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An Outcome-Based Approach for Ensuring Regulatory Compliance of Business Processes

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Graduate Program in Computer Science
A thesis submitted in partial fulfillment of the requirements for the degree in Master of Science

AN OUTCOME-BASED APPROACH FOR ENSURING REGLULATORY COMPLIANCE OF BUSINESS PROCESSES

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Abstract

In service industries, such as healthcare, catering, tourism, etc., there exist regulations that require organisations' service to comply with the regulations. More and more regulations in the service sector are, or are aimed to be, outcome-focused regulations. An outcome prescribed in the regulation is what users should experience or achieve when the regulated business processes are compliant. Service providers need to proactively ensure that the outcomes specified in the regulations have been achieved prior to conducting the relevant part of the business or prior to inspectors discovering noncompliance. Current approaches check system requirements or business processes, not outcomes, against regulations and thus this still leaves uncertain as to whether what the users actually experience are really achieved. In this thesis, we propose an approach for assessing the compliance of process outcomes and improve the noncompliance. The approach is designed through the U.K's. CQC regulations in the care home environment.

Keywords

Regulations; Requirements; Requirements engineering; Method for regulatory compliance; Outcome-based; Checking compliance; Process improvement; Service; Health care.

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Glossary of Abbreviations

CQC	Care Quality Commission
RO	Required Outcome
AO	Actual Outcome
F-ROI	Functional Required Outcome Interpretation
NF-ROI	Non-Functional Required Outcome Interpretation
CRUD	Create, Read, Update and Delete
GRL	Goal-oriented Requirements Engineering
BP	Business Process
BPEL	Business Process Execution Language
BPSL	Business Property Specification Language
FSM	Finite State Machine

Glossary of Terms

Regulatory Compliance - Conforming to a rule, such as a specification, policy, standard or law.

Business Process - a collection of related, structured activities or tasks that produce a specific service or product (serve a particular goal) for a particular customer or customers.

Regulatory Body - Authority that legislates regulations.

Regulated Party - Organisations that are regulated by some regulations.

Required Outcome - Outcomes specified from the outcome-focused regulations that business process need to fulfill.

Actual Outcome - Real outcomes generated by business processes.

Compliance Requirement - Software or systems requirements that are compliant with regulations or derived from the regulations.

Chapter 1

1 Introduction

This chapter gives the introduction of the context and the general work about our research. Section 1.1 describes the underlying context surrounding our topic. Section 1.2 Problem Statement presents what problems currently exist in this area. Section 1.3 introduces the reason why the authority and we look at outcome-focused regulations. Research objectives and originality are presented in Section 1.4. About what we have done and how, we introduce them in Section 1.5. Lastly, in Section 1.6 and 1.7, our research contribution (a systematic compliance ensuring approach) and the structure of this thesis is displayed respectively.

1.1 Context and problem description, and motivation

Laws and regulations constrain the service industries (e.g., healthcare, catering, tourism, etc.) by giving prescriptions to guide and demand the service providers with regard to what and how to serve the targeted users. For example, in the domain of health care, the health care providers (e.g., care homes) need to demonstrate to the governmental regulatory bodies (e.g., CQC – Care Quality Commission of the U.K. [1]) that their operations always satisfy the regulations [2]. In Canada, the Long-Term Care Home Quality Inspection Program (LQIP) [63] in the province of Ontario continuously inspects LTC Homes to ensure they comply with legislation and regulations.

Business organizations in these industries need to make sure their behaviors (business processes) are compliant with related regulations. Failing to comply with regulations has numerous risks to the business, such as: damage to the business reputation [4] (e.g., noncompliant business can lose trust among the public), prosecution and penalties (e.g., non-compliance with HIPPA – a health Act in the USA – in 2009 resulted in a penalty of $2.25 million to CVS Caremark Co. [3]), and negative emotional and physical effects on humans [6].

Besides, an approach that uses technology to do "quick fixes" (i.e., be reactive, fix noncompliance when it happens) to comply against the acting regulations will no longer be adequate [12]. Organizations would thus need to be self-regulatory in order to be proactive [11]. Business operators have to take actions to do self-regulations [11] at the usual running time of service activities.

In addition, recently in the service industry, outcome-focused regulations have been gaining prominence. Traditional regulations generally require an organization to ensure that its processes are compliant. For example, "Unfair Competition Prevention Act of Japan" states that "A person who intentionally or negligently infringes on the business interests of another person through unfair competition shall compensate for damages which result from there". In this statement, the regulation focuses on the constraints (such as *if infringement occurs then compensate*) imposed on the market processes rather than specifying the outcome of these processes (e.g., fairness experienced by stakeholders). Outcome-focused regulations focus on outcomes of a process rather how to achieve the outcomes [1] (see figure 1).

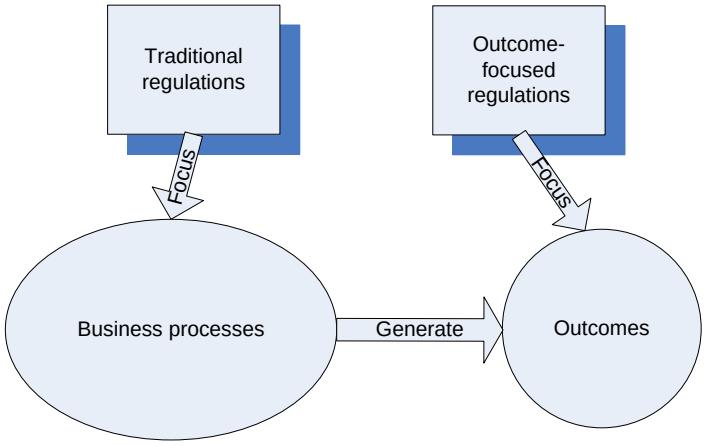


Figure 1: The relationships between traditional regulations and outcome-focused regulations

Because in the service industries, what the regulations emphasize is what users really achieve in the service processes. For example, for a CQC care home or restaurant, there are regulations that give prescriptions on the service they provide to the customers - what

should their service users achieve. E.g., the CQC says “every registered care home should ensure the service users’ dignity and privacy are respected”. These are what served users will experience. An “outcome” is (in CQC’s definition): “…. what we think people who use (care home) services should experience when providers comply with the regulation. This is what we will focus on when we check that providers are meeting essential standards”. Thus, the stakeholders (such business managers) need to demonstrate the outcomes required by the outcome-focused regulation are actually satisfied in their business processes. The systems or business processes need to show that it satisfies these requirements (or constraints).

As mentioned above, stakeholders need to ensure their business processes are compliant with regulations in order to avoid unnecessary penalty. The emergence of outcome-focused regulations adds to the difficulty for stakeholders to check if their business processes are satisfying these outcomes. Meanwhile, current state-of-art approaches are not applicable to this issue. Therefore, it is necessary to solve this problem.

1.2 Background of current approaches and analysis

The context introduced in Section 1.1 raises the need for stakeholders to have an approach to check if their business processes are compliant or not, and if noncompliance is identified, they need to correct the noncompliant business processes. Current compliance checking approaches and practice that focus on checking system (or software) requirement [42] [43] [51] do not ensure that the business processes are compliant. Problems such as requirements may be incomplete or missing, people may not be familiar with the requirements, and if the system is large then modeling the requirements is a non-starter. Approaches checking the runtime systems [5] [23] and business processes [53] [54] [56] deal with traditional regulations (focusing on how to do (processes) rather than outcomes), thus, they still do not ensure that the outcomes specified in the outcome-focused regulations and are not appropriate for our use (outcome-focused regulations mention outcomes rather than processes).

In addition, These approaches use techniques such as modeling techniques [9] [37] [51], logical reasoning [15] [36], etc., they require requirements analysts or software engineers

(a special kind of human resource), however, a service owner who does regular self-checking may not know how to use these techniques (e.g., KAOS (a Goal-oriented Requirements Engineering method)) to elicit requirements from regulations and making such a human resources arrangement may be too expensive. All above then raise the demand to have a convenient method for ordinary stakeholders such as service owners or domain experts to do self-regulation (regulatory check) and process correction with regard to outcome-focused regulations.

1.3 Why outcome-focused regulations?

As mentioned in Section 1.1, outcome-focused regulations have gained prominence recently. They focus on results rather than how to achieve them. In service industries, outcomes are more directly concerned with what users really achieve. In CQC's guidance [1], they declare that they use outcomes because outcomes focus on people's experience of care, the quality of the treatment, and support that they receive. People who use services tell them that this is what matters most to them, rather than the systems, policies and processes needed to deliver their care. Also, as the regulated parties can vary (in CQC's case, it regulates hospitals, care homes, hospices, etc), it is difficult to guide each kind as to how to achieve these outcomes. Therefore, setting outcomes can be regarded as setting the criteria for them to test their service compliance. As long as the business processes meet the criteria, we can say they are compliant with the regulations. In the meantime, as mentioned in [45], since regulated parties are not being told how to achieve required outcomes, such regulations can help promote innovation and enterprises can find ways to comply while satisfying their own business objectives. As the outcome-focused regulations do not mention the business processes (see figure 1), instead, they are centered on outcomes. Therefore, in order to check the compliance, we also choose to look at the actual outcomes from business processes and assess them against the required outcomes from regulations.

1.4 Research objectives and originality

The underlying research objective for this thesis is:

To design an approach for checking the compliance with outcome-focused regulations and doing noncompliance correction.

To the best of our knowledge, there is no published work on a systematic approach for checking compliance of outcomes and noncompliance correction.

1.5 Research contribution and the significance

Our foremost contribution is the approach for ensuring compliance with outcome-focused regulations. It consists of 6 steps: (1) pre-process the regulations, (2) interpret required outcomes, (3) search for related business processes, (4) identify the actual outcomes from the business processes, (5) Assess actual outcomes against required outcomes, and lastly, (6) improve the noncompliance. The approach we developed contributes to the research in the regulatory compliance area, as well as the practice in the industry. Our approach complements current research by proposing a systematic approach for ensuring compliance of outcomes. This approach does help the business people to ensure the compliance of their business processes, and thus help promote the service quality on their clients (service users).

