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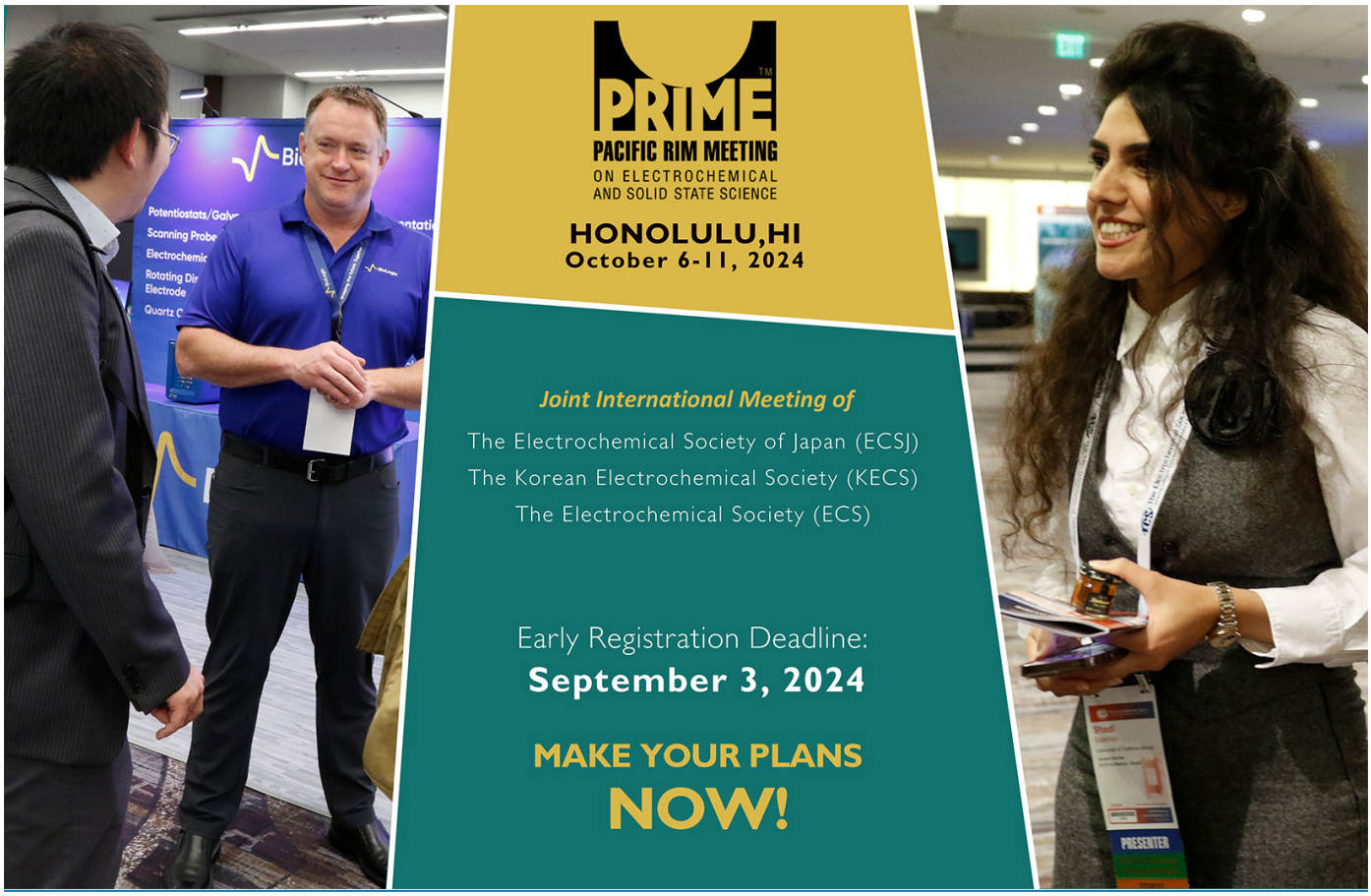

Automated Regulatory Compliance towards Quality Assurance in Healthcare Building Projects

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Abstract. Healthcare building projects are severely constrained by their associated regulatory frameworks. In this context, regulatory requirements define a basic outline upon which design is developed, as well as aid designers towards compliance to minimum standards. Automation has been explored by existing research focusing mostly on compliance checking (i.e., quality control). There has been limited developments within this domain related to quality assurance. This paper aims to highlight what are key needed improvements to enable the use of automation to promote quality assurance for regulatory compliance in healthcare building projects. For this purpose, an ongoing revision of a British healthcare design guidance document (HBN 11-01) was analysed according to a requirements' taxonomy. Key areas of improvement needs were highlighted based on a series of interviews. Our main findings relate to identifying that despite the guidance character of regulatory documents in the UK, they are rarely used for this purpose, revealing the focus on quality control. In this context, the regulatory framework could be repositioned as a catalyst towards automated design quality assurance as long as (i) the regulatory documents are developed and revised to fit automated design processes; and (ii) there are compatible software developments to streamline design processes through automation.

