linearity, and non-determinism. These phenomena characterize the nature of reality in which an organizational rule system exists.

4.1.1 Messiness

Ackoff [22, p. 22] defines messes as "large and complex sets of interacting problems, dynamic systems of problems". Messiness thus refers to a systemic condition in which multiple, interrelated problems coexist and cannot be meaningfully addressed in isolation.

T1. Rule incoherence. Participants expressed how rules collide with other rules, and that there is often no clear guidance for the agents who have to manage the collisions. One high-level example was the sometimes contradictory interests of patients and the interest in stimulating economic growth.

> *To be honest, I don't think they [the rules] go together – which I find very disturbing. I find it difficult to deal with this situation – that they actually don't go together. (Participant 5, I4.2)*

T2. Complex or just complicated? On the other hand, there is a certain degree of order to the rules. For instance, according to Document 1, the CE (*Conformité Européenne*) marking for medical devices usually requires a conformity assessment by a notified body. Knowing this can help address rules in an effective order. Moreover, participants stated that, with much work, it is normally possible to step-by-step disentangle the web of regulations that they encounter.

> *If, for example, you take one point – producing a risk analysis – then you need to know what a risk analysis should contain and what it is, but that's not so difficult to find out. (Participant 3, I2.43)*

Other actions cannot be taken without first having other things in place, which provides a natural roadmap for the order in which to address different problems.

T3. Applicable rules in particular situations. In addition to a more general understanding of the rule system, there was also an expressed desire to break down which rules apply to a particular situation or part of an organization's operations.

> *It would generate a great deal of value if they could be given a framework: if you are this product, this type of product, then you should operate within these frameworks. These are the rules that apply to you, and this is the list of what you need to have in place. In other words, a checklist. (Participant 7, I6.45)*

Also, in a complex system, there are problems that do not reside in the complex domain, but in the complicated or clear domains, using the terminology of Snowden [32]. In these cases, it should be possible to represent in a model that a particular situation has characteristics that, in general, are regulated by certain rules.

To summarize messiness in the Swedish health data regulatory system: In large rule systems, there are often conflicts and other dependencies that are complicated to grasp. Some of these constitute wicked problems and cannot be properly disentangled, and even less so by a model, which is a simplification of reality. What can be done by a model in these cases is to simply point out the conflicts and other types of incoherence (T1). On the other hand, other dependencies are less complex and can be at least partially managed by using step-by-step procedures and by breaking them down into checklists (T2). It is also possible to map a particular situation to the rules that reasonably apply to it; in other words, which rules a situation is subsumed by (T3).

Based on the thematic analysis of the data collected from the analyzed case, requirements could be deduced. The modeling method shall:

- R1. Represent incoherence among rules.
- R2. Represent decomposition of rules and compliance activities.
- R3. Facilitate identifying which rules may be applicable in a specific situation.

As can be seen, R3 is formulated at a higher level than the requirements presented so far, which is distinguished by formulating it with "facilitate" instead of "represent". This distinction is further discussed at the end of Section 4.

Figure 2 shows how the thematic analysis led to the requirements of the messiness theme. For instance, Extract I4.2 contains the quote above from Participant 5, stating that the rules do not always go together. This extract, together with other extracts with similar statements, is grouped into one code, labeled "many rules do not add up". This code is, in turn, grouped into a theme labeled "rule incoherence, from which a requirement is deduced: "R1. Represent incoherence among rules". As can be seen, the requirements are traceable to specific extracts from the collected data.

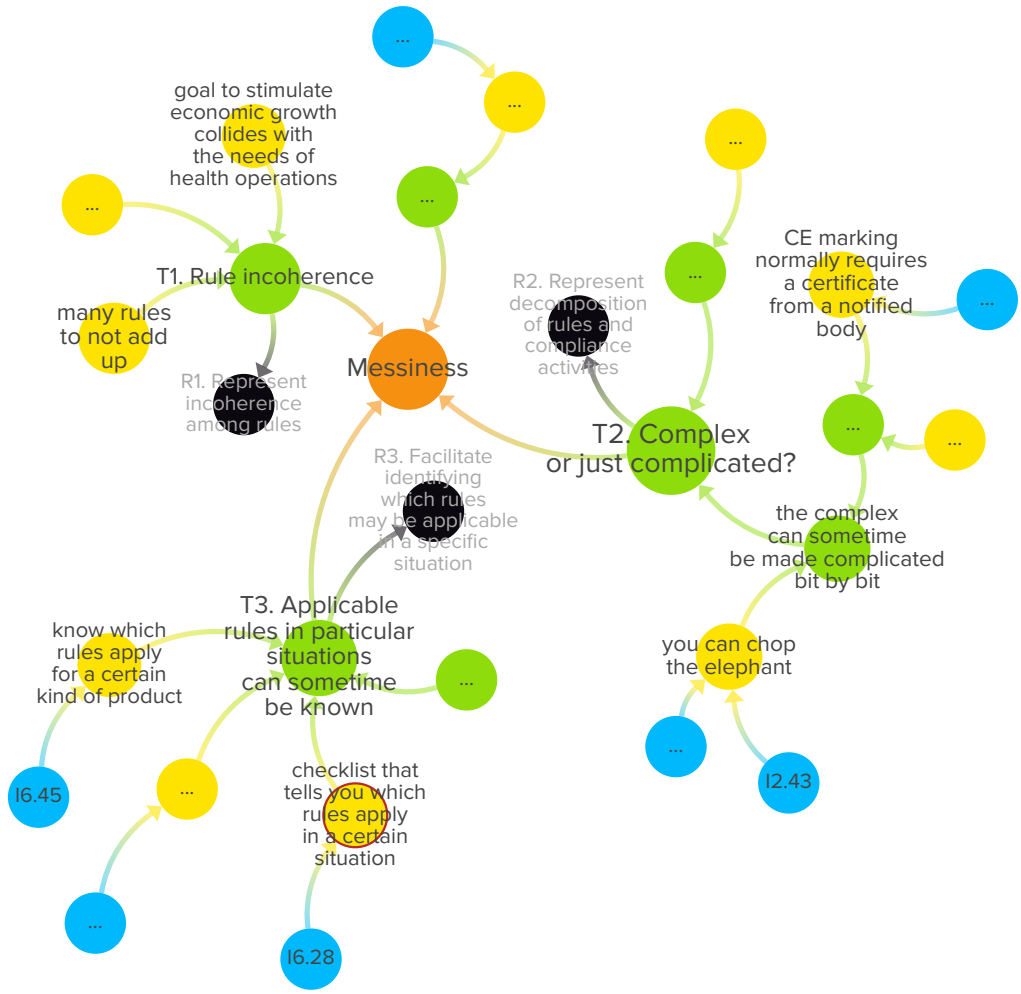

Figure 2. Thematic analysis of the messiness theme. Blue circles are extracts, yellow circles are codes, green circles are themes, black circles are requirements, and the orange circle is the messiness theme. To reduce clutter, the figure does not display all the leaves associated with each theme and code, whether direct or indirect. They are instead represented by circles with three dots ("...")

