Chapter IV

Managing Process Compliance

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ABSTRACT

The current best practice of providing reliable systems is to embody the development process in recent industry standards and guidelines, such as IEC61508 for safety and ISO9001 for quality assurance. These standards are generic, but every application is different because of the differences in project details. While current workflow systems have been used successfully in managing “administrative” process for some time, current products lack the ability to ensure that a process is planned and performed such that it complies with an industry standard that is necessary to support particular engineering processes. This chapter presents a Compliance Flow Workflow System for managing processes. Model-based reasoning is used to identify the compliance
errors of a process by matching it against the model of standards used. Some examples drawing on a draft version of IEC61508 are used to illustrate the mechanism of modeling and compliance checks.

**INTRODUCTION**

In order to provide reliable systems or services, the current best practice of a development process is typically embodied in recent safety standards and guidelines, such as IEC61508. Once a standard has been adopted, it is important to manage compliance with the standard. By compliance we mean that there is a clear description of the design stages and, at each stage, the inputs (requirements) to that stage are fully and unambiguously defined, and finally the objectives and requirements of each practice of the standard are met. The standards are generic, but every application is different due to the differences in the project details. It is neither practical nor desirable to compel compliance at all points in the development process. Thus determining the degree of compliance with specified practices as the development progresses is a challenging task.

Most of the current research, such as by Emmerich et al. (1998), adopts a document-centred approach in which the development process is implicitly represented in the product. The compliance has been treated as a problem that is closely related to inconsistency management in specification, which is discussed in the literature (Easterbrook, Finkelstein, Kramer & Nuseibeh, 1994; Finkelstein et al., 1994). Such approach uses a document schema specification to elaborate and formalise the definitions of document structure suggested in the standard so that properties can be checked against them. Appropriate checks will be triggered only when events occur on documentation during the development process. This approach can ascertain that the expected qualified document is obtained, which matches current quality control practices where the compliance checks are performed at the end of development stages by individual assessors. However, it lacks the ability to manage the development process to proactively prevent unqualified products resulting from a wrongly planned process, which is an essential requirement for the conformance of rigorous standards like IEC61508.

IEC61508 is an international standard that focuses on the process in which a safety product is designed and manufactured, not just the product itself. Therefore, the company can only legitimately develop an IEC61508-compliant product when its development process is compliant with the standard.

*Some companies in our industry claim to have IEC61508 compliant products. In fact, they have only had an assessment done on a single product, not on their company’s processes to design and produce...*
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