1. Introduction

The design phase of healthcare building projects consists of a complex and demanding process, in which requirements evolve and solution development is often related to fuzzy stages and unstructured activities. During design, information from regulatory documents has an important role while establishing minimum requirements related to e.g. function, layout, and services, as well as presenting best design practices to aid designers in their decision-making process.

In the last decades, the use of information technology has gradually increased in the building design domain; and, more recently, automated approaches started to be more widely introduced in design practice, mainly through Building Information Modelling (BIM) applications. As discussed by Eastman et al. [1], 3D parametric object modelling enables the development of computer-interpretable models, which can be associated with multiple 'automated' applications, including compliance. In this environment, automated compliance approaches developed over the years have been mostly related to checking building models against a set of regulatory criteria, which originate from the regulatory framework associated with a specific design context.

There are several potential benefits arising from the use of automated compliance approach reported by the literature (see [1]), which can also be observed in practice. They are mostly related to improving

the efficiency and reliability of compliance 'checks', by freeing human designers to focus on other (and potentially more value-adding) activities. Despite achieving some great benefits and enabling a reasonable degree of automation to be added to the regulatory compliance context in practice, there are important limitations and challenges still to be addressed from a research perspective.

One of the key steps in the above process relates to translating information from regulatory documents to computer-readable formats so automated compliance checking can be achieved. In practice, it consists of a complex procedure, which demands expert knowledge and is prone to misinterpretation and bias. Another challenge is associated with the adoption of a 'checking' standpoint. Automatically checking compliance in building models generally fits within a 'quality control' perspective, happening after design 'errors' or non-compliances have already happened, whereas the use of automation could be further explored from a 'quality assurance' backdrop.

This paper aims to discuss the interplay between these factors through empirical analysis and observations, highlighting what are key needed improvements to enable automated regulatory compliance in healthcare building projects from a quality assurance perspective. It is structured as follows: after the introduction, the key theoretical framework associated with the paper will be presented in two sections; the research design is then described, followed by the main findings and final remarks.

2. Theoretical Background

2.1. Regulatory framework associated with healthcare building design

The regulatory framework associated with healthcare building design projects in the UK consists of a complicated mix of statutory and guidance documents [2]. Statutory documents include legislation and the approved documents of the Building Regulations, which are applied to any building project; whereas guidance documents are specific to healthcare projects, i.e. Health Building Notes (HBNs) and Health Technical Memoranda (HTMs), developed by the Department of Health (DH).

There are multiple challenges associated with the practical use of the regulatory framework identified by existing research. Mills et al. [2] highlighted that those documents are generally outdated and unfit for purpose considering the current needs and scopes of healthcare projects in the country. The same authors argue that some documents have changed over time, being revised without consideration of the overall framework, leaving gaps e.g., associated with referencing. In this context, Soliman-Junior et al. [3] identified that such regulatory framework in the UK includes more than 100 documents, leading to a complex setting that involves multiple interdependencies between requirements, including complementary and potentially conflicting information across documents.

This complexity is also acknowledged by [4], which investigated how HBNs were used in the healthcare design practice through a series of interviews. Their findings highlight the uncoordinated and confusing framework, which also raised questions about the quality of the information included in the documents and demonstrated how professionals used such information in different ways, by varying the rigour in which requirements were adopted in design solutions.

In fact, existing literature highlights that regulatory requirements are associated with aspects of function and operation of the built environment, as they also relate to healthcare service delivery and outcomes [5]. In this context, regulatory information can be associated with different constraining levels in design, defining minimum needs associated with compliance [6,7], as well as assisting in the development of an essential framework around which design should be built [8,9]. In that sense, [10] imply that designers either follow the requirements defined in regulatory documents, taking a prescriptive approach to design; or utilise regulatory requirements as a foundation for their own creative process. Therefore, regulatory compliance consists of an intrinsic activity to building design, and relates to aspects of suitability, constructability, functionality, safety and sustainability, across the building life-cycle [11].