4.1.2 Fuzziness

According to Zadeh [23], fuzziness is the presence of vague boundaries, making classifications and distinctions between elements imprecise or less relevant.

T4. Rules overlap. The analyzed documents and interviews showed the presence of fuzziness in the form of different types of overlap: overlapping or unclear legal concepts, regulations with overlapping content —such as the Medical Device Regulation and the In Vitro Diagnostic

Regulation— and rules whose compliance requires the same actions as other rules, such as the Medical Device Regulation and the AI Act.

> *With several different standards, all of which impose requirements on [product] specifications, it quickly becomes a large collection of documents that is difficult to manage. For example, there needs to be a specification for usability according to IEC 62366, one for software according to IEC 62304, and one for risk reduction measures according to ISO 14971. (Document 1, p. 54, D1.151)*

On the other hand, participants noted that the relation between rules in the form of overlap can also be seen from a positive perspective: If you comply with one rule, you have probably also partially complied with another.

> *I would like to see how they [rules] relate to each other. Whether there is overlap between different rules and how they are applied in different regions. (Participant 1, I1.23)*

T5. Unclear if rules are mandatory. Participants also explained that non-experts often need help to understand which rules are mandatory and which are more flexible. Other participants argued that, since it is often impossible to comply with all formal rules, there is a need to understand which rules are more important than others.

> *And then the question often arises: 'But... is it an obligation, or is it just nice to have?' It's very common to encounter this: 'What do we really need to do – at a minimum – to comply with the regulations?' (Participant 7, I6.27)*

While it is understandable that practitioners want clear and accessible answers to the question of whether a rule is mandatory or not, fuzziness is a reason to believe that the answer will not always be binary but rather resemble a scale. For instance, some standards are formally voluntary but in practice close to mandatory.

T6. Rule priority. Also, among rules that are all formally mandatory, there can be a need to understand which are more important than others.

> *If you have five rules in your department – which in reality is often five hundred – and your staff only has time to follow three of them. (...) Then, as a manager, you have to decide which three are most important. (Participant 5, I4.44)*

T7. Rules influence beyond their lifetime. Another aspect of fuzziness is the time frame during which rules apply. Influential legislation is said to be important to take into account before it starts to apply, and even before it is finally decided. For instance, Document 2 mentioned (D2.19) that the European Health Data Space (EHDS) Regulation — which entered into force in March 2025 to later be complemented by other legal acts — may bring more explicit rules about journal systems and health apps. At the other end, abolished rules can have effects that are observable and need to be understood also after their life-cycle.

> *As a manufacturer of medical equipment, we must comply with European regulations. We are currently certified under the old directive, MDD from 1995. And then there is the new one called MDR, Medical Device Regulation. (Participant 1, I1.5)*

To summarize fuzziness: First, there is overlap (T4) both among rules and concepts. Different rules regulate the same thing, and definitions of concepts in rules can be absent, overlapping, or unclear. Second, it can be challenging to understand whether, or to what degree, a rule is mandatory or not (T5). Third, in practice one may have to prioritize among rules that should all be fulfilled (T6). Fourth, some rules can have relevance before and after their formal life-cycle (T7).

From the above, requirements can be deduced. The method shall:

- R4. Represent how rules overlap.
- R5. Represent variation in stipulated rule enforcement. In particular, the difference between formally binding and non-binding rules.
- R6. Represent rule compliance priority. For instance, which rules —binding or not— are more important to comply with than others.
- R7. Represent temporal aspects of rules. In other words, what has been and can be, not only what is.

4.1.3 Non-linearity

According to Aritua et al. [24, p. 77] non-linearity is when "small changes in the initial conditions or external environment can have large and unpredictable consequences in the outcomes of the system".

T8. Event leads to rule change. Some regulatory changes are the result of particular scandals, created with a "never-again" mindset. Individual events can send shockwaves through a system and provoke rule changes. One intra-organizational example occurred in a hospital unit regarding the use of peripheral intravenous catheters (PIVC).

> *But at some point, an infection had developed – and then the manager introduced a rule: that the PIVC should be checked every day and that this should be documented. This increased the workload – and created frustration among the nurses. It became like a backseat driver checking something that was obvious to them. (Participant 5, I4.28)*

T9. Design process thresholds. Another aspect that innovators struggle with is understanding how much attention they should invest in regulatory issues at different points of the development process. An easy mistake is to wait too long and then realize that the product must be redesigned.

> *I think it's difficult for them to know where to start, so I feel that they often want to have come quite far in their development before they tackle it [the rule and regulation]. So they say, 'Yes, but we're not there yet.' (Participant 6, I5.16)*

To summarize non-linearity, specific events can result in important rule changes, often with the idea that more control will avoid future problems (T8). This relates to the importance of understanding the rationale of a rule, discussed in Section 4.1.4. A second aspect of non-linearity is that it can be difficult to foresee when it becomes very costly to redesign a product to achieve compliance (T9).

From the above, requirements can be deduced. The method shall:

- R8. Represent if a rule was created in response to a particular event.
- R9. Facilitate understanding of how compliance with rules should be developed over time. For instance, understand at which point in the development process to concentrate compliance efforts.

4.1.4 Non-determinism

Non-determinism is the opposite of determinism, which, according to Marion & Uhl-Bien [25, p. 391], "is the belief that all events are caused by preceding events and by knowing the preceding variables one can predict the future with certainty".

T10. Unpredictable interpretations. Non-determinism was present in the analyzed material in different ways. Participants perceived an unpredictability in the rule system; it was often hard to know whether one had complied with a given rule. Sometimes it will also take considerable time before an authoritative interpretation is made. Even legal experts can make very different assessments, as can be seen when, for instance, a court overrules the decision of a lower-level court.

There is a need for clarity in laws that take each other into account and for consistency in their interpretation at national, EU and international level. (Document 3, p. 53, D3.87)

T11. Socially constructed. These disagreements demonstrate the socially constructed nature of the regulatory system. Important rule interpretations are supported by one social agent and disputed by another.