1.6 Thesis structure

The thesis is organized as follows: Chapter 2 describes the background knowledge and related work, as well as the research gap analysis; Chapter 3 explains the work that we did about regulation analysis and decision making so as to develop an approach, as well as the validity analysis; An overview of the approach, the description of each step and the validation are presented in Chapter 4. Discussions are presented and implications are explored in Chapter 5. Lastly, in Chapter 6, conclusions and future works are discussed.

Chapter 2

2 Background and related work

This chapter talks about the literature review that is related to our work to show the related research achievements others did and a foreshadowing of how our work is collaborating with them. There is a number of interesting research on regulatory compliance and they are described and summarized below. Section 2.1 introduces what is so called regulatory compliance. Section 2.2 gives the nature of textual regulations. Section 2.3 introduces research done about representation and analysis of regulations. In section 2.4, the research about the interpretation of regulations is presented. Section 2.5 discusses the current theories for eliciting regulatory requirements. Then checking the requirements for compliance is presented in Section 2.6. Section 2.7 introduces the methods on checking business processes for compliance. Section 2.8 introduces the work on monitoring runtime regulatory compliance. Lastly, Section 2.6, the analysis of research gap is presented.

2.1 Regulatory compliance

Regulation is a legal provision that creates, limits, or constrains a right, or creates or limits a duty [24] which is a definition given by Wikipedia. For example, the Unfair Competition Prevention Act of Japan tells how a right of a company in the market should be, as well as its obligation. Organizations have to conform to the related regulations which give guidance or put constraints on their behaviors. Wikipedia also gives the description of “regulatory compliance” as conforming to a rule, such as a specification, policy, standard or law [25]. Regulatory compliance set the goal that organizations make efforts to ensure their personnel know and take actions to comply with relevant regulations [25]. Bitpipe [26] introduces Governance, Risk and Compliance as three components of conformance within an organization. Anton et al [23] also stated in the keynote paper of RELAW’09 that regulatory compliance means “to maintain a defensive position in a court of law”. It means that when organizations are putting efforts to

conform to the laws, they have to think that they should be able to defend what they adopt to do compliance and the results.

2.2 Properties of textual regulations

The textual regulation itself is written in natural language so that it has some characteristics that make the regulation conforming, especially compliance requirements elicitation a difficult task. Legal texts tend to be well structured and are organized hierarchically [30]. For example, most of the regulations have the level structures such as chapter, section, subsection, etc. For part of this reason and that legal texts often need to refer to other regulations inside (e.g., exception/ precondition/ constraints) and outside (e.g., other regulations or publications), therefore building cross-references and traceability is not easy to complete [31]. Legal terms are often ambiguous and lacunae [22]. For example, what does “necessary qualifications” mean in healthcare regulations? How many is necessary? Legal texts are often full of jargon that requirements engineers do not fully understand. In other words, they contain professional words which are rarely used in the Requirements Engineering community [31]. For example, “full nutrition” may only be understood by nutritionists. Also, organizations may have doubts about their own rights and obligations. In this case, they have to verify whether the lacuna has not been already filled in, for example, by binding judicial decisions (especially in the common law countries). Regulations evolve constantly, usually because the current versions are no longer enough to support new situations [30]. Whenever a new regulation is enacted or the current regulation is revised, organizations must take quick actions to fulfill it. Besides, different levels of laws may refer to each other, have overlaps, and even contradict each other [32]. For example, Federal laws constrain everything inside a country, however, a municipal law may have some provisions which are not consistent.

2.3 Representation and analysis of regulations

Semantic analysis of regulation refers to a process of analyzing semantic structure of regulations. Analyzing the regulations is vital to understand what the regulation provisions mean and it can also facilitate the logic reasoning. Anton and Breaux [27] classify regulation provisions as rights (i.e., what people are permitted to do), obligations

(i.e., what people are required to do) and constraints. They also give formal regulatory semantics. For example, the semantic elements of "*The covered entity (CE) must provide notice to the individual*." are shown in table 1. The same authors [14] proposed a systematic process for extracting rights, obligations and auxiliary concepts such as actors and constraints from legal text thereby generating a formal model of a law. Their method identifies and infers six types of data access constraints, handles cross-references, resolves ambiguities, etc., as part of extracting privacy and security requirements. This is a fundamental milestone to handle the complexity and syntactic ambiguity of legal texts.

Table 1: Example of semantics of an obligation in the regulation

Activity	Subject	Action	Object	Target
Transaction	CE	Provide	Notice	Individual

Kerrigan and Law describe a system that models environmental regulations using first-order predicate logic [36]. The system computes weighted relatedness scores between sections of regulation text using ontology. Hohfeld taxonomy of regulation [33] provides a classification of underlying legal concept (based on the notion of right, which can be defined as "entitlement (not) to perform certain actions or be in certain states") and which are described in the legal documents, into eight categories. This legal taxonomy (i.e., privilege, claim, power, immunity, no-claim, duty, liability and disability) is a landmark and has widely been used in various regulation sensitive domains such as law, systems engineering, health care, financial institutions, etc. where understanding of the legal documents and their underlying notion is extremely critical. These rights described in the Hohfeld taxonomy also have a correlative relationship. For example, privilege and no-claim are correlatives and it means that if someone has *privilege* on something, others *cannot claim* for the same thing. Based on Hohfeld's taxonomy, Siena et al [9] introduces a model to represent legal prescriptions, from regulatory documents, in terms of modeling elements (such as: a right, duty, actor and action) and relationships (such as: holder and counterparty with respect to the right) using ontology from the legal domain. After the normative proposition (the most atomic element in which a legal prescription can be subdivided) is modeled and they use the model in their Nomos modeling language.

Figure 2 shows a model of a normative proposition. Later in 2010, Siena in his PhD thesis [34] introduces the Nomos modeling language to express legal concepts. Nomos is an extension of i* which is a goal-oriented requirements engineering modeling language and Nomos is especially suitable for modeling legal elements [35].

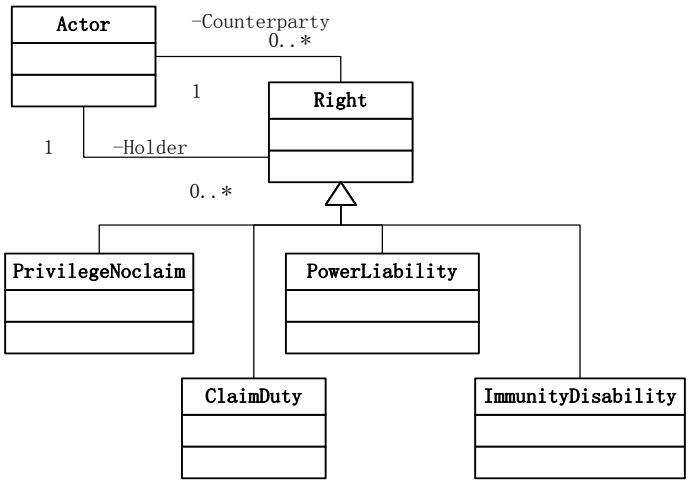


Figure 2: a model of elements in a normative proposition

In the meantime, many logic based methods have been produced to represent and reason about regulations, such as deontic logic [37], defeasible logic [38] and first-order temporal logic [5] [15] [31].The benefits of logic representation of regulations which has ambiguity are computer readability, structured query facility, and searching and classification facilities.

2.4 Interpretation of regulations

Legal terms are ambiguous and abstract, and laws define general directions, therefore, interpretation of legal terms is needed especially in the regulatory compliant requirements elicitation phase. As interpretation strongly depends on an understanding of the law and its internal structure and relations, legal texts are often difficult to understand for the "layman". Under the situation where a term is not certain in its meaning, there are legal interpretation methods that can be used for an organization in interpreting legal texts. These methods can be divided into these groups [28] [29]: lingual (based on grammatical,

morphological, and syntactical rules); logical (using formal logic rules); systematic (interpretation is made with respect to the whole legal order); historic (the meaning is clarified on the basis of circumstances under which the regulation was issued); teleological (based on the purpose and a function of the rule). In 2009, due to the fact that others' works are merely mapping legal concepts to software requirements without any interpretation, Ishikawa et al [15] gave a goal-oriented method to interpret regulations through previous cases and guidance. They then propose a meta-model for legal interpretations that are modeled as refinement relationships (such as and/or) between legal concepts. They manage the interpretation relationships by building them into goal trees so as to serve as criteria of further regulation refinement.

2.5 Eliciting regulatory requirements

Regulations constrain and put requirements on the system-to-be; therefore, it is important to elicit these compliant-requirements before a system starts to be implemented. Sutcliffe et al. [40] and Maiden [41] generate scenarios using use cases and object system models through a partially automated method. Meanwhile, Maiden defines object system models as patterns of requirements that include attributes for agents, actions, objects, and pre-conditions, among others and Maiden's scenarios were generated to be used in requirements validation phase. Siena et al. [7] introduces a conceptual framework which considers both legal concepts proposed in theoretical studies in the legal domain and concepts from goal-oriented requirements engineering. In their framework description, a domain characterizes a set of activities, and with the involvement of law, the sub-set of legal activities is scoped. Also involving users' goals, a sub-set of strategic activities is also scoped. The intersection of legal sub-set and strategic sub-set are legal-strategic activities and requirements to be elicited should be based on this intersection. Because requirements can be modeled as users' goals at a high-level, they view the eliciting, requirements phase as transforming from a model of legal concepts to a model of users goals. Based on this conceptual framework, in [39], the same authors propose the Nomos framework that contains a detailed process of generating law-compliant requirements. Given a model of law and a model of stakeholders' goals, legal alternative requirements are systematically identified and explored by analyzing the strategic goals that can realize

legal prescriptions. Giorgini et al. [46] propose Secure Tropos - a framework for security-related goal-oriented requirements modeling that, in order to ensure access control, uses strategic dependencies refined with concepts such as trust, delegation and permission, to fulfill a goal, execute a task or access a resource, as well as ownership of goals or other intentional elements. Ghanavati et al. [17] use Goal-oriented Requirements Language (GRL) to model goals and actions prescribed by laws. The models of goals and actions can be further refined to requirements. Darimont and Lemoine have used KAOS as a modeling language for representing goals extracted from regulation texts [12]. Such an approach results from the similarity between regulation documents and requirements documents. In 2010, Islam et al. describe in [8] a framework to assist in the elicitation and management of security and privacy requirements from relevant legislation. Conceptually, this framework resembles that in Nomos[39] except that it focuses on the analysis of security and privacy requirements for risks to intrusion and refinement of requirements.