Information is generally expressed in regulatory documents by using subjective sentences, through the use of natural language [1,12]. In other words, this means that requirements have been traditionally written by people, to be read, interpreted, and analysed by people. This characteristic creates an

incompatibility between the way regulatory information is expressed with automated compliance approaches, requiring human interpretation and translation [11]. Indeed, this process is acknowledged by existing literature as challenging [13] and, therefore, has been the main motivation of various research initiatives in this domain [14]. Most of the identified challenges are due to difficulties in ensuring precision and completeness while translating information from the documents [15], as well as the introduction of potential bias and limited cognitive abilities in this process [12].

In this context, analysing regulatory information aiming to better understand how they affect automated compliance is fundamental, as this is the starting point of automated compliance in practice [3,15–18]. The approach that will be adopted in this paper applies a regulatory requirements taxonomy proposed by [3] specifically to healthcare-related requirements and includes different classification elements which are also relevant considering the use of automated compliance towards quality assurance (Figure 1).

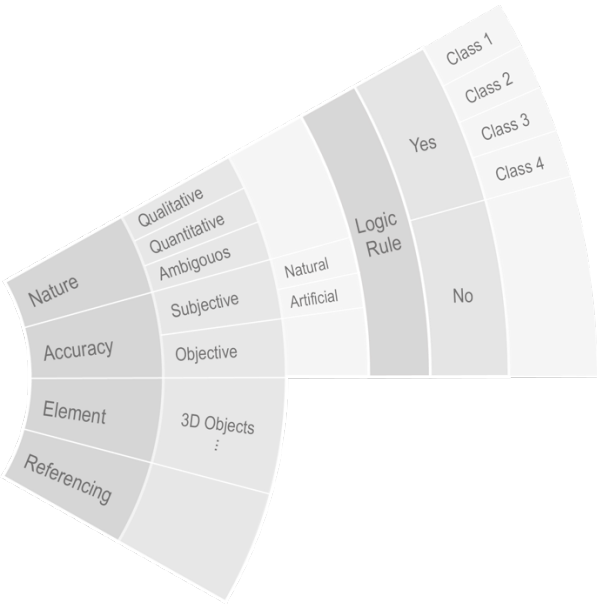

Figure 1. The regulatory requirements' taxonomy proposed by [3]

2.2. Automated Compliance

Automated compliance approaches have been a recurrent research topic over the years, with multiple potential benefits arising from their application. The use of automation enables the development of compliance tasks under a more reliable, efficient and faster process [1]. Two key components are fundamental to the development of automated compliance systems [1,11]: (i) the building model, which includes all design information represented digitally; and (ii) the regulatory and normative information, which needs to be represented under a computer format and is the basic reference for compliance.

Many research initiatives have explored the interplay between these two components with developments proposed mostly within the information technology domain, represented by frameworks, models, systems and programming languages [3]. A recurrent problem that has been addressed relates to the regulatory information and its translation to computable-readable formats, as discussed in the previous section. Other developments are associated with the challenges emerging from the connection between these two components, ensuring that objects in building models are aligned with the definition of rulesets, for example [11]. Reported challenges vary from difficulties in dealing with a large number of requirements [1,13], as well as technological limitations that can affect this process [14].

Regardless of their motivation, one primary orientation is observed across most of the research initiatives: compliance is generally associated with a 'quality control' perspective. [17] identified that such orientation understands that compliance checking is performed separately from design, in which the building model is assessed at predefined or agreed times, usually by importing the model into a

checking software and automatically inspecting it according to rulesets. This standpoint can be limited and might be the source of some of the challenges observed in practice and discussed above, as it will probably lead to difficulties due to the indeterminacy of requirements [11,12].

On the other hand, compliance through a 'quality assurance' perspective relates to different automated approaches that have been less explored by existing research. Amor and Dimyadi [11] reviewed and discussed multiple approaches to regulatory compliance, including add-ons to BIM authoring tools, human-guided automated approaches, and the use of Artificial Intelligence (AI) to compliance. These approaches would be closer to what [17] would define as 'design solution checking', which is understood as a continuous support to the design process, being closer to a knowledge-based engineering system. In his view, the rules arising from regulatory requirements could be connected to objects or external knowledge databases, for example.

