Cradle-7
From concept to creation...

3SL

Regulation Compliance and Traceability

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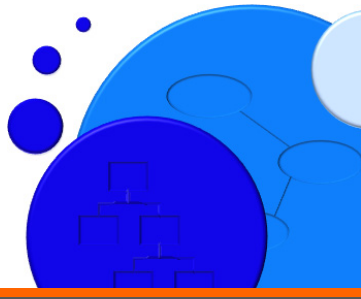

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Introduction

Designing, developing and producing a good product is a significant effort. In many industries, this internal effort is compounded by a layer of external regulatory challenges and requirements, as governments and other regulatory bodies expand, update and alter codes, regulations and standards (*CRSs*) that become a mountain of non-functional requirements imposed on your products' definition and development.

These challenges require three actions:

- ***Discovery*** is the educational and procedural steps to learn which subset of the sets of CRSs apply to you and your products, which stakeholders are affected, and who owns each piece of the product definition and development that will be affected
- ***Doing*** is the execution stage where the needs, impacts and alterations generated from the discovered knowledge affect the design and production of your products, allowing them to withstand the regulatory scrutiny
- ***Showing*** compliance is the ultimate output of any regulatory conversation. Knowing what to do, who is to do it, and then implementing all the changes required to meet a set of rules is of no use if you are unable to demonstrate your products' compliance with these rules to the external parties who must be satisfied before your products can be sold or commissioned into service.

This white paper will attempt to address the factors involved to effectively address these actions and will highlight some key techniques from which a process can be defined to support the definition, design and development of compliant products.

Discovery 1

Deciding which regulations need to be addressed may seem to be an easy task, and for some projects it can be straightforward. However, for most products, particularly consumer goods, medical equipment, nuclear and anything where there is a health and safety concern, the considerations can be substantial:

- Will the product be in more than one country?
- Within each country are there regional, state or local regulations that come into play?
- Which regulatory agencies are involved?
- If your product is incorporated into other products, where do your responsibilities and liabilities start and end?

Only after these basic questions are decided, can you start to examine the regulations.

A single product may have a myriad of jurisdictions and agencies with whom compliance is required. Extensive, exhaustive and detailed work is required to discover this information.

For smaller businesses or those with limited geographic impact, starting to know may be as simple as a web search. However, most businesses are of a size and structure where several people in the organisation have relevant knowledge and experience which needs to be elicited and included.

Some of these, and others, may represent the stakeholders who will formally accept compliance or who will assume responsibility for the necessary changes. The head of engineering may know the electrical certifications required. The lead software developer may know the security certifications relevant to the market. Legal, finance, HR, all may have a role to play in ensuring that the overall mesh of interacting regulations are met.

Doing 2

Once the stakeholders and appropriate CRSs are identified, the doing stage can begin.

The initial conversation in this stage must be interpretation.

Different stakeholders will each view the regulations in a different way. Legal may not think a regulation applies but engineering may know that relevant data is referenced and is managed deep in the software. Regulations in Germany may be different than in Korea or the US.

Very rarely will all questions and viewpoints on regulatory matters be clear and simple. For those regulations on which agreement cannot be reached, the discussion must move towards a risk analysis, mitigation strategies and their associated sets of actions.

The goal in these cases is not to attain 100% agreement but to get to a point of informed decision making based on informed interpretations and consequences that are well understood by all involved.

Ultimately the discussions on interpretation will settle to agreement or a noted risk associated with the varied interpretations.

The process of informed decision making is dependent on correctly and completely associating regulations with relevant portions of the products affected. Collaboration is essential for this to be accurate. Engineering may not be fully aware of the scope of regulations which might apply. Legal, finance and other compliance focused groups will not be fully capable of drawing the associations to the correct levels, components and processes in the product design.

When working to build this level of traceability it is essential for the business analysts and systems engineers of an organisation to help all stakeholders to understand the big picture and guide the team through the process of breaking down both sides of the equation to their lowest common denominators.

Once regulations are associated with product information at the correct level of detail, verification and testing plans can be introduced into the discussions.

Showing 3

Regulatory compliance is not achieved by adjusting design and specifications to meet a regulatory requirement. Compliance is achieved by being able to show that the design meets the regulations and that steps have been taken to ensure that the product has been built as specified by the design.