T12. Rule rationale. Participants also observed that interpreting a rule is easier if one understands its underlying rationale. Either by knowing the particular events that led to their creation (discussed above under non-linearity), or their stated purpose.

If I understand the purpose, it becomes much easier to relate to the rules. It's like an example from small children: If someone says, 'You mustn't pick your nose,' then I want to know why. (Participant 5, I4.43)

To summarize non-determinism: First, the interpretation of rules can vary between experts and over time, leading to uncertainty if one has complied with a rule or not (T10). Second, the reality of organizational rule systems is partly socially and subjectively constructed (T11). Third, knowing the rationale of a rule helps in interpreting it (T12). For instance, which other rules (including goals) it is meant to support.

From the above, requirements can be deduced. The method shall:

- R10. Represent rule interpretation variability.
  - R10a. Represent the agent behind an interpretation.
  - R10b. Represent that rules can be the result of interpretations of other rules.
  - R10c. Represent that an interpretation can conflict with another one, and possibly overrule it.
- R11. Represent the source of a rule and its interpretations.
- R12. Represent the rationale for a rule.

4.2 Constitutive Components

The component theme consisted of two subthemes: constraint and agent. These are the fundamental building blocks of an organizational rule system.

4.2.1 Constraint

According to Snowden [26], constraints "shape a system by modifying its phase space (its range of possible actions) or the probability distribution (the likelihood) of events and movements within that space". Snowden argues that constraints can be both enabling and governing; while some possibilities are reduced, others are expanded.

T13. Enabling constraints. Participants expressed that rules and regulations can be helpful for designing a quality product. Rules in general, and standards in particular, embed best practices and expert experience.

Basically, it's a good thing because it gives you something to work with so you can make a good product that's safe and effective. (Participant 3, I2.17)

Participants also gave examples of rules that clearly allow someone to do something, in other words being enabling rules.

Region Halland sees the EHDS Regulation as enabling legislation that supports the direction the region has already chosen. (Document 3, p. 43, D3.79)

T14. Concepts-rules interplay. During the document analysis it became apparent that rules are formulated with concepts. Many important concepts have legal definitions. For instance, Article 2 of the Medical Device Regulation (MDR) defines a *medical device*. A user who understands the concept poorly will also understand the rule poorly.

T15. Types of rule descriptions. Several different types of rule descriptions were mentioned both by participants and in documents: industry standards, different types of Swedish legislation, EU legislation, and a few examples of US legislation. Understanding the type and status of a rule description is important to interpret the rules it contains.

To summarize the constraint concepts: First, constraints are not only controlling but can also be enabling, increasing the action space of an actor (T13). Second, constraints not only regulate things, but they also define the terms that are used in rule descriptions (T14). Third, there are many different types of documents declaring rules, with different implications (T15).

From the above, requirements can be deduced. The method shall:

- R13. Represent the distinction between restricting and enabling rules.
- R14. Represent that rules may define roles and objects.
- R15. Represent types of rule descriptions, such as standards, regulations, and legislation.

4.2.2 Agent

An *agent* in a CAS is an entity capable of influencing its own goals and making independent decisions [27].

T16. Agents decide. Participants expressed that agents do not always act strictly according to formal rules for many reasons. One is that they believe that doing so would be in conflict with higher goals and principles. Bending the rules can then become a strategy for change.

> *If you are transparent in what you do and have good intentions for the patient, you will go a long way. We must be courageous in what we do —that is how we change the laws— instead of waiting for the laws to change. So we have to push forward and get things done. (Participant 4, I3.47)*

T17. Rule costs. Social agents interact not only according to rules, but also according to their limited time and resources. Some rules can be associated with considerable costs. For instance, Document 1 showed that acquiring and implementing a quality management system (QMS), mandatory for medical device manufacturers, might cost a small company 100,000-300,000 EUR (D1.49). Rules can also have costs in terms of labor time and waiting time, for instance, waiting for public authorities to give their approval. Having to comply with tight deadlines is another form of rule cost.

> *Most [innovators] don't realize how much money and time is needed. (Participant 6, I5.14)*

Arguably, recognizing that factors other than the formal rules themselves strongly influence what agents do implies that it becomes less relevant to try to model the workings of rules in detail.

To summarize the agent concept: First, agents can, to a large extent, decide which rules to follow and how (T16). This also relates to non-determinism. Second, rules come with different types of associated costs for agents (T17).

From the above, requirements can be deduced. The method shall:

- R16. Represent that agents are regulated by both formal and informal rules.
- R17. Represent that resources and other costs can be associated with rule compliance.

4.3 Systemic Structure

The systemic structure theme is composed of three concepts: environment, structural emergence, and multi-level. They all relate to how the building blocks of an organizational rule system form a whole.

4.3.1 Environment

An organizational rule system, like any system, exists within a boundary, which separates it from the external *environment* [28].

T18. Location matters. Also in the digital age, it matters where an agent is located geographically. It was mentioned in the documents that proximity to actors that offer guidance makes interaction with them more effective. Moreover, there is legislation that is specific to a country or a region.

> *The choice of notified body is therefore a strategic decision. There are several important parameters to consider: (...) Proximity – Proximity facilitates cooperation, as it is easier to hold in-person meetings and demonstrate products. It also reduces travel time and travel costs during inspections. (Document 1, p. 34, D1.86)*

From the above, a single requirement (R18) can be deduced. The method shall:

- R18. Represent the geographical area of rule systems and participating organizations.

4.3.2 Multi-Level

According to Wilson et al. [29], a CAS is likely to exist within a larger *multi-level* system. The rules that constrain the behavior of agents in the lower-level system will also affect the higher-level system, positively or negatively.

T19. Bottom-up structures. A multi-level structure can be accessed bottom-up or top-down. Starting with the bottom-up aspects, Document 3 (D3.1) revealed how actors create new structures through collaborations to fill an unmet need. Actors start to interact, form collaborations, which are then formalized and start behaving like actors in their own right.

T20. Conflict referral. Another bottom-up aspect is that when there are disagreements about rules, there is often a process for settling the matter. This process can be in the form of a third party, such as a court, negotiations between the parties, and/or an escalation up through a chain-of-command.

> *You discuss and discuss [the conflict matter] until you can't discuss any more. And then you send it up the line. And it can go all the way to the top. (Participant 4, I3.42)*

T21. Rule refinement. Top-down aspects were also found. The document studied shows how both laws and standards can have other laws and standards that implement or refine them at lower levels. For instance, the GDPR sets the overarching EU rules. This is defined nationally by the Swedish Data Protection Act and the Swedish Data Protection Ordinance. The European Commission also issues implementing acts for technical details, while the Swedish Authority for Privacy Protection (IMY) adds even more detailed regulations and guidance. Finally, organizations translate all of this into their own internal policies and routines. Organizations and administrative geographical units have similar hierarchical levels.