[17] also argues that a quality control approach can (and potentially should) be part of a quality assurance system. This is also discussed by [11], who confirm that the interplay between the two quality systems is needed; so, alongside a quality assurance approach, there is a quality control process to ensure consistency and to detect eventual mistakes. Considering that the focus of existing research has been mostly related to quality control, there is a need to explore how automated compliance could be better understood and applied in practice through quality assurance. As highlighted above, information from regulatory requirements consists of an important component in this context, and it is the starting point of the analysis presented in this paper

3. Research Design

This paper is part of a larger PhD research project which adopts a Design Science Research (DSR) approach. DSR focuses on the creation of artefacts to address real-world problems while also making a prescriptive scientific contribution [19]. It has also been used in previous projects that address a similar research problem e.g., [3,18], as well as projects developed in the healthcare design domain with a focus on requirements management e.g., [20,21].

The main activities that supported the development of this paper relate to: (i) the analysis of an ongoing revision of a Health Building Note document (HBN 11-01); and (ii) the development of an empirical study in close collaboration with an architectural practice in the UK. The analysis and classification of requirements from HBN 11-01 has been developed based on the steps proposed by [3] and according to their regulatory requirements' taxonomy presented above. A comparative approach was adopted across the analysis, contrasting findings from the consultation draft with the currently published document (HBN 11-01, 2013) [22] (originally presented in [3]).

The second activity relates to the development of an empirical study during the design process of an acute healthcare facility in the UK, in collaboration with an architectural practice. It supported reaching the aims of this paper by allowing the development of preliminary observations from practice, describing how regulatory documents are used, and how compliance has been approached from a quality assurance perspective. It is important to highlight that a series of interviews with representatives from the healthcare design context has also been developed as part of the larger research project. They indirectly informed the findings discussed in the following section but are not presented in the paper.

4. Findings

The findings reported in this paper describe different perspectives on how information from regulatory requirements impacts the adoption of a quality assurance approach to automated compliance, highlighting key needed improvements. This section is structured around the two key areas described above: (i) analysis of a healthcare regulatory document; and (ii) preliminary observations from practice obtained during the development of an empirical study.

4.1. Analysis of HBN 11-01 (ongoing revision)

The analysis of a regulatory document consultation draft (HBN 11-01 - Facilities for primary and community care services) was originally developed aiming to identify potential improvements that could

be implemented during the revision process, as well as to identify characteristics of requirements that impact automation. It is important to highlight that the analysis presented in this section might not reflect the final published version of the document, which has not been released by the time authors were writing this paper.

As the analysis presented in this paper follows the method proposed by [3], the first stage relates to the identification of individual requirements. The consultation draft document included 468 requirements, in contrast to 782 from the current version [22] This indicates that either the document has reduced in size, or it includes less information related to attributes of the built environment (which would be understood as design requirements in this context). The following sections will present the analysis of requirements based on the requirements' taxonomy classification criteria described above.

4.1.1. Nature. From the analysis of HBN 11-01 (consultation draft) most of the identified requirements are qualitative (72.4%), which means they contain information that is not quantifiable, numerical, or rely on measurements. From the remaining requirements, 27.6% are quantitative and none has been classified as ambiguous. Most of the qualitative information in HBN 11-01 (consultation draft) emerges from text-based requirements, while quantitative information is mostly related to sketches, floor plans and detailed drawings.

4.1.2. Accuracy. Requirements from HBN 11-01 (consultation draft) are almost equally divided between subjective and objective (45.7% of requirements are subjective whilst 54.3% are objective). In this context, it is important to highlight that subjective requirements rely on human interpretation to be properly defined whereas objective requirements do not [3]. The slight predominance of objective requirements is because when information is presented by sketches, floor plans, and detailed drawings both qualitative and quantitative requirements can often be understood objectively. On the other hand, subjective requirements can be related to either natural or artificial subjectivity [3]. While natural subjective requirements represent 22.4% of subjective requirements and 10.3% of all requirements in HBN 11-01 (consultation draft), artificial subjective relates to 77.6% of the overall subjective requirements and 35.5% of all requirements in this document. This represents a situation in which a considerable share of subjectivity is caused not because of abstract and intrinsically subjective information, but due to inconsistencies associated with sentence structuring, lack of definition and specification, as well as over-generalisation of requirements.