You should establish a process that starts in the knowing phase to document the relationships between regulations and the requirements, designs and verifications. This process enables outputs such as regulatory compliance matrices to be available for customers, government agencies and the like at a moment's notice.

Few things establish confidence more than timely data driven answers.

Tactics for Success 4

Start Early 4.1

Start identifying possible stakeholders as early in your project as possible. If they are experts and/or decision makers they will be busy. Getting their commitment early in the process ensures that you will be well prepared when each project milestone or gate approaches.

Seeking their commitment early also shows that you are concerned for the interests of their department. Even if those you initially approach are not on the final list of stakeholders, you have established a path of communication and both they and you are learning how the organisation will work through the regulatory process.

As you identify regulations, documentation and other key elements, start keeping traceability records. It is much easier to add associations as you build your collection of information than it is to sort through increasing volumes of information as time passes.

Don't Start from Scratch 4.2

Someone has done this before you!

If you are at a medium to large sized business, others have gone before you. They have had to decide who to review and sign off on compliance issues. Look for program managers on earlier projects.

Research your library of past projects' documentation. If existing compliance examples are not easily available, horror stories might be. Listen to how things failed and what they did to fix problems. These are good starting points.

Sometimes when internal data is hard to come by or the business or division is just getting started, outside examples may be needed. Web searches, LinkedIn® groups, trade associations and even regulator's websites are filled with samples, checklists and small business resources.

Pictures 4.3

A 200 page regulatory document thrills very few. A quick sketch from an engineer showing the major components or functions of the project can go a long way toward helping stakeholders understand the context needed to make associations.

If your company is open to a model-based systems engineering (MBSE) process, these pictures can be layers of models/diagrams, associated with relevant data and made available in a collaborative environment.

Once the concepts are modelled and decision makers can follow the concept you can begin to take the full body of regulations and associate sections to sub-systems, and individual regulations can be linked to the specific components and design elements needed to show compliance.

Fundamentally, compliance is asserting that what you have done is consistent with what the regulatory body requires you to do. It is much easier to make this assertion, and for your assessor (regulator or someone else) to accept your assertion of compliance from a set of diagrams to the appropriate regulations than it is to make the same traceability link between section 4.23.117 of your regulation document and requirement number 78.4.221 in a feature specification document.

This is particularly true if the assessor is not as knowledgeable as you in your engineering discipline. Even if they are as knowledgeable as you, making the associations between your product and the regulations as simple as possible is always a good idea.

Simple associations are clear, clarity is simple, simple is quick, and quick is more productive and lower cost.

Traceability 4.4

Identify how you will show that a regulation traces all the way through to a test used to show compliance is key to showing the overall product or program is compliant.

Good traceability allows for easy development of coverage matrices, verification cross reference charts, risk assessments and regulatory compliance documents needed by government entities.

Change will come, it is inevitable. So anything that you produce will not be produced once, it will be produced many times.

Staying organised as you develop your programme and processes is essential to managing change effectively. Change can come from an update in regulations, a customer need can affect the design, the availability of parts or materials may necessitate a change.

If you have mapped your stakeholders, regulations, requirements, designs, verifications and tests well, it will be easier to start at the point of any change and understand how its effects ripples across the project. Establishing a method of traceability that is organised, can traverse the layers of the program information model, and can be easily updated ensures you can spend your time making the changes and not chasing documentation to find what could, or should, be updated.

Avoid Manual 4.5

Your notebook is good for you and you alone. A document is best as an artifact. A tool that can show traceability, dynamically update metrics, dashboards and reports adds layers of intelligence and provides dramatic time savings.

A good tool can provide a method for ensuring a consistent approach is taken by all involved in a project and serve as the starting point for the next project as well.

Cradle and Your Compliance Process 5

The Cradle software for requirements management and systems engineering facilitates the best practices needed to keep control of your compliance process. It provides a flexible platform with powerful analysis and management functionality.

- Flexibility to manage the regulations, requirements, risks and other data types relevant to your specific business and project
- Unparalleled end-to-end traceability across the full scope of your data
- Fully integrated modelling capabilities employing the same user interface and database as your requirements and regulations
- Dynamic metrics, matrices, dashboards and reporting - no need to recreate or manually edit
- Built-in configuration management to help manage approvals and publishing of your formal documentation

For more information on managing compliance in your programs, contact 3SL to arrange for a demonstration and free evaluation of the Cradle software.