Interpretation of the primary legal text can be supported by accessing explanatory resources or refining acts. However, non-experts are not always aware of their existence or do not know how to find them.

> *And then you also understand that there are so many levels of regulatory documentation that can provide guidance. You never reach that level, you only reach this... surface level. (Participant 7, I6.29)*

In summary, the multi-level concept has several aspects: First, organizations can jointly form new, higher-level structures (T19). Second, rule conflicts can be escalated upwards (T20). Third, higher-level rules are often refined by complementary rules and interpretations at lower levels (T21).

From the above, requirements can be deduced. The method shall:

- R19. Represent higher-level organizational structures — organizations of organizations.
- R20. Represent how a conflict about rule interpretation can be escalated to higher-level organizational units.
- R21. Represent how higher-level rules are refined by complementary rules and interpretations at lower levels.

4.3.3 Structural Emergence

Emergence is when a whole acquires properties, often unpredictable, that are qualitatively different from its parts [28].

T22. Need for overview. Participants expressed the need to be able to grasp the larger system and get an overview, including finding out if one is unaware of important regulations.

> *I want to be able to see the big picture of everything that affects me in some way, or that I need to relate to as a company or as a developer of a product or service. Because you can never get that from a text. (Participant 6, I5.31)*

> *It [the planned method] could reveal things that we may not be fully aware of. Perhaps it can reveal some blind spots that we have. (Participant 3, I2.51)*

The systematic discovery of additional important entities can be supported with modeling methods with significant discovery power [33]. This allows the understanding of the system to evolve through experience and iterative work.

T23. Emergent topology. Another approach to providing an overview of an organisational rule system is characterizing its structure, in other words, its topology. For instance, to what extent the power to create new rules is concentrated or distributed. The rules and actors form emergent structures, which are sometimes described using different metaphors in the interviews. The whole system was described by the participants as: a jungle, a spider web, a body of water (with surface and depth), an insurmountable mountain, an elephant that can be cut up piece by piece, and a fragmented landscape. Legal areas were described as bubbles or cans, in which organizations could put too little or too many resources. The frequently produced legal acts from the EU lead to an increased regulatory weight and are considered hard to digest fast enough.

> *The rules can be seen as a kind of spider web, with different levels. And by being aware that GDPR, the Patient Data Act, and the MDR exist, you really only reach the first level. (Participant 7, I6.30)*

T24. Both parts and wholes are regulated. Structural emergence in its simplest form is about aggregation and composition, and hence also its opposite — decomposition — already discussed in Section 4.1.1. Some regulated concepts, such as medical devices, are built from components that are already regulated, or are created by processes that are regulated. The designers of the device must then consider the regulations of both the parts and the whole.

> *It is important to choose a good, effective adhesive that does not damage the skin. And that brings you into contact with chemicals in a completely different way than when you work with electronics. (Participant 3, I2.21)*

Related to the above, sometimes the purpose of a regulated concept is dependent on another concept. For instance, the documentation of a medical device has no purpose without the medical device. On this notion, hierarchies can be built.

In summary, structural emergence has several aspects: First, it is difficult to overview these systems and be confident not to overlook something important (T22). This is supported by a

modeling method's ability to contribute to finding new rules and depends on its discovery power (T22a). Second, sensemaking of complex systems can be improved by describing their topology, for instance, by leveraging already-existing metaphors in users' mental models (T23). Third, objects are often composed of, or existentially dependent on, other objects which in turn are regulated. For instance, a medical device that has a chemical substance as a component (T24).

From the above, requirements can be deduced. The method shall:

- R22. Facilitate making large rule systems easier to overview and explore.
- R23. Facilitate discovering new rules over time.
- R24. Represent the overall structure — emergent topology — of a rule system. For instance, by having a free text property that allows for finding suitable metaphors for its characteristics.

Note that decomposition (T24) is covered by requirements R2, R19, and R21.

4.4 Short-term Dynamics

The short-term dynamics theme was composed of four concepts in the applied analysis framework: interaction, event, behavior, and behavioral emergence. These concepts relate to the short-term behavior of an organizational rule system, i.e., behavior that does not involve redesigning the system itself.

4.4.1 Interaction

In a CAS, there is *interaction* [5] between agents according to their constraints.

T25. Guides and enforcers. Participants expressed that innovators of medical devices need to interact with other agents, both public authorities and other bodies, for guidance on how to interpret the rules. Many regulations also assign an organization or role responsible for their enforcement. These enforcers, and other agents, can also assume a guiding role, advising the regulated agents on what to do in practice. Innovators need to understand both who the enforcer is and who can offer guidance. Some enforcing organizations also provide substantial guidance. An example of this dual role is that of auditing firms, which manufacturers of medical devices need to hire; they both guide about rules and contribute to their enforcement.

> *I think what is particularly difficult is understanding the framework of which supervisory authorities exist, but perhaps above all: where can I get help, what help do I need, and how much help do I need at a given time? (Participant 7, I6.42)*

T26. Communication about rules. Participants expressed the idea of being able to communicate more effectively externally about the rules and limitations within one's organization.

> *When I am sitting in a meeting, when my partner in the municipality or in a department in a municipality says, 'No, that's not possible, we can't do that.' Then you want to understand what they are saying no to. And why are they actually saying no? What is causing the problem? It would be wonderful if we had something for that. (Participant 4, I3.49)*

To summarize the interaction concept: First, the compliance with rules depends very much on the enforcing and guiding roles of other agents (T25). Second, in organizational collaborations, it can be difficult to effectively communicate one's own rules to other parties (T26).

From the above, requirements can be deduced. The method shall:

- R25. Represent that agents can have enforcing and guiding roles with regard to rules.
- R26. Facilitate communication and common understanding of organizational rule systems between people with different backgrounds.

4.4.2 Event

Events are produced by interaction between agents [30]. The thematic analysis revealed that an impactful event can lead to changes in a rule system, as discussed in Section 4.1.3).

T27. Processes. The analysis also showed that some rules form processes, for instance, the manufacturing design process of a new medical device can be broken down into steps in a certain order. This also relates to the discussion about decomposition in Section 4.1.1.

From the above, a single requirement can be deduced. The method shall:

- R27. Represent that organizational rules can stipulate in what order activities should happen.