4.1.3. Logic Rule. Considering the possibility to translate requirements to logic rules, 54.5% of requirements could be directly transformed into a logic rule, based on logical sentence structuring. This number is close the amount of identified objective requirements, as there is an increase in the possibility of translating these requirements to logic rules. It is important to acknowledge that this classification only considers a potential restructuring of requirements' contents so they could be directly represented under a logical format, and it is not linked to any automated rule checking software. Requirements that could not be directly translated to a logic rule represent a situation in which some degree of human involvement still might be necessary to verify if building designs are in accordance with requirements.

4.1.4. Classes. 255 requirements that could be translated to logic rules were analysed according to their internal logical complexity by using the classes of parametric rule (originally developed by [23]). Results indicate that more than 99% of these requirements belong to Class 1. This indicates a high possibility of using automated compliance approaches for these requirements, as they represent the cases which are based on explicit data, hence, situations with the lowest logic complexity.

4.1.5. Elements. Not all analysed requirements in the consultation draft led to a direct relationship to an object in building models. Thus, across HBN 11-01 (consultation draft), 417 relationships were identified. Most of these are related to 'Space' (45.6%) and 'Objects' (32.9%), followed by 'MEP' (17.3%) and 'Door' (2.2%), while the remaining relationships are related to 'Walls' and 'Windows'.

From a design perspective, modelling these types of instances with adequate geometric and semantic information is fundamental so the building models can be further used in an automated compliance process, evidencing the complementarity between models and rulesets discussed in the literature review.

4.1.6. Referencing. HBN 11-01 (consultation draft) has a significant amount of referencing to other documents. Across its text, 86 references have been identified and they are mostly associated with HBN 00-03 (59.3%). In fact, most of the standard room layout diagrams included in the document refer to HBN 00-03. In total, 32 different documents or specific chapters of documents have been referenced, which suggests the strong complementarity and interdependency between different guidance and statutory documents across the regulatory framework.

4.1.7. Comparison with the current document (HBN 11-01, 2013). The HBN 11-01 under consultation that has been the object of analysis in the paper has considerable differences when compared to its previous version (HBN 11-01, 2013). By analysing all information in the main body of the document, the focus has been expanded to incorporate aspects not only of building design but of an overarching project (e.g. funding, affordability, and value for money analysis). Hence, the document has a less prescriptive and more informative character, when compared to its previous version. While this may be positive in providing guidance to the overarching construction project, requirements tend to become more generic, with lower specificities if compared to HBN 11-01 (2013) and making automated compliance harder to be achieved. Even though the consultation draft has fewer requirements, generally they have similar characteristics to the previous document. A note on language usage was included in the ongoing revision, and it consists of an important improvement. As identified in the literature review, one of the main issues related to using information from this type of document as an input to automated compliance is vagueness and ambiguity. Hence, clearly defining the intended meaning of modal verbs such as ‘must’, ‘should’ and ‘may’ is an important step towards enabling a degree of automation – and ensuring a consistent judgment of requirements and their criteria. This makes clear to the reader what requirements consist of an obligation, recommendation, or permission.

4.2. Preliminary observations from practice

During the development of an empirical study in collaboration with an architectural practice during the design development stage of a healthcare facility in the UK, different preliminary observations could be made in relation to the context and aims explored in this paper. They are mostly related to the use of regulatory documents in design practice, as well as how designers attempt to promote a quality assurance compliance approach with the support of digital technologies and automation.

The context in which this empirical study was developed consists of an architectural practice with a large experience on the use of digital technologies during the healthcare design process. Therefore, it is important to highlight that the findings presented in this section are not representative of a broader environment, but rather relate to the specific setting in which the study was developed.

4.2.1. The practical use of regulatory documents. The designers involved in the development of a healthcare facility project had different views on how regulatory documents are used in practice, and which are the difficulties associated with this process. Designers who are mostly involved with healthcare planning and initial design stages suggest that regulatory documents are fundamental to benchmark and to ensure early compliance in relation to the project feasibility and procurement. These findings highlight the importance of compliance in relation to the project business case approvals and financial acquisition. Designers more involved with developed stages expressed that regulatory documents are rarely used as guidance, generally working in practice for the identification of non-compliances. Nevertheless, they argue that the process of searching requirements and interpreting their content is very difficult because of the large number of documents and requirements, and due to the format they are provided, which is not interactive and easily searchable (i.e. plain text-based PDF documents).

