QOC-E: A Mediating Representation To Support The Development Of Shared Rationale and Integration Of Human Factors Advice

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Designing and manufacturing medical devices is a complex and specialist effort. Throughout the process, there is an opportunity to consult across those involved in various aspects of development (for example Human Factors (HF), Human Computer Interaction (HCI), Design and Manufacture). Developers report difficulties in this area, speaking of isolated team members and organizational / cultural barriers. We illustrate the use of a mediating representation (Questions, Options, Criteria and Evidence – QOC-E) that promotes shared reasoning and can be used to capture design rationale. Application is demonstrated using an illustrative example involving the specification of a number entry mechanism. The benefits of the QOC scheme include making tacit reasoning explicit, articulation of trade-offs, traceability, allowing compartmentalization of the design and avoidance of fixation in any one particular area. Downsides include the fact that the representation may require prohibitive amounts of effort to maintain or fail to scale to large or complex systems. These issues are discussed and directions for further investigation outlined.

INTRODUCTION

"Wicked problems" (Hershey, Churchman, & Kruytbosch, 1967; Rittel & Webber, 1973) cannot be easily defined or solved because the solution criteria are not immediately explicit and/or the goals and outcomes are innumerable, subjective or conflicting. Solutions may generate unanticipated knock on effects or internal interactions that put the system into unknown states or generate additional wicked problems (Ritchey, 2011). Examples of wicked problems include global climate change (Chapin et al., 2008), planning and housing development (Adams, 2011), educational policy (Garrick, 2011) and business strategy (Camillus, 2008).

Design can involve wicked problems (Rittel, 1988). This is because there is a need to optimize and integrate with a wider system that is complex, dynamic and unpredictable. For example standards and conventions change, users have differing expectations and it is impossible to anticipate all combinations of user and usage. There is a need to optimize a device for a given use or context, but also a need to ensure generic functionality and norms across a range of clinical domains.

Tackling wicked problems can involve authoritative, competitive or collaborative approaches. In the context of design, an authoritative approach could involve mandating a solution, a competitive approach allowing (market) forces to self-select and a collaborative approach consulting across a range of opinion holders to arrive at a commonly agreed solution.

Collaborative approaches have the benefit that multiple perspectives are applied to the problem space. During this process, it is important that barriers to communication are overcome, tools are provided to structure the area of analysis and individuals have a genuine understanding of why a design option has been chosen.

Taking the design and manufacture of infusion devices as an example, design is a complex and specialist effort involving multiple trade-offs. For example, the choice of number entry method may reflect the availability of display real-estate, likelihood of number entry error, chance of component failure, match to user expectation, conventions used within the hospital environment, availability of standard solutions or precedents set by other devices. Balancing competing objectives may require an extensive dialogue and collaboration across multiple entities. This paper is about the use of a mediating representation to support this process. The aim is to provide a common, consistent and coherent understanding of design rationale across a team of individuals.

Design Rationale

Design rationale is the reasoning behind design decisions. This may include an expression of the relationship between an artifact and design conceptualization, context and purpose. It may also include the logical reasoning, methodology, process and/or documentation that underpin the above. Rationale may be expressed in various forms: for example logical structures, informal narratives, links to social behaviors or norms, templates or argumentation structures. Statements of design rationale aim to structure the decision making process and promote quality of decision making (Lee & Lai, 1991). In crafting a design rationale, desirable properties include: accessibility across multiple domains, scalability for complicated systems, flexibility and ease of adoption (Moran & Carroll, 1996).

Design Space Analysis (DSA) is an argumentation based approach to representing design rationale. It involves

techniques accessible across multiple disciplines. There are many structures that have been proposed in response to these needs, examples from the Human Computer Interaction (HCI) literature include; Claims Maps (Moran & Carroll, 1996), Decision Representation Language (DRL) (Winston & Shellard, 1990), the Issue-Based Information System (IBIS) (Rittel & Webber, 1973), Jackson System Development (JSD) (Jackson, 1983), Procedural Hierarchy of Issues (PHI) (Glaeser, 1981), The Liskov and Guttag Abstraction-Based Method (Liskov & Guttag, 1986), and VERDI (Shen, Richter, Graf, & Brumfield, 1990). Organizations have taken these techniques and integrated them with existing documentation process or toolsets - for example as demonstrated by the Design Rationale EDitor (DRED) (based on IBIS) (Bracewell, Ahmed, & Wallace, 2004).