4.4.3 Behavior

Events form patterns of *behavior*. According to Meadows [30], a system's behavior over time is more interesting to observe than isolated events in order to understand the workings of its internal structure.

T28. Non-compliance. One type of behavior is patterns of non-compliance. For instance, it appears that some researchers ignore certain regulations.

> *However, there are a number of research projects that share confidential information with foreign organizations in international research collaborations, without having any legal basis for doing so. (Document 3, p. 67, D3.100)*

From the above, a single requirement can be deduced. The method shall:

- R28. Represent to what extent a rule is violated or complied with.

4.4.4 Behavioral Emergence

Behavioral emergence is about behavioral properties at the system level [28], often unexpected and undesired.

T29. Joint rule effect. Participants expressed that it is not easy to know how rules jointly will affect the behavior of an agent or system.

> *I think it's very difficult to understand how many regulations you're affected by if you're going to get involved in this. That there are so many, and that they interact with each other. (Participant 6, I5.24)*

The conflicting rules about innovation support, health data use, and patient safety jointly appear to lead to a system that, in spite of much effort, does not appear to gain momentum.

> *Innovations are not being used to improve processes, treatments or whatever else is needed in the region. Allowing innovation to benefit citizens is extremely often hindered. (Participant 5, 4.25)*

To summarize behavioral emergence: An organizational rule system will develop system-level behavioral characteristics (T29).

From the above, a single requirement can be deduced. The method shall:

- R29. Represent how a system as a whole can have properties, including behavioral characteristics. For instance, a rule system can have a property *'activity level'*, with the predefined values from *suffocated* to *vibrant*.

4.5 Adaptive Dynamics

The adaptive dynamics theme includes two concepts: feedback and adaptation. These concepts are necessary for understanding how and why an organizational rule system redesigns itself, in other words its long-term dynamics.

4.5.1 Feedback

Feedback "provides the learner with information on the real or projected outcome of their actions" [31, p. 802], and can spark adaptation.

T30. Feedback in many forms. Analysis of the interviews showed that feedback can come in many forms. One type is criticism from monitoring authorities or auditing bodies.

> *We are not afraid of audits; we see it simply as a tool for getting things right. (Participant 3, I2.25)*

Another, more indirect, type is when competitors or other actors with common denominators receive feedback, for instance, in the form of judicial decisions. Yet another type is external guidance before a decision.

At the political level, lawmakers create feedback channels in the form of, e.g., official government investigations that analyze the effects of existing rules. Document 2 explains how to leverage these channels:

> *Next, you need to submit your views to the forum where the legal discussion in this area is currently taking place. First, contact a government inquiry or committee if you can identify one that seems to have a suitable focus. (Document 2, D2.5)*

To summarize feedback: Feedback, by design or by chance, can come in many forms from different types of sources (T30).

From the above, a single requirement can be deduced. The method shall:

- R30. Represent how feedback regarding rule impact can reach an organization in many forms from different types of sources.

4.5.2 Adaptation

Adaptation can happen through different mechanisms. One is that an agent observes how the behavior resulting from its interactions aligns with its goals, changing its own constraints accordingly [27].

T31. Adaptation in many forms. As discussed in Section 4.2.2, when staff do not agree with existing formal rules, they may start to bend them; in other words, create informal rules that they think better align with, for instance, higher-level goals. Sometimes, after a while, formal rules may also be changed to reflect the informal rules. A formal rule change can be made in different ways. One is to write new rules. Another is to write a rule that, in turn, adopts or endorses existing rules, for instance, standards. A third is decisions from, for instance, courts (especially those courts whose decisions are considered jurisprudence).

To summarize adaptation: Rules can be changed in many ways (T31). First, rules can be explicitly declared through changes in the rule documents. Second, rules can also be changed through practitioner praxis. These rules can be observed and described, even though they have never been declared. Third, rules can also be created through subscription to existing rules. Fourth, authoritative interpretations also modify rules.

Based on the above, requirements can be formulated. The planned modeling method shall:

- R31. Represent how rules are changed.
  - R31a. Rules can be declared in formal rule descriptions.
  - R31b. Represent how rules — for instance customary rules and informal practice — are changed through the behavior of agents.
  - R31c. Represent how an actor chooses to subscribe to voluntary rules, such as standards.
  - R31d. Represent that an authoritative interpretation by an agent changes rules.

In total, 31 main requirements and 7 sub-requirements were collected based on the five CAS themes. A compiled list of all elicited requirements is available in Appendix Appendix A.

Requirements can be formulated at varying levels of abstraction, from directly supporting the main design goal to detailed specifications [34], [35]. This is also the case for the requirements in this study, which fall into two categories, reflected in their formulation as either "Represent" (n = 33) or "Facilitate" (n = 5). The first category closely resembles competency questions and can generally be operationalized as simple subject–predicate–object statements. The second category instead captures higher-level goals rather than representational demands. Higher-level original requirements can be broken down into lower-level created requirements [35]. However, in this study we did not do this, for a number of reasons. First, this study focuses on capturing stakeholder needs. Second, not all requirements will be possible to implement. Third, the design process of the method will be an iterative, exploratory exercise, in which we expect to gain insights that will make detailed requirements from this study obsolete.

Later in the DSR process, these requirements must be evaluated. The first category can be evaluated using informed argument [9], or by demonstrating the method to experts, while the second, higher-level, category should be evaluated with users.

5 Discussion

This section discusses the trustworthiness of the study and revisits the research question.

5.1 Trustworthiness of the Study

The trustworthiness of qualitative research can be assessed using the criteria of credibility, dependability, transferability, and confirmability [36].

Regarding *credibility*, the study benefits from using two complementary data collection methods. The fact that one of the authors is engaged in a project that supports health data innovation also strengthens the credibility.

No member checks were done with the participants. On the other hand, after having designed the method, an extensive evaluation with practitioners is planned.

As mentioned in Section 3.3, subthemes and corresponding requirements can sometimes be created that are grounded in just one interview or document. This was the case for requirements R6, R12, R19, R23, R27, and R28.

The credibility was arguably enhanced through the use of an analytical framework, which constrains interpretations and should improve analytical consistency. On the other hand, a strongly theory-driven collection and analysis of data can also lead to results that would confirm the theory regardless of the data sources. In this study, and the PhD project that it is part of, we adopt the position that organizations, collaborations, and rule systems (including legal systems) can and should be viewed as CAS. Multiple scholars in management and organization studies support this view. However, there are of course other scholars in the same field who would argue for other theories. Thus, there is a risk that the analysis is somewhat blind to insights that do not align with CAS theory. We expected to find codes and themes that would not fit as subthemes to any of the predefined themes but did not. This could be seen as a sign that the predefined themes provided good coverage of the area. However, it could also indicate unconscious Procrustean classification, that is, a tendency to shoehorn observations into existing categories. On the other hand, the themes were open to unexpected mapping. Most notably, the messiness theme was used to group statements in which the participants effectively stated that some problem situations are not very messy. In other words, the messiness theme was also used to describe "un-messy" results.

