Towards addressing Legal Compliance in Manufacturing Automation Systems

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Abstract

Manufacturing companies that are purchasing softwares have the same legal concerns as the organizations developing softwares, but have less control on the development process. Depending on the situation the manufacturing organization maybe heavily involved in the development or they could only be reviewing the requirements suggested by the supplier. The paper introduces a preliminary extension of SQUARE process that could incorporate legal manufacturing (LM) compliance for metalcasting automation. The next steps would be to use this LM-SQUARE process on actual projects.

Keywords: ***Law, manufacturing, SMEs***

1. Introduction

Government administration of Nordic countries is comprehensive and plays a central role in providing welfare to the citizens. Government services both exercise authority and produce services through a diversity of schemes. In the United Nations ranking of e-readiness Sweden, Denmark and Norway held the top three rankings. [1]. In the interest of establishing evidence of having exercised reasonable care to protect data on the manufacturing companies networks, legal counsel have begun urging companies to invest in procedures and technology that will allow collection of forensically sound data defensible by law. [2] There is an urgent situation to 're-evaluate' traditional models for incidence response to include this readiness.

Laws and regulations are having an increasing impact on legacy and future manufacturing software supplier solution systems that must comply or face penalties. Effective standardized communication between lawyers and manufacturing engineers is a challenge. These professionals use different terminologies. Manufacturing engineers themselves will not perform a proper analysis of the system of law and characteristics of legal regulations, and lawyers will not create a correct specification of manufacturing system requirements.

The security quality requirements engineering (SQUARE) method is a security requirements engineering method developed by Nancy Mead et al. to help organizations consider security issues in the early stages of the life cycle leading to more cost-effective development of a more secure and survivable system. [3] SQUARE consists of nine steps: agree on definitions, identify security goals, develop artifacts to support security requirements definitions, perform risk assessment, select requirements elicitation technique, elicit the security requirements, categorize the security requirements, prioritize the security requirements, and inspect the security requirements. In this paper, we propose a modification and preliminary extension to SQUARE called the LM SQUARE, or SQUARE for law compliance of manufacturing companies. Regulatory heavy manufacturing industries such as nuclear, aerospace, energy, medical etc. should address legal compliance when developing software or internal systems. While all manufacturing systems may not require legal review if there is no risk of non-compliance, when such concerns arise, LM SQUARE can be used as a methodology to develop requirements traceable to a compliance requirement. A potential reordering and extension of steps of the SQUARE methodology can develop a more effective legal compliance methodology for manufacturing which is described in the paper.

2. Taxonomy and Compliance

The legal taxonomy based on 8 elementary concepts classified as privilege, claim, power, immunity, and their correlatives no-claim, duty, liability, disability. [4] Privilege is the entitlement for a person to discretionally perform an action. Claim is the entitlement for a person to have something done, and to legally pretend it. Power is the (legal) capability to produce changes in the legal system. Immunity is the right of being kept untouched from other performing an action. Two rights are correlatives [4]. The concept of correlativeness implies that rights have a relational nature. In fact, they involve two subjects: the owner of the right and the one, against whom the right is held – the counterparty. Two types of actions exist: behavioural and productive. Behavioural actions are

described by the actual behaviour performed by actors, productive actions attain the results that are produced by the behaviour of the actors [5].

A. Compliance

Legal suggestions can't be univocally converted into requirements: legal suggestions generate alternative possibilities to be compliants. This means that legal compliance is a matter of decision making that involves the goals of the stakeholders. An allocation of goals - a strategy - is in compliance with a law if some condition holds for stating that the strategy is inside the boundaries defined by the law.

Intentional compliance can play an important role in guiding the development of a manufacturing system, and ensuring compliance through all phases of development, so that the running system will also result compliant. If the manufacturing system or the supported processes is not compliant, a non-conformance may occur and they need to have corrective actions in place. Manufacturing requirements models characterised by intentional compliance should allow for early detection of non-conformances, avoiding the need of imposing strong compliance using means such as an audit later, and thus reducing costs.

B. Requirements Engineering and Flexibility in Manufacturing

The area of manufacturing requirements includes the fundamentals such as product vs. process, function vs. non-functional and system vs. component. It entails *requirements process, elicitation, analysis, specification and validation.* An appropriate requirements management is becoming a crucial part of certification of dependability of manufacturing systems. Functional requirements to manufacturing automation in software are taken from product engineering specifications. However, non-functional specifications are becoming a focus of increased attention these days. Due to inceasing globalization, one of the main trends in non-functional requirements of manufacturing automation systems these days is their flexibility.[7] The flexibility aspect of manufacturing automation systems aims at accommodating changes in manufacturing requirements.

3. Methodology

The security quality requirements engineering (SQUARE) method is a security requirements engineering method developed to help organizations consider security issues of a more secure and survivable system. SQUARE consists of nine steps: agree on definitions, identify security goals, develop artifacts to support security requirements definitions, perform risk assessment, select requirements elicitation technique, elicit the security requirements, categorize the security requirements, prioritize the security requirements, and inspect the security requirements. The steps include identifying suitable techniques to systematically perform each step.

Why LM Square is needed?

Regulatory heavy manufacturing industries should address legal compliance when developing software or internal systems. LM SQUARE can be used as a methodology to develop requirements traceable to a compliance requirement.