2.6 Checking requirements for compliance

Once system or software requirements are elicited from regulations or the existing requirements from legacy systems, it is necessary to validate them against the regulations. In [27], Anton and Breaux propose semantic parameterization which expresses legal texts as semantic models of rights and obligations with the purpose of comparing semantics to check for compliance. In [17], a checking approach is provided by Ghanavanti et al. to deal specifically with privacy law. They use the Goal-oriented Requirements Language (GRL) to model goals (high-level requirements) established by laws and use a framework to model the processes of a hospital. Then they combine both models to check the compliance. Maxwell et al. [51] use the production rule model describing the legal domain knowledge that can provide the functionality for requirements engineering to query so as to identify potential areas of noncompliance in the requirements, and specify new compliance requirements to address the compliance gaps. Breaux et al. [52] propose the Frame-Based Requirements Analysis Method (FBRAM) to check the Cisco accessibility requirements for compliance with the U.S. accessibility law. They compare

the compliance requirements with the existing requirements of Cisco's by analyzing the gap and aligning both of them additionally.

Rather than systematic analysis of legal knowledge and requirements for noncompliance, another branch is to conduct an argumentation among stakeholders as long as the consensus is finally reached. Habli et al. [48] have shown how argumentation is used to assure the decomposition and traceability of requirements. Haley et al. [49] have shown how argumentation can be successfully employed to clarify how a system can satisfy its security requirements. Moreover, Ghetiu et al. [50] introduce the concept Argument-Driven Validation (ADV), structured arguments used as validity building elements. Based on these works, Ingolfo et al. [35] give an argument framework that integrate models of the requirements (expressed in i*) and the regulations (expressed in Nomos) for capturing arguments and establishing their acceptability of the elicited requirements.

2.7 Checking Business processes for compliance

Business organizations have a number of Business Processes (BP) that fulfill business tasks. The managerial layers of the organizations need to ensure that all business processes are compliant with regulations. This issue is emphasized when the organizations are super huge or distributed. There are two kinds of BP compliance checking approaches introduced in [55]: (1) Forward compliance checking which targets the verification of business rules during design time or execution time. (2) Backward compliance checking which aims to detect that noncompliant behavior has taken place by looking at the history of BP instances' execution, but this is unable to prevent actual noncompliant behavior.

Ghose et al. [56] propose an approach based on the patterns of compliance (i.e., pre-defined BP models for which compliance to regulations have been proven). The main idea is to compute the deviation of a given BP model to a certain compliance pattern. El Kharbili et al. [53] propose a BP checking framework. The checking framework rests on a semantic level for the compliance management. Regulations formalized as semantic policies are modeled into BPs as sets of semantic business rules. BPs are also modeled using languages adapted to BP execution. Then compliance checking engine consisting of

generic compliance checking algorithms is implemented by building on an inference engine. In [54] Liu et al. propose a method of model checking of business process models and legal models for compliance. They use Business Process Execution Language (BPEL) to model BPs as finite state machines and Business Property Specification Language (BPSL) to capture compliance rules as temporal linear logic. The benefit of their method is to enable the automated compliance verification of BPs. In [57], regulation definitions are integrated into BPs and rely on BP events and transactions for run-time compliance monitoring.

2.8 Runtime compliance monitoring

Regulatory compliance generally has two types: *intentional compliance* and *actual compliance* [39]. Intentional compliance means assigning the responsibilities to actors and the compliance is achieved if the actors fulfill their goals. Usually, intentional compliance is achieved through requirements-based methods, however it is important to stress that requirements are limited to the scope of software systems because the regulations also govern the broader scope of business operations (processes) [5]. Actual compliance means the running systems should be ensured compliant and laws prescribe actions on certain events that can only be detected at run time [23]. In [5], Breaux proposes a method to acquire finite state machines (FSMs) from stakeholder rights and obligations for compliance monitoring. In his method, the semantic models of regulations will be taken as the input sequentially into the consistency checking and FSM generation phases, and FSMs will be generated as the output. Run-time systems are then instrumented with FSMs to report events and detect violations.

Some other methods also have been proposed to have the capacity to specify and deploy regulatory requirements monitors in real-time systems. Spanoudakis et al [42] identify the differences between expected and runtime system behaviors by modeling the relationships between events. Robinson [43] introduces a runtime requirements monitoring framework which can be used to align regulatory compliance requirements monitoring with design methodologies. In [44], the author proposes a method to query runtime assumptions though a generalized interface. Peters and Parnas [45] address the

issues about real-time notification under discrete-time sampling and sample quantization which can be used in compliance requirements runtime monitors.

2.9 Analysis of the research gap

To the best our knowledge from the literature review, no one is investigating regulatory compliance in terms of "outcome" of a process with respect to outcome-focused regulations (regulation outcomes are ones that are what is actually checked against by CQC inspectors).

In Nomos-like approaches, it models the regulations and compliance solutions in terms of goals and system (or software) requirements. The key difference of our work from the Nomos framework [14] is that we check the "outcomes" of a business *process* against regulations, not system goals or requirements (as in Nomos). Methods such as frame-based requirements analysis method (FBRAM) [52] and the production rule model [51] help to check if the requirements are compliant. However, while the compliance of requirements is established, these methods still do not ensure that either business processes comply with the regulations or process outcomes are sufficient to satisfy the required outcomes. Also, for an existing system such as a legacy system, requirements might be absent; therefore checking requirements for compliance is a non-starter.

Runtime system monitoring methods such as [42] monitor runtime systems against compliant requirements to ensure that these requirements are correctly implemented and performed. However, as requirements are limited to the scope of software (and systems), a broader range of business processes (including manual processes) are not covered by these methods.

In addition, traditional regulations focus on procedures or processes rather than outcomes. Business process checking methods such as [53] [54] generally focus on business rules derived from traditional regulations which means a regulation describes constraints or changes of a business process. However these methods are not suitable to address the issue of outcome-focused regulation compliance as the outcome-focused regulation focuses on outcomes rather than the processes or procedures that result in the outcomes.

Therefore, the process outcomes are not necessarily ensured compliant with the outcome-focused regulations.

Our work complements their works by proposing an approach to ensuring compliance of outcome-focused regulations. Business process outcomes will be analyzed and assessed to see if they are sufficient to satisfy the required outcomes from the outcome-focused regulations.

Chapter 3

3 Analysis and decision making

This chapter introduces the process of data collection, analysis and decision making that we have done so as to design a method that could be applied for regular self-inspection, compliance confirmation and noncompliance correction. We conducted it by analyzing the CQC regulations and actual business processes of a care home in Britain. Section 3.1 is to give an overview of the environment we analyzed including the company introduction, regulation introduction and the problem overview. Section 3.2 describes the procedures of data collection, analysis and decision making. The process includes regulation analysis, regulation interpretation, analyzing the business processes for actual outcomes, checking for noncompliance and correcting noncompliance.

3.1 Context overview

As mentioned in Chapter 1, our goal is to design a method that can be used to detect and improve noncompliance based on outcome-focused regulations. Based on this goal, we decided to look at concrete outcome-focused regulations (the CQC guidance) and the business processes in a care home to support the method design. We focus on two things here: regulation outcomes and business process outcomes which we examined for identifying and correcting noncompliance

3.1.1 Overview of the Care Quality Commission (CQC) Regulations

The Care Quality Commission (CQC) of the U.K. issues a guidance to help make sure that the care people (service users) receive meet essential standards of quality and safety and to encourage ongoing improvements by those who provide care [1]. CQC's guidance focuses on outcomes rather than systems and procedures and it contains outcomes which are what users will experience or achieve. For example, in CQC's Outcome 5, it states that "people who use the service can express their views, so far as they are able to do so…" rather than specifying the procedures that service providers should do to achieve the outcome - service users "can express their views". This is because CQC places the

views and experience of users at its center [1] as they say “results are the most important” and that what matters most to users are their experience of care, the quality of care and support they receive rather than on how to achieve it.

CQC will frequently send assessors and inspectors to review the service of providers before any service provider can legally operate or during their operation and will use enforcement power if necessary. In the meantime, they will focus on outcomes when they check the business operations.

CQC guidance is to help service providers meet the requirements of the Health and Social Care Act 2008 and CQC regulations. Even if the guidance itself is not enforceable in its own right, however, as CQC will send their inspectors to evaluate the outcomes before service providers can start their operations (register their service) and will continuously send them to check if the operations of service providers are compliant or not in the running time, it in effect results in that this CQC guidance can have legal validity as service provider face a binary selection (being compliant or being shut down). At the same time, this guidance will also be used by courts and tribunals when stakeholders appear in the court from time to time [1].

3.1.2 Overview of the company

The company of which the business processes we plan to investigate is a care home in the U.K. This care home has three branches: The first branch has 40 beds registered for four types of patients (i.e., Dementia (DE), Physical Disability (PD), Mental Disability (MD) and Old age (OP)); the second branch has 29 beds (i.e., DE, PD, MD and OP) and the third branch has 28 registered beds (i.e., DE, PD, MD and OP). The main responsibilities are giving sufficient care to service users and supporting them so as to have a better recovery process. Stakeholders in this care home include the board members, management team members, staff and service users. The ordinary processes that the care home has are, for example: admission process of new service users, processes of giving care and treatments, processes of medicine management, processes of medicine purchase, processes of handing users’ complaints, etc.

3.1.3 The problems and needs of the company

The care home that we have investigated has been registered under CQC. Every registered organization has to fulfill what the governing institution requires. As the CQC guidance comes out, the care home needs to confirm that the outcomes specified in CQC guidance have to been achieved, otherwise, it can suffer from the danger of being forced to stop its business (as interviewed by us, they declared it as "suspension of the business operations which will take up to one year plus the penalty"). Some example problems in this care home are given below:

A problem scenario: Outcome 4 of CQC guidance says "People who use services experience effective, safe and appropriate care, treatment and support that meets their needs and protects their rights." The managers of this care home are not sure if their business processes are compliant or not. For example, how do they decide if their business processes "protect users' rights"? How do they decide if their business processes will let people experience "effective, safe and appropriate care"? How much do they need to do to ensure these non-functional requirements such as "effective"?