Some of the predefined themes attracted considerably fewer themes and codes from the collected data than others, in particular, the environment theme. There were competing predefined themes from different angles, making the environment theme rather redundant. Also, the predefined themes

of non-linearity, non-determinism, behavioral emergence, and feedback were clearly less used than others. One possible reason is the focus on what non-rule experts need to know (Documents 1 and 2), even if we did also include a document (Document 3) in order to touch upon dynamics and emergence of the overall system. However, this could be addressed in future studies that focus more on what rule-makers need to understand about the behavior of a large system over time.

The *dependability* was enhanced by developing the thematic map available online, allowing readers to trace how codes and themes were developed and related.

Regarding *transferability*, the case study could be criticized for being too focused on (a) external rules, in particular, legislation, compared to intra-organization rules; and (b) on a particular field and country, namely health data innovation in Sweden. Regarding the focus on external rules, we concede that having had more access to internal rules would have been preferable. Regarding the focus on health data in Sweden, we have tried to avoid deducing requirements that seem specific to this country. Moreover, since the Swedish health data regulations are, to a large extent, dependent on EU regulations, there is reason to believe that there is considerable transferability to other EU member states. On the other hand, Sweden has one of the highest levels of digitalization in the EU [37], which could reduce the transferability to less digitalized countries. We plan to amend these limitations in future studies. As argued in Section 3.1, in-depth understanding through a comprehensive case study was preferable to other research strategies.

The *confirmability* could be negatively affected by the main author's involvement in the HDS project. On the other hand, the findings were discussed with the other authors who were not involved.

5.2 Revisiting the Research Question

The research question was: What are the requirements for a modeling method for sensemaking of organizational rule systems?

As shown in Section 4, practitioners consider it challenging to, for instance, estimate the legal implications of their choices, overview how rules overlap, interpret the meaning of legal terms, and explain their own rules to other parties. The elicited requirements are presented in Section 4. In short, they specify a method that allows the user to move up and down in multi-level hierarchies, sometimes drilling deep into details, sometimes looking at high-level emerging patterns.

We did not find any particular conflicts between the requirements. However, EM methods generally need to strike a balance between expressiveness and simplicity in order to be useful. It is therefore probable that not all 35 requirements of the first type ("represent") can be directly implemented. Here, there is a need for a broader design target concerning how to maximize the uptake of the method among practitioners. In this respect, and continuing with using CAS, information infrastructure design theory [38] provides pointers on how the envisaged modeling method could be designed to maximize adoption. This design theory uses complexity and adaptive systems (CAS) theory as its kernel theory and emphasizes that designers of artifacts intended for widespread use must relinquish some precision and control in order for the artifact to gain traction. Among other things, it recommends designing for immediate usability for a limited target group of users, prioritizing crude abstractions over correctness, and focusing on modularity and layering. In this way, there is an increased likelihood that the artifact will obtain a critical mass of users who then can continuously co-create and adapt it. Information infrastructure theory can thus guide the design, together with the identified requirements.

5.3 Comparison with Existing Modeling Artifacts

Some requirements identified in this study can already be partially addressed through existing enterprise modeling approaches. For instance, modeling of actors, goals, and business rules is supported by artifacts such as 4EM [3], iStar[**], UFO-L [15], BMM and SBVR. However, the

[**] https://www.cin.ufpe.br/ jhcp/pistar/

elicited requirements combine these perspectives while also supporting exploration of large, adapting, and interconnected regulatory systems.

6 Conclusion

This study elicited requirements for a modeling method for sensemaking of organizational rule systems. It did so through a case study on the Swedish regulatory system for health data innovation. The concrete results were a thematic analysis presented as a Kumu map and a set of requirements for the planned modeling method. The study moves the DSR process from a stage of having theoretically explicated the problem and mapped previous studies to a point of having defined concrete requirements informed by practitioners.

As for future research, the identified limitations of this study can be addressed in future design iterations. Moreover, we will (as mentioned in Section 5.2) use the information infrastructure design theory [38] to inform the design for the foreseen method. However, the next step will be to design the modeling method according to the elicited requirements and demonstrate it. The subsequent step will be to conduct a formative evaluation to refine the method.

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References

[1] K. E. Weick, K. M. Sutcliffe, and D. Obstfeld, "Organizing and the Process of Sensemaking," *Organization Science*, vol. 16, no. 4, pp. 409–421, 2005. Available: https://doi.org/10.1287/orsc.1050.0133

[2] J. Stirna and A. Persson, *Enterprise Modeling: Facilitating the Process and the People*. Springer International Publishing, 2018. Available: https://doi.org/10.1007/978-3-319-94857-7

[3] K. Sandkuhl, J. Stirna, A. Persson, and M. Wißotzki, *Enterprise Modeling: Tackling Business Challenges with the 4EM Method*. Springer, 2014. Available: https://doi.org/10.1007/978-3-662-43725-4

[4] D. Karagiannis and H. Kuhn, "Metamodelling platforms," in *E-Commerce and Web TechnologiesEC-web, Lecture Notes in Computer Science*, vol. 2455, 2002, p. 182. Available: https://doi.org/10.1007/3-540-45705-4_19

[5] J. R. Turner and R. M. Baker, "Complexity Theory: An Overview with Potential Applications for the Social Sciences," *Systems*, vol. 7, no. 1, article 4, 2019. Available: https://doi.org/10.3390/systems7010004

[6] J. B. Ruhl and D. M. Katz, "Mapping law's complexity with "Legal Maps"," in *Complexity Theory and Law*, 2018. Available: https://doi.org/10.4324/9781315158976-2

[7] J. Lindeberg, M. Henkel, and E. Svee, "Modelling Languages and CAS Concepts for Systematic Mapping Study," 2024. Available: https://github.com/JoranL/organisational-rules/raw/main/supplementbir2024lindebergetal.ods

[8] A. R. Hevner, S. T. March, J. Park, and S. Ram, "Design Science in Information Systems Research," *MIS Quarterly*, vol. 28, no. 1, pp. 75–106, 2004. Available: https://doi.org/10.2307/25148625

[9] P. Johannesson and E. Perjons, *An Introduction to Design Science*. Springer, 2014. Available: https://doi.org/10.1007/978-3-030-78132-3