Step 1. Perform risk assessment

This step expands the SQUARE risk assessment to include legal manufacturing risks of non-compliance. The step serves the purpose of connecting the security requirements goals to the legal risks that have the greatest impact on manufacturing business operation or its mission. Stakeholders in this process would include representatives from the manufacturing engineering, control software, quality audit, risk managers, legal, security and HSE. Since the regulations evolve it would be relevant for a manufacturing company's legal team to research whether pending regulations would suggest new ones. This step is suggested to be performed first as compared to the traditional SQUARE method.

Step 2. Agree on Definitions

In this step the identified stakeholders agree on terminologies to reduce the ambiguity of the process to communicate the requirements clearly. To address the legal challenges that could arise in this step could be that the legal terms are domain specific and defined differently than the engineering community. The law compliance might be difficult to interpret or when manufacturing firms are located in different countries or states with different jurisdictions, complexity might increase. It is important to answer the define the laws that a manufacturing company must comply to, before starting this step.

Step 3. Identify assets and manufacturing compliance goals

In this step stakeholders identify compliance regulations that are known to apply to the manufacturing organization which provides a scope to proceed. The input to this step would be definitions from the previous step, goals, business

drivers, policies, procedures and examples. In this step the alignment of legal manufacturing compliance to organization goals is conducted which links it to the traditional SQUARE methodology.

Step 4. Select elicitation technique

In this step elicitation techniques can be selected to ensure compliance to legal specific to the manufacturing business needs. The input to this step are the goals, definitions, techniques, expertise of the stakeholders, level of compliance, cost benefit analysis etc. SQUARE methodology at the moment does not dictate an elicitation technique including text such as regulation, standards etc; the legal text way such as prescriptive, goals based, standards based and whether if the legal texts are applicable to multiple jurisdictions.

Step 5. Elicit manufacturing compliance requirements

The inputs to this step are artifacts, risk assessment results and selected techniques. This step serves the purpose of documenting a complete set of requirements which are verifiable on project completion. The output of this step is a list of selected elicitation techniques.

Step 6. Categorize requirements to system levels

The input to this step is the set of initial requirements and architecture. SQUARE categorizes the requirements into five groupings as essential, non-essential, software, system and architectural, using the input provided by the stakeholders. This step generates categorized requirements as an output.

Step 7. Prioritize requirements

The categorized requirements and risk assessment results from the previous steps act as an input to this step. The participants in this activity are the stakeholders being facilitated by the manufacturing and control software engineers. The need to be compliant to laws is differentiated from the need to have a manufacturing system designed for the purpose. The different scenarios of weighing priorities between legal compliance and manufacturing privacy could be

a. When the requirements by law and security of manufacturing systems match. This scenario occurs when both requirements are sufficient to the same degree.

b. When the requirement by law is tenacious and of a lower baseline than the security requirement of the manufacturing system. The manufacturing requirement is prioritized in this case over the legal.

c. When the legal requirement is more stringent than the manufacturing requirement then, it is prioritized over the latter.

d. When the law requirements are misfits when compared with the manufacturing requirements, then nevertheless they need to be incorporated into the manufacturing system for compliance purpose.

The output from this activity is the prioritized requirements.

Step 8. Develop Artifacts

This step identifies the misuse cases and compliance goals. An example use case for this step for a metalcasting manufacturing company could be

***Process Traceability*:** The company should be able to record the raw material batch, metal composition, the complete manufacturing process of the part including automated machining and the handling processes used by them internally in the facility.

Machine Status Traceability: The operator working on the part should be able to record (depending on the downstream and final customer requirements) the manufacturing processes and parameters used in the system. Depending on the machine it may include heat lot number, metal batch number, holding time etc.

Authentication Support: The manufacturing system and its users must be able to use the data stored in the system to authenticate their claims based on the complete data set.

Customer Regulations Compliance: Using the traceability system, the manufacturing system actors should be able to retrieve data to show that the manufacturing processes comply with the customer requirements.

Company Integrity Protection: The system users must be able to protect the integrity of their company through the traceability in the system. For example, if the part is claimed to be produced under controlled process parameters the

system should support traceability to those parameter values.

Step 9. Requirements Inspection

In this step the stakeholders candidate formal inspection techniques to draw a consensus on law requirements for compliance. The aim of this step is to ensure that each law requirement derived from the laws has traceability to the manufacturing requirement goals. SQUARE enforces the connection between legal texts and derived requirements here. The outcome of this activity is the documentation of decision making process and rationale.

Step 10. Maintain documentation and track revisions

Maintenance of the relevant documentation and tracking document revisions is crucial. The tracking plan should be modified according to the changes in regulations, customer demands or any other factors that cause a change in the business process. The subsequent steps would need to be carried out again every time there is a change in the tracking plan.

The authors suppose that profit of using the systematic approach is most significant in manufacturing organizations where the manufacturing engineers continuously discover and document efficient procedures in an iterative manner. [6] However, there have been no studies conducted aiming at quantifying the impact of the systematic approach, so the main contribution here is the description.

4. Discussion

The process of validation using a real-world study can be conducted according to the criteria consistent with the SQUARE analysis. It would be beneficial to observe if the manufacturing process owners would go through an adaptation exercise so we can compare and contrast results.

Requirements and systems evolve and hence the compliance to those will vary as well. The manufacturing organization would then have to be synced to the legislative and regulatory environment to act in a timely fashion.

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