The care home management team does not have a relatively easy and efficient method to proactively identify where the business processes go wrong with reference to the outcomes required in the CQC guidance and they need to act upon the deviation promptly (as CQC sees it as a very positive step learnt from the interview). The inspectors from CQC will come to the care home to check their business processes every now and then ("unannounced and depending on what they find they will come back with a minimum once a year to 4 or more times a year"). The care home needs to gather the evidence of meeting the outcomes and be confident in demonstrating that they meet the regulations.

Meanwhile, also learned from the interview with them, they stated that the cost of hiring special experts (such as requirements experts and software experts for doing technical system and business modeling, etc) and time is not a luxury they have. They need to have "practical" solutions that their staff, once trained for some degree, can perform.

3.2 Description of analysis and decision making

In this process, we analyzed the CQC guidance and the business processes of this care home so as to build a systematic approach for the care home to check and correct the noncompliance.

We started with a question and a sample outcome from the CQC guidance.

The question is: what are the targeted variables that exist in the CQC guidance? (variables such as actors, activities, objects, conditions, constraints, etc.)

For the legal texts from the CQC guidance, we picked up a fragment that shows an outcome of the CQC guidance:

> *Outcome 9: What should the service users experience?*
>
> *People who use services:*
>
> *(1) Will have their medicines at the times they need them, and safely*
>
> *(2) …*

Figure 3. Partial description of CQC guidance Outcome 9

Item (1) in figure 3 above is a required outcome description. It is about what service users will experience when having their medicines. We analyzed the semantics of the sentence and identified the target variables that we are tracking for checking the compliance. The identified variables are shown in table 2.

Table 2: Example of semantics of an obligation in the regulation

Subject	Activity	Object	Constraint/conditions
Service users	Have (medicine)	medicines	• At the time they need them; • Safely.

We found that these variables are usually ambiguous or abstract and cannot match easily to concrete business processes for checking compliance. For example, what does “safely” mean? How do we evaluate “service users take medicine safely”?

Therefore we need to explain the outcome, and we later found almost every outcome specified in the CQC guidance is abstract and ambiguous. We interviewed the stakeholders from the care home and we got this answer: because the CQC guidance aims for regulating different kinds of health care organizations such as hospitals, hospices, care homes, etc., the legal texts cannot be very detailed and local. The legal texts should be trying to cover all the situations with limited sentences of descriptions.

We made the decision: if the outcome is ambiguous, then we interpret them. This interpreting process is transforming the required outcomes (high-level) to concrete and domain specific (low-level) outcomes. Hence, the domain knowledge is needed by involving domain experts.

We selected again the outcome above - “users will have their medicine safely” and asked the managers of the care home as an input of the domain knowledge to interpret the outcome. The interpreted outcomes (sub-outcomes) are displayed in table 3:

Table 3: The interpreted outcomes of “users will have their medicine safely”

ID	Sub-outcome description
I1	Service users’ medicines will be: (i) accessed only by the staff (ii) ensured to have validity w.r.t the expiry date and (iii) stored in a safe environment.
I2	Service users will take the right type of medicines and right volume.
I3	Service users will be instructed on how to take the medicines properly.
I4	If some accidents happen because of taking medicines improperly, service users will get immediate rescue.

The relationship among the four sub-outcomes is “and” which means the sub-outcomes collectively represent the original outcome.

We did analyze all the sub-outcomes during our research procedure. Here, in order to avoid repeatability, we just picked sub-outcome I1 for explanation in this thesis. We again analyzed the semantic variables of it and the result is shown in table 4:

Table 4: Semantic variables of the sub-outcome I1

ID	Subject	Activity	Object	Constraint/conditions
I1.1	Service users’ medicine	Be accessed	staff	only
I1.2	Service users’ medicine	Be ensured	Validity of expiry date	/
I1.3	Service users’ medicine	Be stored	environment	safe

With these variables identified, we need to check the real performance of business processes in the care home to check for compliance against the variables in table 4.

For sub-outcome I1 (in table 3), there are three partial sub-outcomes (in table 4): I1.1 “service users’ medicine is accessed by staff”; I1.2 “service users’ medicine is ensured to have validity w.r.t the expiry date”; and I1.3 “service users’ medicine is saved in a clean environment”. We need to identify where these partial sub-outcomes I1.1, I1.2 and I1.3 exist. We then identified the business processes of “S1: medicine management” where the “accessing (medicines)” and “stored in a safe environment” exist and business processes of “S2: medicines purchase” where “ensured validity w.r.t the expiry date” exists and we identify and describe related business processes as below:

S1: Medicine management.

P1: The staff adds every medicine with its owner’s (user) tag and save them in the clean fridge which never has power outage.

P2: Whenever users need to access their medicines, the staff will let them show their IDs, help them get the medicines that only belong to the users and keep record of access history in the database. The repository room is secured and users can not touch the medicines inside the repository room.

S4: Medicine purchase.

P3: Before the agent decides to purchase any medicine, s/he will negotiate with the user on the issues of users' needs, price, producers, brands, etc.

P4: The agent who purchases the medicine carefully checks every medicine they purchase to ensure the validity of expiry date, authenticity of medicine, etc.

P5: The agent keeps record of every medicine in the database after the purchase.

From the business processes above, we identified the actual target variables which can match target variables (in table 4) as below in table 5:

Table 5: Actual target variables from the medicine management processes

ID	**Subject**	**Activity**	**Object**	**Constraint/conditions**
AI1.1	Service users' medicine	Add tag	Staff	/
AI1(2)	Service users' medicine	Be accessed	Staff	/
AI2(1)	Service users' medicine	Stored in	Fridge	Clean, never has power outage
AI3(1)	Service users' medicine	Be checked	validity	When purchase

Some constraints/conditions in table 5 that are not easily identified (need analysis of business processes) are left empty (we identified them later in *Analysis of business*

processes). We now need to assess if the actual target variables in table 5 can match and satisfy variables of legal texts in table 4.

Analysis of business processes: As the medicines of users are stored in the repository room, and (1) the medicine can only be touched by the staff in the repository which means common users need to get the medicines through the staff, and (2) staff adds the tag to every users' medicines which means the staff knows which medicines belong to whom, and (3) users need to show their ID when accessing their medicines which means the staff knows if the medicine has been given to the right people. In sum, if the staff follows the correct routine, the medicines of users can not be accessed by other users and can just be accessed by the staff. This fulfills the constraint of I1.1 in table 4, therefore, the sub-outcome I1.1 is satisfied. Also, we found that users' medicines are saved in the clean fridge which never has outage, so I1.2 – "users' medicines are saved in a safe environment" is also satisfied. In the business processes of medicines purchase, we found that the medicine agent will check the validity of medicines to ensure the medicine is not expired. However, as we discussed with the manager of the care home, "the medicines are ensured valid in the purchase time" does not ensure they are always valid. We could not find any evidence that in the process of medicine management showing they are checking the validity of medicines periodically (e.g., every half a month). Therefore, we declare the I1.3 is not satisfied. This business process in the medicine about ensuring medicine validity periodically is missing; hence, we need to implement the missing process.

To sum all above, we analyzed a fragment of legal texts, identified target variables from the regulation and made the decision of interpreting outcomes in the regulations. We then identified the matched actual variables from the business processes and analyzed the business processes so as to assess if actual variables satisfy the regulation variables or not. Different compliance situation are analyzed and shown. All of these form the basis of designing our approach.

3.3 Threats to validity

This section describes the threats to the validities of our research results including external validity and construct validity. Because our research is done so as to develop an approach (a solution-seeking study), not a case study or an experiment, therefore the internal validity does not apply here. Analyzing the threats of validity helps to find the truthiness of our approach.

3.3.1 External validity

External validity is, in scientific studies, the extent to which the results of a study can be generalized to other situations and to other people, usually based on experiments as experimental validity [60]. External validity decides the extendibility of the research result to other situations such as places, time and backgrounds. A threat to external validity is an explanation of how it might be wrong in making a generalization. We analyzed the external validity of our research results and conclude several threats as below:

Population validity

Population validity means the extent to which the sample research objects can be extended to a whole population. Our research procedure has the threat to this validity because we were just looking at one outcome-based legal document (CQC's guidance) and it may have something unique that is different from other outcome-based regulations. For example, in the CQC guidance, the outcomes specified in it are all about what the users shall experience or achieve. Perhaps, in a regulation of other domains, such as the unfair competition prevention act in the market, the outcomes may be mostly about the company behaviors in the market. Also, we just look at one set0 of business processes (those in the care home). Some processes in other domain may be much more complicated (e.g., processes in a nuclear sector). What is more, the people we ask to interpret the outcomes might also be one-sided. It could be possible that if another group of people perform this task, the interpreted results are different. Thus the decisions that decide the steps of our approach might be changed accordingly. Making deeper investigation of more regulations and more domains can help to lessen this validity.

Ecological validity

Ecological validity is a form of validity in a research study and for a research study to have ecological validity, the methods, materials and setting of the study must approximate the real-world that is being examined [62] as opposed to artificially simulated laboratory environment. In our research procedure, we were investigating the real outcome-based legal documents (Care Quality Commission's guidance) and the real business processes from the care home in the U.K., therefore, we can say, there is no threats to the ecological validity in our research procedure.

Temporal validity

This is present when the results of a study can be generalized across time. In our research of which the result is an approach to ensure compliance, as long as the regulation is outcome-focused, then we can say at any time our approach is applicable. Therefore, there is no threat to the temporal validity.

3.3.2 Construct Validity

Construct validity is the degree to which inferences can be made legitimately from the operationalizations in the study to the theoretical constructs on which those operationalizations were based. Construct validity answers the question: "Are we actually measuring what (the construct) we think we are measuring?" In our research, the constructs are compliance situations between regulations and business processes (including outcomes specified in legal texts and actual outcomes from business processes). We measure them through analyzing the semantic variables in regulations and the corresponding variables in business processes. The threat of this validity is the degree to which we have extracted or observed the right information from regulations and business processes, as well as their compliance situations. We mitigate construct validity by involving domain experts (managers and operators of the care home) and legal experts (CQC experts) in our analysis process.