Examples from the safety and assurance case literature include Claims Arguments and Evidence (CAE) (Bishop, Bloomfield, & Guerra, 2004) and Goal Structured Notation (GSN) (Kelly, 1998). For software development, the Unified Modeling Language (UML) is in widespread use but may be limited in the extent to which it can support the development of a detailed rationale and/or link to non-functional requirements.

Representations that contain design rationale allow the development community to come together and justify why a device should be designed in a particular way. An ideal representation would provide an indication of the degree of confidence attributed to a given option, state assumptions, avoid ambiguity, be accessible at multiple levels of technical granularity, highlight areas of incomplete or uncertain data and maintain clarity and completeness.

The advantage of using these structures is that they allow reviewers to critique reasoning and check for mistaken argumentation such as circular reasoning. Examples may reference standards, or include analysis to demonstrate safety in use. Where multiple analytical techniques need to be combined, techniques like Questions, Options and Criteria (QOC) can be used to show the underlying constraints for User Interface (UI) problems that are novel, complex or difficult to address through user studies. They also help avoid the tendency for developers to converge on sub-optimal solutions early in the development timeline (Jansson & Smith, 1991) and help optimize the framing and fidelity of the questions asked during the design process (Tang, Tran, Han, & Vliet, 2008).

Making a Case for Safety and Usability

Incorporating and balancing multiple perspectives is important when outlining how the design has been modified as a result of Human Factors Engineering (HFE) and Usability Engineering (UE) activities. For example, the US Food and Drug Administration (FDA) has produced draft guidance relating to the application of HFE and UE asking manufacturers to state that "the <Name Model> has been found to be reasonably safe and effective for the intended users, uses and use environments." It also requires a statement that "any residual risk that remains after the validation testing would not be further reduced by modifications of design of the user interface (including any accessories and the IFU [Instructions For Use])…" (FDA, 2011, Table A-1).

It is hard to meaningfully commit to these declarations without assimilating the rationale behind a given design. Although there is no one single solution to achieving this, promoting shared reasoning across the development community is likely to be beneficial.

In this work, we propose a lightweight semi-formal technique that allows development teams to share design rationale across individuals from varying backgrounds. Questions Options, Criteria and Evidence (QOC-E) builds upon the QOC scheme originally applied to DSA (Bellotti, Shum, MacLean, & Hammond, 1995; MacLean, Young, Bellotti, & Moran, 1991). The scheme can also be integrated with formal proofs (Bramwell, Fields, & Harrison, 1995).

We extend the scheme so that the evidence used to inform criteria is made explicit (Figure 4). As the scheme is relatively accessible and flexible, it serves the purpose of getting multiple stakeholders "onto the same page" and can therefore address barriers to communication. Although we use an example relating to number entry, the paper is intended to demonstrate the use of the representational scheme, rather than define an optimal number entry mechanism.

Analyzing an Artifact – Infusion Pump Number Entry Example

We applied and extended the scheme originally proposed by (MacLean et al., 1991) to an example involving the definition of a number entry mechanism for an infusion device. The example is not based on any particular infusion pump design, but has been selected to illustrate the point. This problem has a history of human factors and ergonomic investigation and recent medical device standards and guidance provide recommendations on how the mechanism can be specified: "For numeric keypads, the telephone-style keypad should be used unless the user needs and testing clearly indicate otherwise…" (AAMI, 2009, p273).

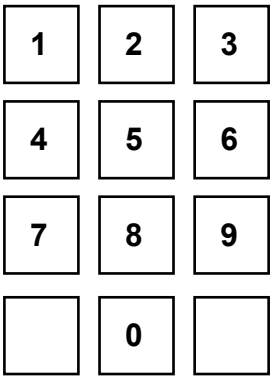

Figure 1. Number entry specification according to HE75 (illustration, not to scale).