[10] K. Peffers, T. Tuunanen, M. A. Rothenberger, and S. Chatterjee, "A Design Science Research Methodology for Information Systems Research," *Journal of Management Information Systems*, vol. 24, no. 3, pp. 45–77, 2007. Available: https://doi.org/10.2753/MIS0742-1222240302

[11] J. Lindeberg, M. Henkel, and E.-O. Svee, "What does complex adaptive systems theory mean for modelling of organisational rules?" in *Joint Proceedings of the BIR 2024 Workshops and Doctoral Consortium*, ser. CEUR Workshop Proceedings, vol. 3804, 2024, pp. 106 – 111. Available: https://ceur-ws.org/Vol-3804/short5m.pdf

[12] E. van der Linden, K. Smit, M. Berkhout, and M. Zoet, "The business rule type jungle: An explorative analysis," in *BLED 2019 Proceedings*, 2019. Available: https://aisel.aisnet.org/bled2019/24

[13] Publications Office of the European Union, "ELI, the European Legislation Identifier : good practices and guidelines," 2024. Available: https://op.europa.eu/en/publication-detail/-/publication/514875b4-5efd-11e8-ab9c-01aa75ed71a1

[14] C. Griffo, J. P. A. Almeida, and G. Guizzardi, "Legal Theories and Judicial Decision-Making: An Ontological Analysis," in *Frontiers in Artificial Intelligence and Applications*, vol. 330, 2020, pp. 63–76. Available: https://doi.org/10.3233/FAIA200661

[15] R. Hoekstra, J. Breuker, M. D. Bello, and A. Boer, "LKIF Core: Principled Ontology Development for the Legal Domain," in *Law, Ontologies and the Semantic Web*, ser. Frontiers in Artificial Intelligence and Applications, 2009, vol. 188, pp. 21–52. Available: https://doi.org/10.3233/978-1-58603-942-4-21

[16] R. K. Yin, *Case Study Research and Applications: Design and Methods*. SAGE Publications, 2017.

[17] M. Henkel, E. Perjons, K. F. Lappalainen, U. Fors, and C. M. Sjöberg, "Digitalization of Health and Social Care Collaboration: Identification of Problems and Solutions," in *Joint Proceedings of RCIS 2024 Workshops and Research Projects Track*, ser. CEUR Workshop Proceedings, vol. 3674, 2024. Available: https://ceur-ws.org/Vol-3674/RP-paper8.pdf

[18] *Handbok för effektivare framtagning av medicintekniska produkter*. Medtech4Health, Smartare Elektroniksystem, 2024, (in Swedish). Available: https://medtech4health.se/handbok-for-effektivare-framtagning-av-medicintekniska-produkter/

[19] R. Lövström, M. Nymark, and H. Palm, "Hälsodatavägledningen," 2024, (in Swedish). Available: https://halsodata.se/

[20] "DIGIfor1healthSE – ett samarbete för hållbar tillgång och nyttjande av hälsodata," SciLifeLab, Stockholm, online resource, 2025, (in Swedish). Available: https://doi.org/10.17044/scilifelab.28882028

[21] V. Braun and V. Clarke, "Using thematic analysis in psychology," *Qualitative Research in Psychology*, vol. 3, no. 2, pp. 77–101, 2006. Available: https://doi.org/10.1191/1478088706qp063oa

[22] R. L. Ackoff, "The Art and Science of Mess Management," *Interfaces*, vol. 11, no. 1, pp. 20–26, 1981. Available: https://doi.org/10.1287/inte.11.1.20

[23] L. A. Zadeh, "Outline of a New Approach to the Analysis of Complex Systems and Decision Processes," *IEEE Transactions on Systems, Man, and Cybernetics*, vol. SMC-3, no. 1, pp. 28–44, 1973. Available: https://doi.org/10.1109/TSMC.1973.5408575

[24] B. Aritua, N. J. Smith, and D. Bower, "Construction client multi-projects – A complex adaptive systems perspective," *International Journal of Project Management*, vol. 27, no. 1, pp. 72–79, 2009. Available: https://doi.org/10.1016/j.ijproman.2008.02.005

[25] R. Marion and M. Uhl-Bien, "Leadership in Complex Organizations," *The Leadership Quarterly*, vol. 12, no. 4, pp. 389–418, 2001. Available: https://doi.org/10.1016/S1048-9843(01)00092-3

[26] D. Snowden, "Constraints," 2022. Available: https://cynefin.io/wiki/Constraints

[27] P. E. Plsek and T. Greenhalgh, "Complexity Science: The Challenge of Complexity in Health Care," *BMJ: British Medical Journal*, vol. 323, no. 7313, pp. 625–628, 2001. Available: https://doi.org/10.1136/bmj.323.7313.625

[28] J. J. Colchester, *Systems + Complexity An Overview*, 1st ed. CreateSpace Independent Publishing Platform, 2016.

[29] D. S. Wilson, G. Madhavan, M. J. Gelfand, S. C. Hayes, P. W. B. Atkins, and R. R. Colwell, "Multilevel cultural evolution: From new theory to practical applications," *Proceedings of the National Academy of Sciences*, vol. 120, no. 16, 2023. Available: https://doi.org/10.1073/pnas.2218222120

[30] D. H. Meadows, *Thinking in Systems: A Primer*. Earthscan, 2008.

[31] S. W. Fraser and T. Greenhalgh, "Complexity Science: Coping with Complexity: Educating for Capability," *BMJ: British Medical Journal*, vol. 323, no. 7316, pp. 799–803, 2001. Available: https://doi.org/10.1136/bmj.323.7316.799

[32] D. J. Snowden and M. E. Boone, "A Leader's Framework for Decision Making," *Harvard Business Review*, 2007. Available: https://hbr.org/2007/11/a-leaders-framework-for-decision-making

[33] I. Bider and E. Perjons, "Discovery Rules for Depicting Tacit Knowledge Usage and Management in Fractal Enterprise Models," in *Perspectives in Business Informatics Research*, ser. Lecture Notes in Business Information Processing, vol. 529, 2024, pp. 209–224. Available: https://doi.org/10.1007/978-3-031-71333-0_14

[34] A. van Lamsweerde, “Goal-oriented requirements engineering: a guided tour,” in *Proceedings Fifth IEEE International Symposium on Requirements Engineering*, 2001, pp. 249–262. Available: https: //doi.org/10.1109/ISRE.2001.948567

[35] T. Gorschek and C. Wohlin, “Requirements Abstraction Model,” *Requirements Engineering*, vol. 11, pp. 79–101, 2006. Available: https://doi.org/10.1007/s00766-005-0020-7

[36] Y. S. Lincoln and E. G. Guba, *Naturalistic Inquiry*. SAGE, 1985.