Chapter 4

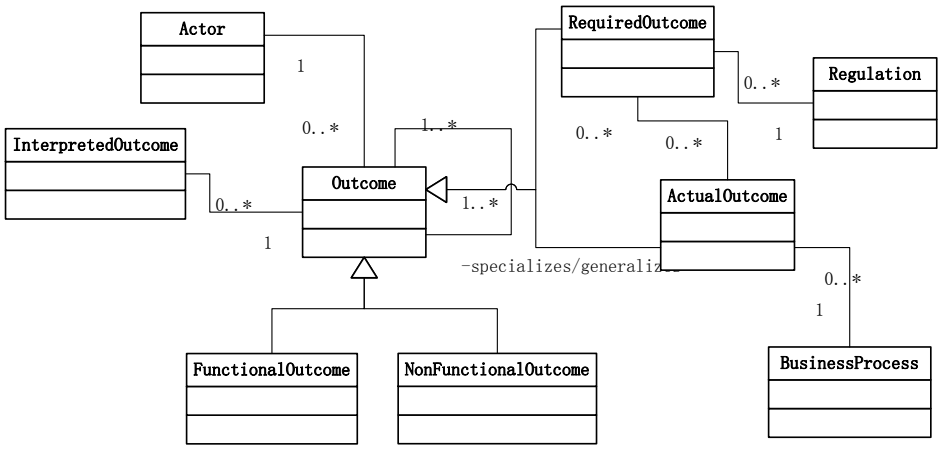
4 Research result: the outcome-based approach

In Chapter 3, the process of analyzing the real data from legal side and the business side has been displayed, and how decisions should be made in solving the problem is also presented. In this chapter, we describe how the resulting approach looks like and how it works. Each step of this approach is presented clearly and specifically. Section 4.1 gives an overview of our outcome-based regulatory compliance checking approach. Section 4.2 unveils the method to pre-process the regulations. Section 4.3 introduces how a high-level required outcome should be interpreted. Section 4.4 presents how to search for specific business processes for a required outcome is given. Section 4.5 discusses the detail of checking required outcomes against actual outcomes. In Section 4.6, how to correct the indentified incompliance outcome is presented. Lastly, a preliminary validation is made for the approach through expert evaluation.

4.1 Approach overview

An overview of the outcome-based regulatory compliance ensuring approach is shown in figure 5. It contains six steps to support the purpose of analyzing regulations and business processes, and identify the noncompliance. The main inputs of this process in figure 5 are legal texts, legal knowledge and domain knowledge. The main stakeholders here are legal experts (such as lawyers or staff from the authority) and domain experts (such as business analysts or related industry experts). Because the regulations have professional legal terms which are difficult to understand, a term library is built for the understanding among stakeholders as well as to facilitate the later interpretation of the regulations. The relationships (traceability) between the textual regulatory provisions within themselves and outside are analyzed and maintained. For example, some provisions may refer to some others and some can be embedded into other provisions. The outcomes in the outcome-focused regulations are high-level requirements established by the regulations (abstract and global from the regulations) and will be passed through an interpretation (refinement) process participated by domain and legal experts. Outcomes from the

regulations following the steps above are called *Required Outcome (RO)*. RO is prescribed by regulations. Correspondingly, there should be outcomes that are derived from actual existing business processes to match RO that we denote as *Actual Outcome (AO)*. AO depicts what users will experience or achieve from actual business processes. However, we will let AO to be identified and analyzed right before the checking time. AO differs from RO because: (i) RO refers to a global subject as derived from regulations, whereas AO refers to a set of local instances from all kinds of real subjects regulated. E.g., "registered persons" (RO) stated in regulations can be referred to long-term care homes and emergency care homes (AO). (ii) RO is an abstract characterization of a set of potential AOs as perceived by regulatory bodies while AOs are concrete from real business operations. This is a specialize/generalize relationship between RO and AO. For example, "user information is protected" is abstract and the corresponding concrete behaviors can be "users records in the database is protected using password" happening in our care homes. The outputs of the interpretation process are *Required Outcome Interpretations (ROI)* which can be classified into *Functional ROI (F-ROI)* and *Non-Functional outcomes (NF-ROI)*. A metamodel of these elements is given in Figure 4.



This figure shows that an Outcome has one or more Actors (agents are associated with outcomes) and has two sub-classes: FunctionalOutcome and NonFunctionalOutcome. Also, another two sub-classes are RequiredOutcome and ActualOutcome including a many-to-many relationship in between. An Outcome can contain several other outcomes. RequiredOutcome has a many-to-one relationship with Regulation. ActualOutcome has a many-to-many relationship with BusinessProcesss. Meanwhile, an Outcome can have multiple InterpretedOutcomes (one-to-many relationship).

Figure 4: A meta-model depicting the relationship among outcomes, addressees, regulations and business processes

To check the F-ROIs, we need to match NF-ROIs and with AOs identified from the business processes. For checking the NF-ROIs, legal and domain experts make assessment criteria after which the assessment tables are produced to facilitate assessing the business operations. Finally, all the incompliant business processes identified from above will be improved through a process improvement stage. Detailed depictions will be presented in the following sections.

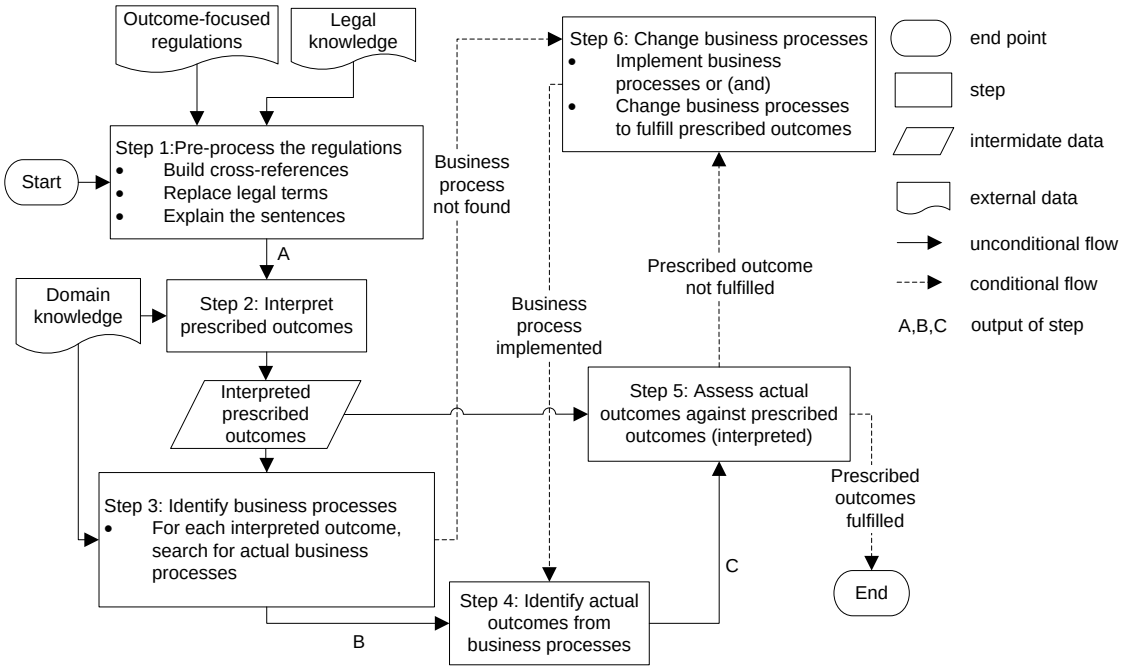


Figure 5: Overview of the outcome-based regulatory compliance ensuring approach

4.2 Steps of the approach

In this section, details of each step of our approach are explained. Examples and reasons are also presented.

4.2.1 Step 1: Pre-processing the regulations

This step of this approach is to analyze the regulations and find the references between the regulations and references between regulations and external resources. The inputs of this step are the outcome-focused regulation and legal knowledge, and the outputs are explained and organized (traceability built) regulation outcomes.

First, we need to link some regulation provisions to some others referred by them. For example, in CQC guidance, an outcome saying "users shall receive safe medicine" shall happen inside the outcome "users receive safe and comfortable care and treatment". Also, some regulation provisions will be traced to some other documents (i.e., another act or material, e.g., one of the CQC provisions "…providing sufficient nutrition to users" may be linked to some nutrition standards about what is the sufficient quantity of different kinds of human's nutrition). We then identify the legal terms so that a term library can be built with the explanations of these terms (e.g., what does "parental nutrition" mean?). Here the explanations of the terms are not interpretations or refinements, while they are merely the direct translations from the legal perspective. The source of the legal explanation can be legal experts or any legal domain reference (in CQC, these are legal experts and the glossary appendix within the guidance). Besides the explanation of legal terms, some sentences may be confusing for the law "layman" (such as business analysts), therefore, if necessary, an explanation of the whole sentences is required. We propose to use the web browser to render these regulations and the associated links so that operators who use our approach can have a visualized and operational tool in this step. Figure 6 shows an example of prototype of this kind of web-based tool. Optional operations could include: (1) Create, remove, update and delete operations of regulations; (2) Add links to regulations for traceability; (3) Add explanations to terms, etc.

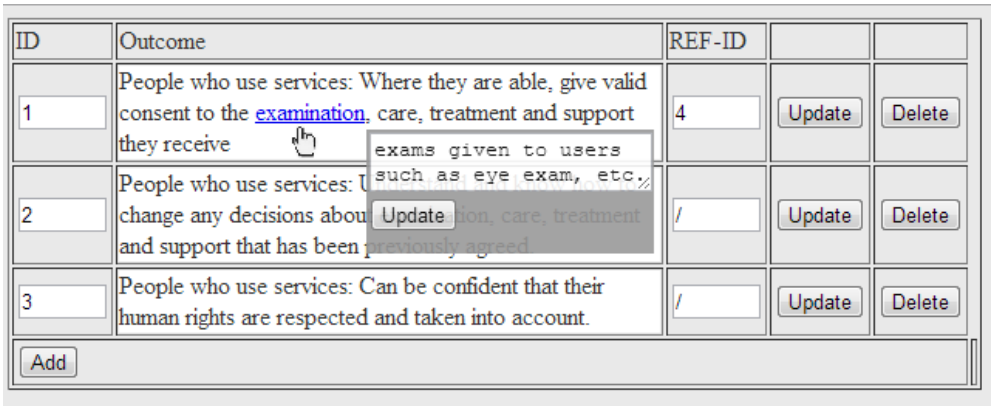


Figure 6: A snapshot of the prototype of regulation management tool

4.2.2 Step 2: Interpreting the required outcomes

This step is to interpret required outcomes from the outcome-focused regulations to required outcome interpretations. The inputs of this step are explained and organized required outcomes from Step 1 as well as the domain knowledge, and the outputs are required outcome interpretations.