The current UK guidance reflects this suggestion; however, it applies an additional (apparently conflicting) constraint in that the decimal place and zero buttons should

not be placed next to each other and should be placed on the bottom row. It also recommends consideration of analogue methods such as dials and chevrons based upon the following extracts:

> The extensive use of mobile phones, and its frequent additional function as a calculator, supports a recommendation that staff are more familiar with the telephone layout. This layout, where the number '1' is in the top left corner, should be used on all devices…
>
> The numerical layout should not be altered. The '0' and '.' should always be positioned below the rest of the numbers and not adjacent to each other…
>
> Consideration should be given to analogue methods of input such as dials and chevron keys. These can be more intuitive with regard to quantity and allow the user to monitor the screen during input. (NPSA, 2010, p25 - p27)

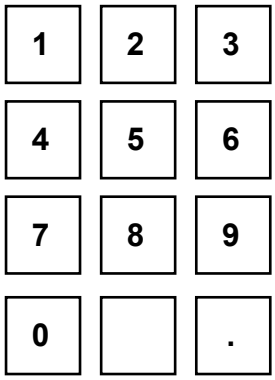

Figure 2. Number entry specification according to "Design for patient safety: A guide to the design of electronic infusion devices" – Variant 1 (illustration, not to scale).

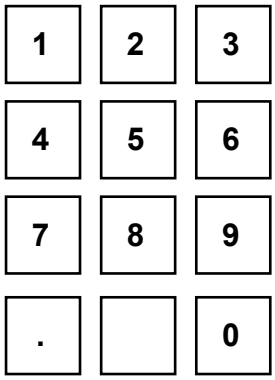

Figure 3. Number entry specification according to "Design for patient safety: A guide to the design of electronic infusion devices" – Variant 2 (illustration, not to scale).

Although these recommendations are open to interpretation, they appear to be contradictory. Manufacturers often report that recommendations of this type are underspecified and do not take into account wider aspects such as the potential for alternative superseding standards (Vincent & Blandford, 2011).

Recommendations are often linked to corresponding evidence, however novel studies may challenge previous findings or provide additional insight that was not available when the guidance was produced. In the example depicted in Figure 1- Figure 3, since the guidance was produced, numerous research papers have been published to inform the situation.

CASE STUDY

The rest of this section outlines the use of QOC, described by (Moran & Carroll, 1996), which is a semi-formal technique that allows developers to form a statement of design rationale. QOC is semi-formal in that the descriptions within the nodes are unrestricted. The benefit of the technique is that it can be used to illustrate multiple and sometimes conflicting criteria of the type described in the previous section. The method is as follows:

A diagram is produced providing an indication of a subset of design decisions and underlying rationale. The diagram contains the following components:

Questions. These are the key issues for structuring the design space.

Options. These are possible alternative solutions.

Criteria. These provide issues against which to assess the strengths & weaknesses of alternative options. Criteria relate to a property of an artifact that is controlled indirectly through the choice of an option.

It is possible to show whether options support or challenge criteria by selecting between dashed (challenges) or solid (supports) lines.

Once an option has been chosen, subsequent questions may be generated; in the chosen example the use of chevron input generates subsequent questions as to how to specify increments, range limits etc. (see below).

QOC-E: Assertions and Evidence

We propose an extension to the scheme that details how criteria are related to evidence of varying type and origin. In the original scheme, assertions were generated by recording and transcribing design sessions and extracting / indexing substantive points. An assertion could refer to reasoning, analogies, scenarios or statements. Assertions were used to produce the QOC diagram and cross-reference components within the diagram to the recorded data (transcript). The advantage of the method is that it produces a rich and structured definition of the underpinning rationale that is grounded in the understanding of the development team and traceable. It can also support the generation of ad-hoc theories and be used to expose contradictions or biases formed during the development process. The disadvantage is that it may be time consuming, viscous, require off-line analysis and is restricted to the perspective of those contributing to the data gathering sessions (Moran & Carroll, 1996).

In the case of medical device design, a review of documentary evidence (for example, standards, research articles, precedents and heuristics such as (Zhang, Johnson, Patel, Paige, & Kubose, 2003)) is also likely to be helpful. We suggest an extended / modified version of the original scheme that substitutes the use of assertions with reference to various type of documentary evidence or analysis (right hand side – Figure 4).

