

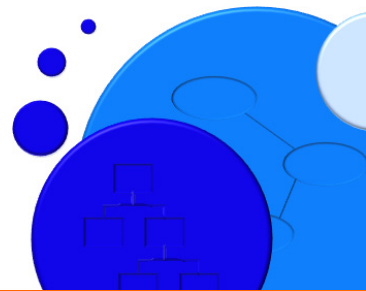


Cradle-7
From concept to creation...



Regulation Compliance and Traceability from Cradle

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Introduction

Designing, developing and building a quality product is a major effort. In many industries, this internal effort is compounded by layers of external regulatory requirements, as governments and other 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:

1. **Discovery:** the exploration to learn which of the CRSs affect you and your products, the relevant stakeholders, and who owns each part of the product definition and manufacture that will be affected
2. **Implementation:** the execution stage in which the needs, impacts and alterations from **Discovery** modify the design and build of your products, allowing them to withstand the regulatory scrutiny
3. **Demonstration:** proof is the end of any regulatory conversation. Knowing:
 - What to do
 - How to do it
 - Who is to do it
 and implementing changes to meet a set of rules is only of use if you demonstrate your products' compliance to those who must be satisfied before your products can be commissioned or sold.

This white paper describes some of the factors involved in effectively addressing these actions and highlights some key techniques from which a process can be defined to support the definition, design and development of compliant products.

Benefits

Application of the concepts in this paper to a project using Cradle will:

1. Simplify regulatory compliance
 2. Improve governance
 3. Provide evidence for external assessors
- without more demands on project resources.

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 identified (*find the people*), elicited (*learn the nature and extent of what they know*) and included (*use what they know*).

Some of these people, 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.

Implementation

2

Once the stakeholders and the appropriate CRSs are identified, the implementation work can begin.

The initial conversations in this stage must be to confirm a common 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 to those 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 converge, either to an agreement, or a noted risk associated with the various 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 in the 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.

Demonstration 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 discovery phase to document the relationships between regulations and the requirements, designs and verifications. This process provides outputs such as regulatory compliance matrices for customers, government agencies and the like at a moment's notice.

Few things establish confidence more than timely data driven answers.

Cradle offers a variety of visualisation methods that can help:

- **Nested tables.** Shows one set of items (normally the regulations or standards) and one or more directly or

indirectly linked set(s) of items (such as the design elements that prove compliance). The linked items are typically shown to the right or below the first set. The extent of compliance is often recorded in an attribute of the links between the sets of items, and are shown in the table.

- **Matrices.** Shows one set of items as rows and a second set of items as columns. The cells show the link between the two, displaying the extent of compliance from an attribute in these links. Three sets of items can be shown, with the third set shown as the cells.
- **Hierarchy Diagrams (HIDs).** Shows items (as boxes) and the links between them (as lines) in a picture that conveys an information structure with elegance and simplicity. Attributes can be shown in the boxes so the diagram can tell a full story. Some SysML diagrams come close to the expressive power of HIDs, but HIDs can show more structure with greater clarity.
- **Graphs.** Can show the historical progress as a time-based graph of increasing compliance or decreasing non-conformance.
- **Metrics and KPIs.** Numerically summarise the degree of compliance achieved using user-defined key performance indicators (KPIs), shown either as tables or graphically.

Tactics for Success 4

Some things that may help...

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 in the final list of stakeholders, you have established initial communications that helps both they and you to explore how your 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.

Do Not Start from Scratch 4.2

Someone has done this before you!

If you are in a medium to large sized business, others have gone before you. They have had to decide who will review

and authorise all the compliance issues. Look for the programme 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 own 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, then use it. MBSE produces layers of models and diagrams, often associated with relevant data and behavioural details. If you have them, make them available in a collaborative environment.

If you are expert in MBSE, choose your modelling notation carefully. Think first and foremost about the audience for the models, and think last and least about the intricacies of a notation that may be popular at the moment. MBSE notations come and go. Follow the 80:20 rule. For example, 80% of your audience will understand 20% of what your model contains. The closer you stay to what your audience could draw in PowerPoint®, the more likely your model is to succeed. But, of course, don't draw it in PowerPoint, use a modelling tool (such as Cradle from 3SL!).

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 the regulation document and requirement number 78.4.221

in a feature specification.

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 easy, easy 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 successful test is key to showing the overall product or programme 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 ripple across the project. Establishing a method of traceability that is organised, can traverse the layers of the programme 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.

This is where doing all your initial work will pay dividends. Tools such as Cradle make the review of the scope of changes easy, and the update of related information becomes trivial. The publication of updated compliance documents becomes as simple as a couple of mouse clicks.

Limit Documents

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 that 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 with a choice of many modelling notations including SASD, IDEF, eFFBD, process flow, ADARTS, UML, architecture and SysML
- 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 programmes, contact 3SL to arrange a demonstration and free evaluation of the Cradle software.