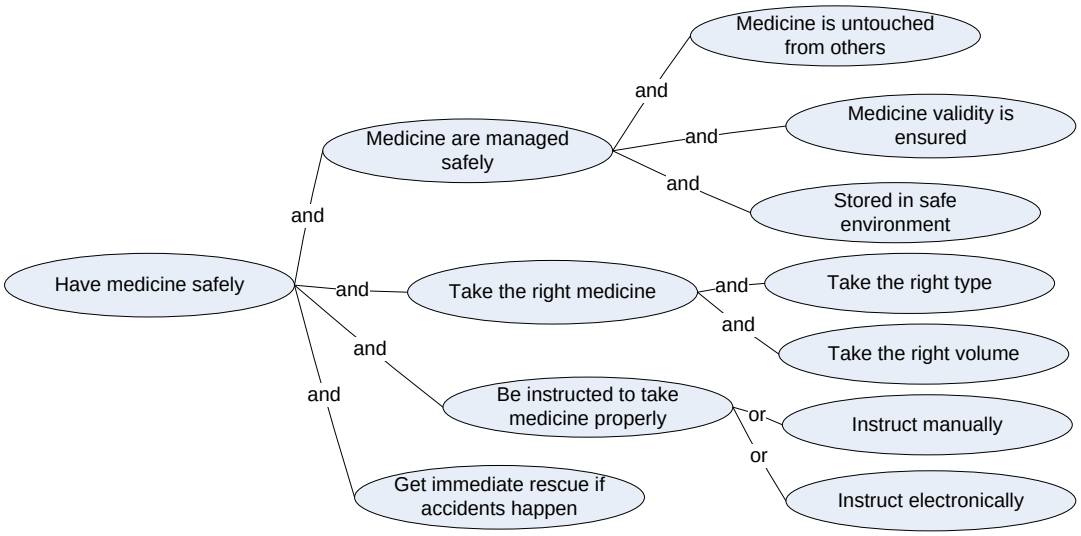


Figure 7: An example of outcome interpretation in the hierarchical form

The interpretation process resembles the goal interpretation process in Goal-Oriented Requirements Engineering (GORE) [16]. A required outcome which is abstract from the regulation is interpreted into concrete sub-outcomes (interpretations). Figure 7 shows an

example of the hierarchical form of the interpretation of an outcome “people who use services will have their medicines safely”. There are two relationships between the interpreted sub-outcomes. One is “and” that means in order to fulfill the outcomes, every sub-outcome has to be fulfilled. Another is “or” that means for a potential set of sub-outcomes, as long as one of them is fulfilled then the outcome in their father node is satisfied.

4.2.3 Step 3: Identify related business processes

This step is to identify the business processes according to the interpreted outcomes in Step 2. The inputs of this step are interpreted outcomes and domain knowledge and the outputs of this step are identified business processes. This step consists of two parts: (1) setting the scope, and (2) identify business processes.

(1) Setting the scope

For each of the interpreted outcome chosen, with the domain experts’ help, the scope of the business processes can be identified. A behavior can be identified from the chosen outcome. E.g., from the outcome “service users shall take the right volume of medicine”, a behavior of “take medicine” is identified. This behavior can thereby be used in identifying the business process scope where potential relevant business processes exist to generate the outcome. The scope of the processes set the boundary of related business processes of which one or more processes’ outcomes can be used for later checking. The purposes of setting the scope are: (1) to correctly identify where the potential business processes should be, and (2) to reduce the efforts of searching for related business processes by shrinking the boundary. For example, the interpreted outcome stating “service users will be instructed on how to take the medicines properly” just results from the process of delivering the medicines. We do not need to look at the whole environment and therefore just focus on this scope.

(2) Identify the business processes

Once a scope is given, related business processes that can potentially generate the actual outcomes to satisfy the chosen required outcome are then searched within this scope. For

example, taking the same instance above, for the outcome which is "users are instructed to how to take medicine properly", inside the scope of delivering medicines, the business process of staff's explaining how to take medicine is being searched for. If no business process is found which means no chance of generating the actual outcomes exists, go to Step 6 to implement the missing processes. If any business process is found, go to Step 4 for identifying actual outcomes.

4.2.4 Step 4: Identifying actual outcomes

This step is to identify the actual outcomes by analyzing the business processes identified in Step 3. The inputs of this step are business process(es) and the chosen required (interpreted) outcome from Step 3, and the outputs are actual outcomes that are identified from these business process(es).

For the chosen required outcome, analyze the workflows of the business processes and the final results to identify the outcomes. For example, given a required outcome interpretation "service users' medicines are kept separate from others", a business process can be identified that is described in Figure 8:

> …Whenever users need to access their medicines, the staff will let them show their IDs, help them get the medicines that only belong to the users and keep record of access history in the database. The repository room is secured by entrance guard. Service users can not touch the medicines inside the repository room…

Figure 8: An example of a description of a business process

An outcome from this process is: Users' medicine cannot be taken by others (because of the need to show IDs to take the medicine).

A business process can have multiple outcomes in multiple aspects. For example, from the business process above, outcomes can be "medicine managers have seen users' IDs", "access history is saved in the database", etc. Only those that are able to (partially) positively (or negatively) support satisfying the required outcome are what we needed.

4.2.5 Step 5: Checking the actual outcomes against required outcomes for compliance

This step is to check the actual outcomes against required outcomes for compliance. The inputs of this step are actual outcomes indentified from Step 4 and required outcome interpretations (sub-outcomes) from Step 2.

As we found, there two types of outcomes: (1) Functional Outcome – the actions or behaviors performed on service users. E.g., in CQC guidance, "users are supported to have adequate nutrition and hydration" and "users are protected from abuse or the risk of abuse" are functional outcomes. (2) Non-Functional Outcome – outcomes that specify criteria that can be used to judge the operation of a system, rather than specific behaviors. For example, outcomes such as "users should experience effective, safe and appropriate care" and "users can be confident (that their human rights are respected)" are non-functional outcomes. Non-functional outcomes are sometimes embedded inside functional outcomes to describe the degree of the behaviors (functions).

For checking functional outcomes, we need to judge that if the actual outcomes satisfy the required outcomes or not which means the actions designated by required outcomes occur or not. The answer will be binary (Yes/No). For checking non-functional outcomes, actual outcomes behave as the evidence collected to be evaluated against the required outcomes. A similar assessment table as in [45] can be used for evaluation and the assessment table contains several levels to describe the non-functional property. In Table 6, an example of the assessment table is given.

Table 6: Example of an assessment table to evaluate the non-functional outcome "users experience effective treatment"

Result/Level	No/1	No/2	No/3	Yes/4	Yes/5
Level Description	The treatment is totally wrong and messy	The treatment is not technically right	The treatment is technically proper but the users feel uncomfortable	The treatment is careful and users feel good	The treatment is very careful and users get many useful suggestions

4.2.6 Step 6: Improving business processes

This step of improving the business processes includes two parts: (1) implement the missing business processes, or (2) improve the existing business process. The inputs of this step are noncompliant information and required outcomes (interpretations) for part (1); or noncompliant information, existing business processes and required outcomes (interpretations) for part (2).

(1) Implement missing business processes

In Step 3, if some business processes are found missing, a goal-oriented scheme of implementing the business processes is taken. For the corresponding required outcome, a goal is searched. For example, if a required outcome is "the users' medicine saved should be ensured valid", a goal "medicine managers want to check periodically that the medicine is not expired" is identified. Therefore the process of periodically checking medicine validity will be implemented. Once the process is implemented, it will go to Step 4 again for identifying actual outcomes and then Step 5 for checking compliance iteratively.

(2) Improving noncompliant business processes

Step 5 helps to identify the business processes that are noncompliant. Noncompliant business processes can be classified into two types: (1) business processes that do not generate actual outcomes that can support satisfying the required outcomes and (2) business processes that do generate the actual outcomes but are not sufficient to support satisfying the required outcomes. To improve them, here we can use Goal/Question/Metric (G/Q/M) – Quality Improvement Paradigm (QIP) [20] process improvement method. Generating actual outcomes to sufficiently support satisfying an expected required outcome is a "Goal" in G/Q/M. E.g., a Goal could be that the business processes of medical treatment given shall generate the outcomes to support "users receive effective treatment". "Questions" that define the goal as completely as possible in a quantifiable way are generated. For example, is the treatment giver explaining to users carefully? Does the treatment giver follow the right procedure of giving a treatment?

Lastly, specify the "Metrics" needed to be collected to answer those questions. QIP method is displayed as below in figure 9. QIP is broken into two closed loop cycles – the organisational (larger) and the project (smaller) cycle to support continuous process improvement and engineering of the development processes. G/Q/M can be integrated in to QIP to do the process improvement and noncompliant business processes will be improved by it.

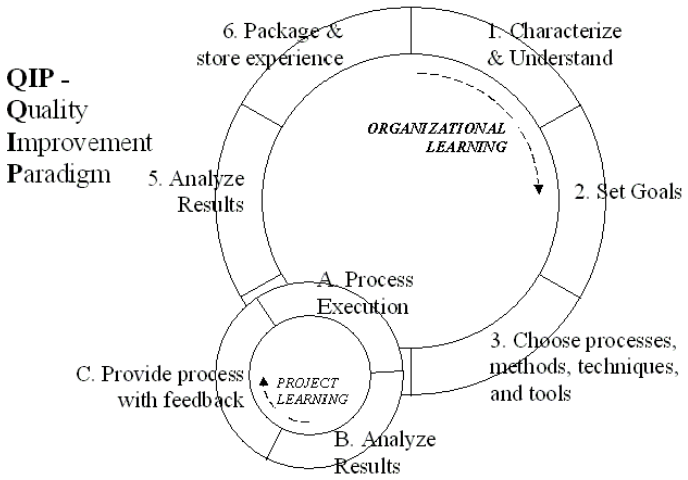


Figure 9: The Quality Improvement Paradigm cycle

4.3 Validation of the approach

Validation of a method or approach is the process of demonstrating that the performance characteristics of a tested method meet the requirements of the intended use and the full range of interest. Validation ensures that the method produces data of acceptable quality according to the following performance criteria: accuracy, precision, linearity, specificity, reproducibility, robustness, ruggedness, and limit of detection/limit of quantization. Validation ways usually include, according to Shaw [19], analysis, evaluation, experience, example, persuasion, etc. Because our developed approach is an emerging result and a general high-level guidance-like approach, we choose to use Expert Evaluation to preliminarily validate our approach. Expert evaluation looks at the whole system (or approach in our case) from their professional experience, and from many perspectives and reveal potential problems such as inconsistency, support for different ways of

working, validity, etc. The benefit of Expert Evaluation is: usually for a complex problem, because experts have long time of professional experience in this area, they can give a roughly accurate and quick feedback on the object to be evaluated.