In the following example, a novel design of infusion pump requires the method of number entry to be specified. There are multiple parameters that could be required during a typical programming sequence including the Volume to Be Infused (VTBI), the rate of infusion and/or the time taken to complete an infusion (Furniss, Blandford, Rajkomar, Vincent, & Mayer, 2011).

Figure 4 outlines an illustrative and simplified representation of design decisions corresponding to the specification of number entry input (for a more in detailed treatment see (Campos & Harrison, 2011; Cauchi et al., 2011; Masci et al., 2011; Oladimeji, Thimbleby, & Cox, 2011; Thimbleby & Cairns, 2010; Wiseman, Cairns, & Cox, 2011)).

The example does not fully specify a number entry mechanism. Decisions include the choice between a keypad or (pseudo) analogue method such as a chevron mechanism (Qu1). In the case shown in Figure 4 the term "chevron" is an analogy for a set of four buttons labeled with upwardly or downwardly pointing arrows that increment or decrement a selected value, displayed on the screen using large or small increments (see (Oladimeji et al., 2011)). Given the use of the chevron mechanism, additional questions are generated relating to the properties of the mechanism (Qu2, Qu3, Qu4).

Question 2 (how should increments be defined?) regards the consistency of the increment. Fixed increments (O3) have a greater level of predictability, whereas variable increments (O4) are advantageous in that they allow the user to reduce the number of key-presses required by (for example), increasing the rate of change dependent on user behavior (Oladimeji et al., 2011).

Question 3 (how should range limits be established?) relates to the way in which the device handles an increment that is out of range (boundary handling). For example the device may be designed to use any one of a number of