4.2.2. Compliance through quality assurance. During design development, different approaches were adopted by designers in relation to compliance. Whereas there is a major focus on quality control using an automated compliance system based on rule checking, there are also attempts to develop quality assurance tools, using information from the guidance documents (i.e. HBNs and HTMs) to support better decision-making during design development. A pilot initiative observed in this context that fits within the quality assurance perspective relates to the development of a Dynamo routine (Visual Programming Language application) to support the definition of properties from internal partitions according to sound levels requirements from HTM 08-01. This specific routine used the procedure described in the guidance document to determine the acoustic rating of internal wall partitions according to the types of adjacent rooms and their specific uses. In this context, the use of Dynamo informed the design process and enabled the definition of objects' properties (i.e. walls) with higher assertiveness, following the guidance character of HTM 08-01.

4.3. Key needed improvements towards regulatory quality assurance through automation

The findings presented above shed some light on the characteristics of regulatory documents and their impacts within an automated compliance environment, as well as illustrated preliminary observations from practice arising from the development of an empirical study within an architectural firm. Considering the challenges highlighted in the literature review, these findings enabled the identification of two key needed improvement areas to better support regulatory quality assurance in design through automation: (i) thorough revision of the regulatory framework; and (ii) compatible software development. They will be summarised below.

4.3.1. Revision of the regulatory framework. The analysis presented in section 4.1 was related to an ongoing revision of one specific healthcare regulatory document. It highlighted that despite substantial modifications to its contents, there were no great advancements that could better support the use of automation during the design process. This has been evidenced by the great number of subjective requirements and especially artificial subjectivity. In order to enable automated compliance approaches in practice, such documents must be reviewed not only in terms of their content (e.g. updating requirements according to emerging needs and standards, such as those triggered by Covid-19) but also concerning the format in which requirements are presented, as well as how documents are stored and published. In practice, the documents' revision process should also be driven by the current digital design agenda, considering aspects related to how designers and regulators use these documents in practice and how information is created and shared within a digital design environment. Considering this backdrop (which is often the reality in practice), there is a clear disparity and unfitness between existing regulatory documents and digital agendas, which hinder their use in practice and specifically impact the use of automation to support the development of design quality assurance systems.

4.3.2. Software development. Preliminary observations from practice described in section 5.2 highlighted an important element in the development of automated quality assurance processes during building design, related to software development. The use of rule checking, which is dependent on software development and application, has been extensively associated with automated regulatory compliance checking from a quality control perspective. Currently, different commercial tools can be used for this purpose, with emphasis on Solibri Model Checker (SMC) [24]. As discussed by existing literature, this approach is not only needed but desirable to support the development of quality assurance systems ensuring consistency and assertiveness. Alternatively, different approaches can be used for quality assurance. In the above, an example of an algorithm developed with the support of a visual language programming (VPL) tool (i.e. Dynamo) aided designers in the definition of acoustic wall ratings. Similar approaches can potentially be used to support the development and implementation of alternative algorithms to better inform the design process, relying on objects parameters, properties, and modelled constraints. In this case, efforts on software development shift from commercial and large-

scale applications to customised and in-house tools, which require an accessible and flexible interface to be explored by different user profiles.

5. Final Remarks

The two improvement areas discussed in the previous section relate to fundamental drivers that need further exploration to better support regulatory quality assurance in design through automation. We understand that they are interdependent to a certain level and are both associated with the digitisation of the building design process. In practice, this means that revising the 'format' of regulatory documents is fundamental to better fit current digital agendas, whereas software development is continuously needed to accommodate the constant developments from the information technology domain.

Findings presented in this paper confirmed what has been discussed by existing literature, in relation to the diversity of information existing on regulatory documents as well as the considerable number of subjective requirements, which have a great impact on the practical adoption of automated approaches to compliance. Through the analysis and classification of requitements from one document currently under revision, improvement needs were identified and exemplified.

The development of the empirical study also shed some light on how information from regulatory documents is used in practice, and their influence on compliance from a practical perspective. It also highlighted that current efforts in developing regulatory quality assurance systems rely on customised in-house applications developed by end-users (e.g. designers), aligned with rule checking software to ensure quality control. This micro-scale perspective suggests that flexible, accurate, yet easy-to-use applications are needed, considering the diversity of documents and the different interpretations designers might have on subjective requirements. This process is fundamental from a design perspective, as it enables design creativity and innovation. Furthermore, the guidance role of the healthcare regulatory framework in the UK indicates a fruitful setting for the development of such regulatory quality assurance systems, whereas most of the existing efforts in this context have been associated with quality control.

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