In order to be applicable for reviewing our approach, the experts we asked for evaluation are generally from areas such as software engineering, legal domain and health care domain. Specifically, these experts are briefly introduced as follows in table 7:

Table 7: The brief review of experts we asked to evaluate our approach

ID	**Expert role**	**Experience**
A	Senior researcher and software process domain expert	35 years' experience in software engineering
B	Researcher	8 years' experience in software engineering
C	Researcher and software process domain expert	15 years' experience in software engineering
D	Business analyst and health care and CQC domain expert	35 years' experience in software engineering, IT, CQC regulation and healthcare domain

We explained our approach and showed real concrete examples to them. After they discuss and exchange their opinions, we asked them to fill the evaluation table shown in table 8 as below:

Table 8: A rating table showing the feedbacks of experts (multiple-selection)

Rating levels	Very useful	Quite Useful	Useful	Somewhat useful	Not useful

77	◯				
B		◯			
C	◯				
D	◯				

As we can see from the evaluation result, all the participated experts give the positive rating. Therefore we can preliminarily say this approach is valid in solving its designated problem.

Chapter 5

5 Implications and discussion

This chapter describes the implications and discussions of our method. Section 5.1 introduces the implications of our work on the industry practice, existing research, too support and regulation drafting. Section 5.2 discusses some issues about our approach where open discussion remains.

5.1 Implications

This section talks about the implications about our approach.

5.1.1 Implication on the industry practice

(1) Practicing our approach

Business stakeholders who need to fulfill the outcome-focused regulations can use our method to guide their practice of ensuring that all the outcomes specified in the regulations are satisfied. For example, CQC in Britain regulates thousands of different care homes and hospitals. The management layer of these organizations can thus use our approach to check compliance and improve their business processes. They can also adjust our approach in order for their special requirements. For example, CQC also gives out suggested but not mandatory causes/prompts that can be referred to for outcomes. If stakeholders want to uses these causes/prompts, they can make alteration to our approach. An adjusted version of our approach is provided in Appendix A for this use.

(2) Human Resource Management

Different work or activities need people with different kind of skills. When using our approach for ensuring compliance, our approach can help them better assign the human resources. For example, in our approach, we mention that this will involve the legal experts in the regulation pre-processing (Step 1 in Section 4) and outcome interpretation (Step 2) steps, and involve domain experts in outcome interpretation (Step 2), business process searching and analysis (Step 3) steps. Business managers need to put the right

people in the right place and the right time in order to be efficient and cost-effective. For large companies, they could consider adding a solid position for this kind of people. For small and medium organizations, they can collectively hold one position to do this kind of work or hire some legal professionals for short time as consultants.

5.1.2 Implication on the research

Currently, research such as [53] [54] [57] focus on fulfilling traditional regulations which are drafted in a fashion that puts the processes or procedures first. Traditional regulations directly constrain the business processes or procedures; however, as the outcome-focused regulations start to step into people's sight and put into the enforcement, current research approaches are limited to handle this issue. Our method is complementary to the current research by aiming at ensuring the compliance of the outcomes specified in the outcome-focused regulations. Our method can serve as a basis for future work on the outcome-focused regulations. For example, other researchers can improve any step in our method to promote the efficiency or integrate our method into their research results (such as a framework, a tool, etc).

5.1.3 Implication on tool support

Our approach demonstrates that systematically ensuring outcomes for the outcome-focused regulations is possible. For stakeholders (such as business operators) who are involved in the activities, they need a tool to facilitate them to conduct this activity. This tool could provide some fundamental functions such as (1) The Create, Read, Update and Delete (CRUD) operations of regulations; (2) Traceability functionalities such as cross-references among different outcomes, regulations and external documents; (3) Functionality of describing and CRUD operations of the business processes; (4) Functionality that reminds operators intelligently of what to do next; (5) Functionalities of logging records, records comparisons and records analysis. Current tools such as IBM Business Process Manager [59] can facilitate the business process modeling work. XTie-RT (Cross Tie Requirements Tracer) [58] can help to do the traceability work. However, even though these tools do help partially and indirectly to perform our approach, they are generally for professional practitioners and are not user-friendly for non-professionals, as

well as not tailored for applying our approach. Common stakeholders (such as business operators) are not familiar with these professional tools, instead, stakeholders wish to have an integrated dedicated tool that integrate all the functionalities

5.1.4 Implication on the regulation drafting

Currently, although several authorities such as Care Quality Commission and Solicitors Regulation Authority in Britain are using the outcome-focused paradigm to draft their regulations or guidances, many other regulations still use the process-focused paradigm (i.e., focusing on procedures rather than outcomes) for drafting regulations. Therefore, if the outcome-focused regulation really brings benefits, an open discussion of switching from procedure-focused to outcome-focused can be put into agenda. On the other hand, current outcome-focused regulations could also have been drafted better so as to better facilitate the processes of practicing our method. For example, from "regulation interpretation step" section of the Chapter 3, "taking medicine safely" is abstract (i.e., it is interpreted into "take the right medicine", "medicines are managed properly", etc.). Besides, it can also be found from current literature that ambiguity also exists [16] [23]. In other words, the outcomes given by the regulation could be more specific so as to lower the difficulty level of interpretation.

5.2 Discussions

This section discusses the open topics about our approach such as limitations, potential improvement, etc.

5.2.1 Refining the approach

Our approach currently provides a relatively high-level guidance or directions as to how to ensure the compliance for the outcome-focused regulations. The steps such as "outcome interpretation", "search for business process" and "analyzing business processes for actual outcomes" in our systematic process need to be refined to offer better guidance for practitioners. Concrete details and techniques about how to get through each step need to be produced and recommended for practitioners.

5.2.2 Interpreting regulation outcomes

As mentioned in the Threats of Validity Section of Chapter 3, the success of our approach largely depends on the interpretation of required outcomes as they are regarded as criteria for both searching business processes and checking for compliance. However, different people have different interpretations and even for inspectors that are from the same authority, they still can have their different (maybe slightly) understandings for the same required outcome. Some interpretations may thus be omitted. Therefore, a guidance to instruct the interpreters on how to interpret regulations is badly needed. Also, because different kinds of organizations may have different operations or context thereby to cooperate with the party of regulation legislators to collectively issue universal official interpretation guidance seems impossible. Currently, when practitioners are involved in the interpretation step, our suggestion is that they should try to achieve as full coverage of interpretation as possible. Accordingly, pair-working (two or more people cooperating on the same work) could be a good idea.

5.2.3 Checking a business process for compliance (down-top)

Currently, our approach is "top-down" which means: given a required outcome from regulations, related (multiple) business processes will be identified so as to identify the actual outcomes. Actual outcomes are gathered to be put into evaluation to justify if they are sufficient to support the given required outcome. In other words, an outcome results from one or multiple (usually) business processes. For example, the outcome "people take safe medicine" may result from medicine purchase process, medicine management process and medicine delivering process. However, it's also worth mentioning that, very often, given a specific business process, stakeholders would like to know if it is compliant with outcome-focused regulations or not (down-top). Therefore, defining a schema for checking this kind of non-violation is required.

5.2.4 Measures of the approach

Each step of our method needs some measures to evaluate the outputs in order to decide whether to go to next step or not. But how to decide the measures remains to be discussed.

For example, how do we decide if the interpretation is complete? Using what to evaluate it? In the future, these questions need to be addressed.

5.2.5 Applicability to other domains

Our approach is developed based on a healthcare regulation (the CQC guidance). Although we believe that it could be applicable in any domain as long as the regulation is drafted in the outcome-focused fashion, the truth remains to be verified. For example, given an outcome-focused regulation of the mining industry, is our approach still applicable? Answering these questions is put into our future work.

5.2.6 Accommodating for regulation evolution

Regulations are subject to change all the time. The reasons for the regulation evolution could be a new kind of crime, a new case in the court or just a new legal need. Likewise, our approach should be able to accommodate this challenge. As a matter of a preliminary assessment, our approach already suggests itself of this capacity. When an outcome changes or a new outcome appears, stakeholders just need to follow our approach – interpret the outcome -> search for actual business processes -> identify actual outcomes -> evaluate for compliance.

Chapter 6

6 Conclusions and future work

This chapter concludes the work above that we did. Section 6.1 gives the conclusion. Section 6.2 presents the future work we will do.

6.1 Conclusions

Outcome-focused regulations are gaining more and more prominence nowadays. Several current works [42] [43] focus on checking requirements against regulations which leaves uncertain to whether the systems or business processes are compliant or not. In the meantime, other works focus on checking business processes [53] [54] [56] or runtime systems [5] [23] for compliance; however, they handle the issues with the traditional regulations not outcome-focused regulations. These methods are not appropriate for checking compliance with outcome-focused regulations as the outcomes are mentioned rather than processes.

In this thesis, we introduce the work we have done on analyzing the outcome-focused regulations and business processes in order to develop an approach for ensuring the compliance of outcomes. We also introduce the approach we developed to check the compliance and improve the noncompliant business processes. A preliminary validation of this approach is done by expert evaluation. This approach is useful so that it can help the stakeholders systematically ensure the compliance.

6.2 Future work

Currently, given an outcome from the outcome-focused regulations, our approach can help ensure compliance with it, by checking the compliance and improve the noncompliance. As one outcome is contributed usually by multiple business processes, therefore given a business process, how to check its compliance is one of our future works.