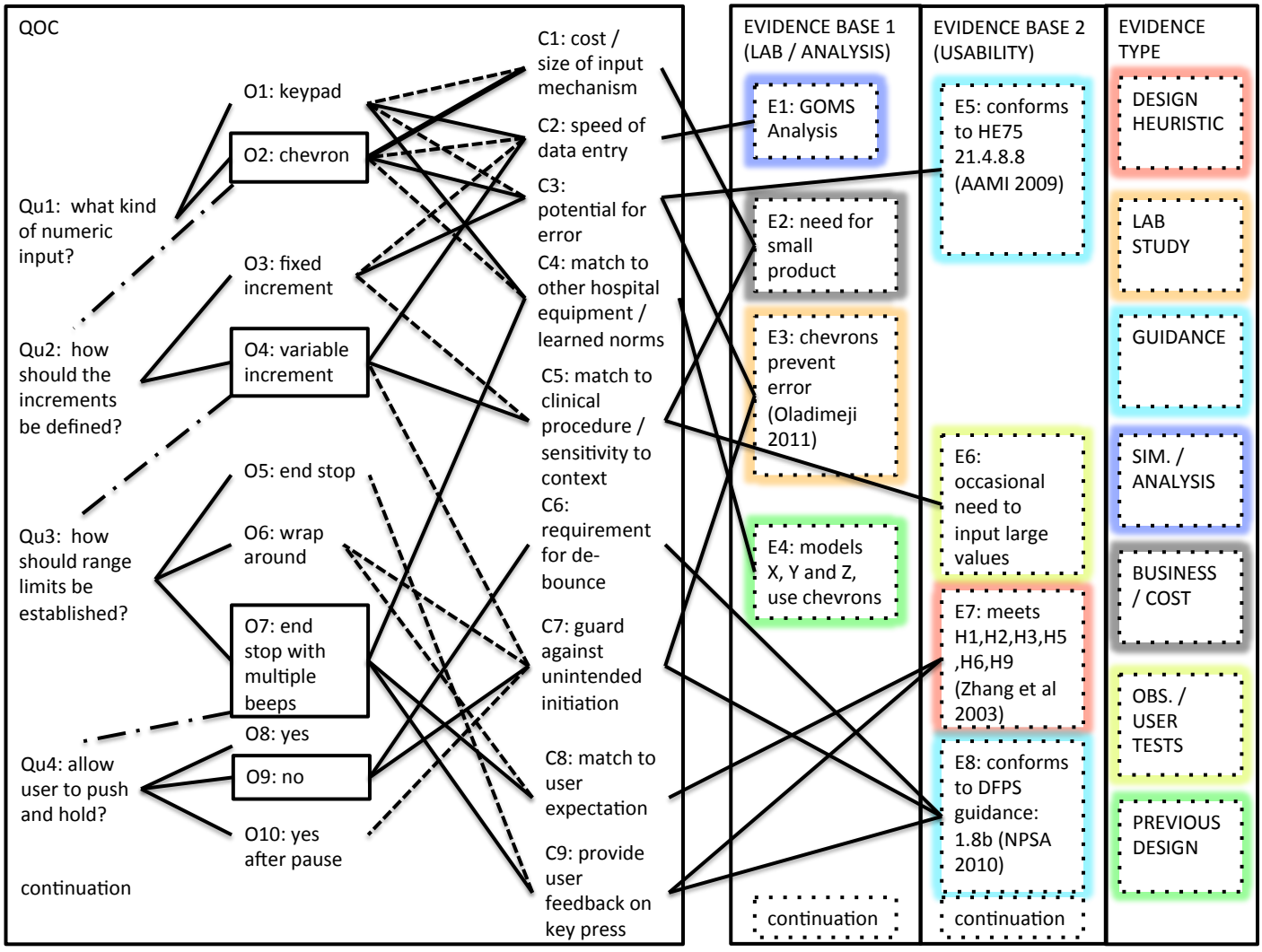

Figure 4. Illustrative example of original QOC scheme (left) with supplementary evidence (right). Color surrounding evidence boxes indicates evidence type (see far right). Types may vary dependent on application. Thickness of line can be used to indicate weighting towards given Criteria (for example C1) or Evidence type.

techniques specified in (Cauchi et al., 2011) including "clamped " (O5) or "wraparound" (O6) schemes. If an end-stop is specified, various options arise regarding the action on the breaching of a limit. These may include alerting the user using a beep or series of beeps (O7).

An additional question (question 4: allow user to push and hold?) emerges regarding the behavior on a continual button press (O8). Continual increment on a single button press may reduce the time taken to program a device, however forcing multiple button presses (O9) may reduce the potential for error (Oladimeji et al., 2011).

QOC-E provides the means to convey this type of information and previous studies have highlighted many useful properties that can aid developers. These include the use of bridging criteria, articulation of trade-offs, contrasting of configurations (for example product variants to support differing criteria) and flexibility in the focus of analysis (feature by feature or global design).

Bridging Criteria

In the original scheme, MacLean and colleagues allowed the possibility of multiple criteria justifying each other through the use of bridging criteria. These are criteria that allow the relation of specific criterion (for example "ease of hitting with a mouse") to more general criteria such as "fast user actions" and/or "usability" (Moran & Carroll, 1996). Within the scheme shown in Figure 4 a similar principle exists in that criteria are linked to "columns" of evidence. For example the criterion "guard against unexpected initiation" is linked to evidence regarding the fact that empirical studies have shown the mechanism in question to be more likely to reduce error (Oladimeji et al., 2011) and the fact that guidance recommends such a scheme (NPSA, 2010).

Tradeoffs

Another feature of the original scheme is that patterns or principles (akin to the relationship described above) can be extracted that may suggest good design or show a tension in requirements. An example is when a pair of options is linked to conflicting constraints. This is shown by two options linked to two constraints with parallel solid lines and crossed dashed lines. Each of the constraints supports one of the options and challenges the alternative option. These situations will often warrant additional investigation. For example, a speed/accuracy tradeoff is shown in the top right hand side of Figure 4 (O1, O2, C2, C3).

Contrasting Configurations

Given a prevalence of tradeoffs, the scheme allows consideration of multiple product types or configuration options that allow satisfaction of a range of criteria. For example in the outlined case, the manufacturer may want to set the definition between fixed and variable increment as a configuration option. This may then be set dependent on clinical context or intended purpose.