[37] European Commission, Shaping Europe’s digital future, “Sweden in the Digital Economy and Society Index,” DESI Country Profile, 2022. Available: https://digital-strategy.ec.europa.eu/en/policies/desi-sweden

[38] O. Hanseth and K. Lyytinen, “Design theory for dynamic complexity in information infrastructures: the case of building internet,” *Journal of Information Technology*, vol. 25, no. 1, pp. 1–19, 2010. Available: https://doi.org/10.1057/jit.2009.19

Appendix A Aggregated List of Requirements

Appendix A.1 Complexity Characteristics

Appendix A.1.1 Messiness

R1. Represent incoherence among rules.
R2. Represent decomposition of rules and compliance activities.
R3. Facilitate identifying which rules may be applicable in a specific situation.

Appendix A.1.2 Fuzziness

R4. Represent how rules overlap.
R5. Represent variation in stipulated rule enforcement. In particular, the difference between formally binding and non-binding rules.
R6. Represent rule compliance priority. For instance, which rules — binding or not — are more important to comply with than others.
R7. Represent temporal aspects of rules. In other words, what has been and can be, not only what is.

Appendix A.1.3 Non-linearity

R8. Represent if a rule was created in response to a particular event.
R9. Facilitate understanding of how compliance with rules should be developed over time. For instance, understand at which point in the development process to concentrate compliance efforts.

Appendix A.1.4 Non-determinism

R10. Represent rule interpretation variability.
  R10a. Represent the agent behind an interpretation.
  R10b. Represent that rules can be the result of interpretations of other rules.
  R10c. Represent that an interpretation can conflict with another one, and possibly overrule it.
R11. Represent the source of a rule and its interpretations.
R12. Represent the rationale for a rule.

Appendix A.2 Constitutive Components

Appendix A.2.1 Constraint

R13. Represent the distinction between restricting and enabling rules.
R14. Represent that rules may define roles and objects.
R15. Represent types of rule descriptions, such as standards, regulations, and legislation.

Appendix A.2.2 Agent

R16. Represent that agents are regulated by both formal and informal rules.
R17. Represent that resources and other costs can be associated with rule compliance.

Appendix A.3 Systemic Structure

Appendix A.3.1 Environment

R18. Represent the geographical area of rule systems and participating organizations.

Appendix A.3.2 Multi-level

R19. Represent higher-level organizational structures — organizations of organizations.
R20. Represent how a conflict about rule interpretation can be escalated to higher-level organizational units.
R21. Represent how higher-level rules are refined by complementary rules and interpretations at lower levels.

Appendix A.3.3 Structural Emergence

R22. Facilitate making large rule systems easier to overview and explore.
R23. Facilitate discovering new rules over time.
R24. Represent the overall structure — emergent topology — of a rule system. For instance, by having a free text property that allows for finding suitable metaphors for its characteristics.

Appendix A.4 Short-term Dynamics

Appendix A.4.1 Interaction

R25. Represent that agents can have enforcing and guiding roles with regard to rules.
R26. Facilitate communication and common understanding of organizational rule systems between people with different backgrounds.

Appendix A.4.2 Event

R27. Represent that organizational rules can stipulate in what order activities should happen.

Appendix A.4.3 Behavior

R28. Represent to what extent a rule is violated or complied with.

Appendix A.4.4 Behavioral Emergence

R29. Represent how a system as a whole can have properties, including behavioral characteristics. For instance, a rule system can have a property *'activity level'*, with the predefined values from *suffocated* to *vibrant*.

Appendix A.5 Adaptive Dynamics

Appendix A.5.1 Feedback

R30. Represent how feedback regarding rule impact can reach an organization in many forms from different types of sources.

Appendix A.5.2 Adaptation

R31. Represent how rules are changed.
  R31a. Rules can be declared in formal rule descriptions.
  R31b. Represent how rules — for instance, customary rules and informal practice — are changed through the behavior of agents.
  R31c. Represent how an actor chooses to subscribe to voluntary rules, such as standards.
  R31d. Represent that an authoritative interpretation by an agent changes rules.

Appendix B Semi-structured Interview Script

Appendix B.1 Background Questions

1. Age
2. Education
3. Current role
4. Previous roles
5. Types of companies worked with
6. Experience of health data

Appendix B.2 Substantive Question

The subquestions — 3(a), 3(e)iii, 4(a), etc. — were prepared as potential follow-ups that were made depending on the answers of the participant.

1. Which rules affect your organization / the organizations you support?
2. Who interprets the rules, and who ensures that they are enforced?
3. How is the organization / are the organizations affected by the regulatory system, positively or negatively?
   (a) Are there any individual decisions or interpretations that are particularly important?
   (b) Do any distinct patterns emerge from individual decisions or interpretations?
   (c) Are there any unexpected or undesirable consequences that arise from the combined effects of multiple rules?
   (d) How do those who are able to influence the rules find out about their effects in practice? Is there any feedback channel?
   (e) Are there rules that lead to unreasonable consequences?
      i. Are there rules that each appear reasonable on their own, but whose combined effect is unreasonable?
      ii. Are there rules that force actors to choose between unreasonable alternatives ("damned if you do, damned if you don't")?
      iii. Are there measurable targets that create crowding-out effects, such that important activities without measurable targets are neglected?
      iv. Are there targets that promote short-termism?
      v. Are there targets that lead actors to prioritize their own goals over those of the larger system (sub-optimization)?
   (f) Do threshold effects occur (so-called "ketchup effects"), meaning that initially little happens, followed by a sudden large impact?
   (g) Do similar situations sometimes lead to unreasonably different outcomes, for instance, due to differences in interpretation or enforcement of a regulatory framework?
   (h) Are there cases where rules are circumvented, ignored, or unknown?
4. Is there anything in the regulatory system that you, or others, have found — or currently find — difficult to understand?
   (a) Does everything seem to be interconnected ("everything is connected to everything")?
   (b) Are there rules that are contradictory, either internally or in relation to other rules?
   (c) Are rules vague or ambiguous?
   (d) Is it difficult to delineate actors or regulatory frameworks from one another?
   (e) Is it difficult to get an overview of how different levels of the system relate to each other?
5. Which regulatory system would you today have the greatest need to understand better? Which aspects of the rules?
6. Among the problems we have discussed earlier, which ones would you primarily like the model to help make visible?