In addition, given our approach, a tool to support using our approach can be developed. Our future works include developing such a tool or some components packages that can be used for customization for mutant situations.

Lastly, as our approach is developed from the environment of a healthcare regulation and business processes of a care home, to see if it is applicable to regulations in other domains, such as catering, fire, etc. is also one of the future works.

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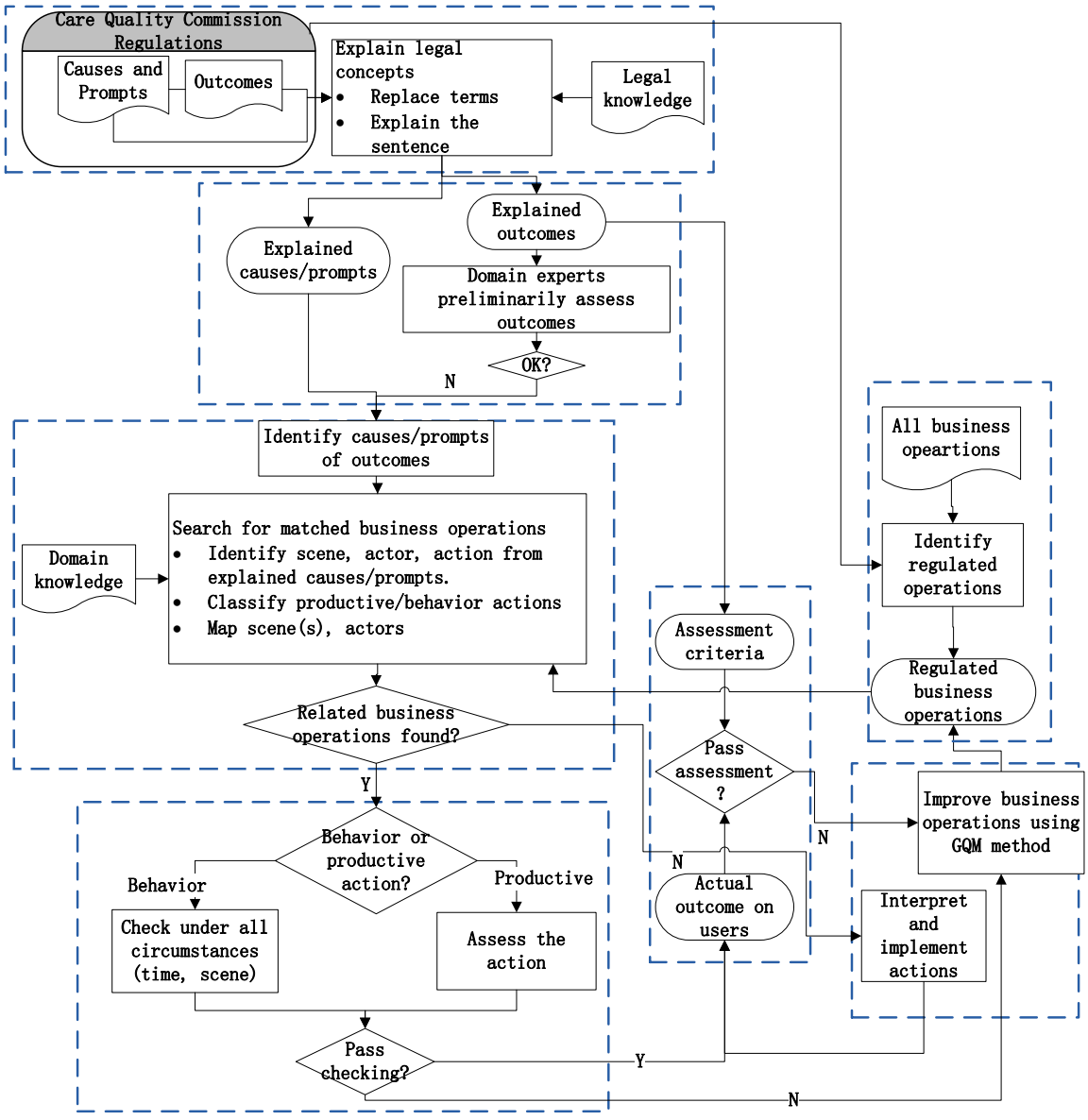
Appendices

Appendix A: An adjusted version of our approach that is applicable in CQC's special situation where they provide causes/prompts to outcomes.



Appendix B: in the meantime of the development of our approach, some interviews with our stakeholders.

from: (Anonymous)

to: (Anonymous)

cc: (Anonymous)

date: 2 October 2012 03:04

subject: RE: Some questions -- urgent please!!!

(1) Name of your home care operation.

Company Name: (Anonymous)

(2) How many branches?

Homes: 1) Vishram Ghar (registered for 40 beds – Dementia (DE), Physical Disability (PD), Mental Disability (MD) and Old Age (OP))

2) Willows Court (registered for 29 beds – DE, PD, MD and OP)

3) Ellesmere House (registered for 28 beds – DE, PD, MD, OP)

(3) For interpreting the CQC regulations and the precise specification of the outcomes, would we need to talk to CQC (Govt.) staff or would *YOU* know all the details of compliance requirements?

I think this would be useful as they are ones who do the inspection and are more inclined to interpret the regulations which is a challenge as the interpretation at times is individually biased i.e. each inspector can interpret the expected/required outcome differently and thus make decisions based on their findings

(4) Which of the following two schemes would you prefer, and why:

(i) a self-checking scheme whereby *YOU* (as business operator) [or your business staff] can easily check the compliance of your business operations (**actual** outcomes) against CQC's (required) outcomes and fix the specific anomalies in your business.

This is preferred as we can gather the evidence of meeting the outcomes and demonstrate that we meet the regulations – also we can see any deviation and act upon it promptly – CQC sees this as a very positive step and gets the confidence that we can find any issues and can act upon it asap.

(ii) a self-checking scheme whereby you need to hire "TECHNICAL/REQUIREMENTS modelling experts* to first model the REQUIREMENTS of your business and then compare these models against the CQC outcomes and then fix the anomalous REQUIREMENTS and then accordingly fix the business operation.

This is good but the cost of hiring and time taken is not the luxury we have. We need to have practical solutions. This approach would be useful if we can develop compliance solutions quickly and can automate as much of the process as possible.

(5) How often do auditors come to inspect your business?

They come unannounced and depending what they find they will come back. Minimum is once a year but you can get them more often at times 4 or more times a year. In addition to CQC We also have others who audit – council or local authority, fire, Health and safety, environmental etc…

(6) How much effort do you normally have to put in fixing things AFTER the auditors make an assessment?

Again depends – at times they can suspend new admissions which can than take long time – maximum was one year plus nad the cost was very high

(7) How much do you expect to save in time/cost by doing the self-checking regularly and not having to react to auditor's reports?

If we can show and demonstrate compliance and we have robust system we will save lot of time and money – we need a simple system that can be implemented that shows clearly whether we are achieving the outcomes or not. If not have a plan of action either automatically generated or guidance given by the system.

Appendix C: a snapshot of part of our preliminary work – translating outcomes to requireme

CQC Requirements revised 3.xlsx - Microsoft Excel

	A	B	C	D	E	F
1	ID F	Fundamental Requirement Description B	Softwar e Wholy	Manull y Only	Part of Softwer e,part of Manull y.	The Statement of regulation
2	R1.1	The system shall have staff explaining online and have a place for users to discuss their care, treatment, and supporting them. Revised: The system shall remind the staff who explains and discusses their care, treatment and support options with them when? ? . extent? every month review. can be changed. review form	1			Prompts 1A.1 The service explains and discusses their care, treatment and support options with them.
3	R1.2#	Added: The system shall remind the staff to respect their right to take informed risks, while balancing the need for preference and choice with safety and effectiveness.when? ? Database. All risks.signiture,before he came, show it.	1			Prompts 1A.2 The service respects their right to take informed risks, while balancing the need for preference and choice with safety and effectiveness.
4	R1.2##	Added: The system shall remind the staff to place the needs, wishes, preferences and decisions of people who use services at the centre of assessment, planning and delivery of care, treatment and support.When? ?	1			Prompts 1A.3 Promotes and respects their privacy, dignity, independence and human rights by: – placing the needs, wishes, preferences and decisions of people who use services at the centre of assessment, planning and delivery of care, treatment and support.
5	R1.2	Every user's information must be kept private.				Prompts 1A.4 – ensuring that the environment allows privacy in which the intimate care, treatment and support needs of the person who uses services are met.
6	R1.3	The system shall provide a clear procedure to ensure the staff understand the concepts of privacy dignity, independence and human rights and how they should be applied to the people who use the service, as well as can monitor, review this procedure.			3	Prompts 1A.5 – having clear procedures followed in practice, monitored and reviewed that ensure staff understand the concepts of privacy, dignity, independence and human rights and how they should be applied to the people who use the service
7	R1.3#	Added: In the assessment of the individual circumstances, the system shall remind the staff to consider the need to maintain confidentiality.	1			Prompts 1A.6 – ensuring that the need to maintain confidentiality or disclose information is taken account of in the assessment of the individual circumstances
8	R1.4	The system shall have a portal to achieve users' feedback and notify(by which way? ?) the users in every decision making.			3	Prompts 1A.7 – actively listening to and involving people who use services, or others acting on their behalf, in decision making.
9	R1.5	The system shall display the information about users'care, treatment and support, including the risks and benefits, and their rights to make decisions. Revised: The system shall remind the staff to provide the information to help people who use services, or others acting on their behalf, to understand their care, treatment and support, including the risks and benefits, and their rights to make decisions.			3	Prompts 1A.8 Provides information to help people who use services, or others acting on their behalf, to understand their care, treatment and support, including the risks and benefits, and their rights to make decisions.
10	R1.6	The system will display to the staff the information about recognising and respecting the diversity and human rights of people who use services and will need the staff to sign electronically of obeying.? ?				Prompts 1A.9 Ensures that staff recognise and respect the diversity and human rights of people who use services.
11	R1.7	The system will display the independent advocacy service when available and notify users revised: & the system shall remind the staff to explain to users independent advocacy services where they are available.			3	Prompts 1A.10 Makes people who use services aware of independent advocacy services wherever they are available.

Sheet1 Sheet2 Sheet3

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