Breadth First / Depth First Analysis

Previous literature has proposed two modes of designing (Moran & Carroll, 1991). In one mode, designers consider global principles, properties and "big decisions" and in another mode, they look at finer level detail that may involve "evolving" a given feature or aspect of design. The authors term these as breadth-first and depth-first design. Our example is breadth first, however there are several examples of the scheme applied to finer level technical detail such as messaging protocols, configuration options, or revision control schemes. The scheme is therefore flexible to suit purpose.

DISCUSSION

Advantages of Statements of Design Rationale

It is difficult (if not impossible) for any single person to have a full understanding of the design space and the risks associated with designing in isolation have become apparent in many cases (AAMI/FDA, 2010; FDA, 2010). Avoiding design flaws prior to deployment can offer order of magnitude cost savings (Karat, 1997) as it can be difficult or impossible to rectify problems post deployment.

Tools that make design reasoning explicit and allow the rationale behind a design to be shared are in the interests of a cross section of stakeholders accountable for safety, usability and efficiency. For example, those not directly involved in the development process can inspect the diagram to quickly expose flaws in reasoning or to compartmentalize parts of the design. If a piece of evidence or assumption is found to be incorrect then the areas that are impacted can be identified. Assuming independence of evidence, it is also possible to examine how many lines of evidence are in support. There may also be patterns, principles or markers that are reflected in safe or successful structures that can be used as a measure of optimality or suitability across design types.

Integrating with Existing Process

Question arise as to how the tool applies to modern development practice where design is often characterized by rapid iteration and frequent revision of assumptions and structure. If the technique produces a greater cost in revision effort than benefits achieved from adoption then it is unlikely to be implemented. This is analogous to the property of viscosity (Green, 1990), where a system becomes resistant to change, in this case through the potentially prohibitive amount of work required to implement modifications. Types of viscosity include repetition viscosity where the same operation has to be repeated many times or knock-on viscosity where a ripple effect requires multiple revisions to maintain the integrity of a system or structure.

One solution to viscosity is automation and software tools may provide functionality to support. For example, most modern software environments provide search functionality and/or find and replace tools that can be used to ease the process of modification. It would also be possible to formalize the content of nodes, by constraining syntax or including a

coding system. For example, it may be that parts of the structure are differentiated based upon functionality, product type, customer, those involved in creation, revision number or links to requirement tracking systems. This makes it easier to track changes, compartmentalize parts of the design and apply global changes.

An additional concern is that representations of this type become unwieldy, complex and difficult to interpret when applied to complex systems. The term “bloat”, applied to the provision of software functionality, corresponds to the tendency to add new features and complicate systems without provision to mask complexity (McGrenere, 2000). We suggest that if compiling a design rationale is overly arduous, then there may be inherent “bloat” within the system. Schemes of this type help the process of compartmentalization, or encapsulation of technical detail. Node structures lend themselves particularly well to this type of requirement in the expanding or collapsing of multiple layers of detail.

Concerns have also been raised that techniques of this type have not been applied in the industrial context and have yet to be validated. Since the original inception, QOC has been widely applied in numerous domains including Air Traffic Control (ATC) (Dutoit, 2006; Shum et al., 1996), neuroradiology training (Sharples et al., 2002) User Centered Design (Moran & Carroll, 1996), technology enhanced learning (Ouraiba, Choquet, & Cottier, 2011) and interactive cockpit display systems compliant with Aeronautical Radio Incorporated (ARINC) 661 (Martinie, Palanque, Winckler, & Conversy, 2010).

Questions also emerge about the utility of the technique compared with tools in widespread use such as GSN. QOC-E has been specifically crafted to support design and development, whereas GSN has been applied predominantly to the task of safety case or assurance case development. Although there is overlap, the delivery of a safety case often follows a formalized process and is predominantly focused on why a design meets regulatory requirements. QOC-E is focused on expanding and comparing alternative design options and would therefore be suited to formative stages of the design process, where the solution may be fluid and iterations rapid. It may be that in compiling this information there is a corresponding benefit when it comes to making a case for the release to market or incorporating feedback following deployment (Li et al., 2011). We therefore propose that QOC-E provides a useful way of checking the maturity of the design rationale, although at the time of writing the scheme has yet to be established or evaluated in an industrial context.

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