

Introduction

Is your team maximizing the time it spends on risk management? Probably not. Identifying, assessing, and tracking risk is a complex and time-consuming process, and even after all of that effort, many companies fail to sufficiently expose and address serious potential harms. Risk management doesn't have to be that difficult, however.

with Automated Traceability

This white paper provides a high-level overview of risk management in safety-critical environments, and discusses how automated traceability can improve safety and reduce the time and cost of the risk management process.

Companies operating in safety-critical industries must manage risks to the safety of their products' users as well as those affected by their use — in other words, the driver of the car and the passengers; the medical technician and the patient, etc. In many industries, risk management must meet guidelines defined by industry or government regulations. This adds additional considerations to the already difficult process of developing and managing product requirements.

For example, IEC 61508 specifies a functional safety process for manufacturers that is the basis for several industry-specific regulations. These regulations mandate detailed steps that product development teams must take to identify and mitigate safety risks throughout the entire product development process.

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Despite the importance of managing and mitigating risk in the product development process, risk management rarely gets the attention and visibility it deserves. Usually, this is due to the fact that identifying, assessing, and tracking safety is incredibly time-consuming. The good news is, it doesn't have to be that difficult.

The trick to simplifying risk management is to utilize traceability as a glue to bind requirements and risk controls, ensuring that the entire organization has visibility into risk throughout the product development process. If the traceability matrix is started early in the development cycle and updated regularly, it becomes a tool for ensuring that risk controls aren't lost in the sea of requirements that make up a typical product.

Traceability-based risk management practices can be successfully applied to a range of product development projects — not only to cut down on the time spent assessing and managing risk, but also to support customer and regulatory audits.

Risk Management Starts When Risk Analysis Ends

Once risk analysis has been completed and risk controls have been added to the requirements plan to mitigate identified risks, the real risk management begins — and where the development process often breaks down.

Typically, the requirements development and risk identification processes are managed in separate sets of documentation, or even in separate systems. Risks are usually tracked in spreadsheets, while requirements are managed in a separate word processing document or requirements management system. Product teams need a better way to analyze, identify, and control safety risks not just during requirements definition, but also throughout the entire development lifecycle.

The problems begin when the product moves from requirements into specifications, hardware/software development, integration, and testing.

Safety requirements or risk controls may be forgotten or lose priority as the team focuses on implementing product features.

The problems increase the longer development effort takes and the more the team changes. Original team members have first-hand knowledge of the relationship between risks and requirements. If they leave and new members join, that knowledge becomes diluted, increasing the potential for hazards to leak through to the completed product. The result is often inadequate or missing coverage of safety defects in the final product.

Manually linking hazards to requirements and artifacts is a maintenance nightmare.

Unless team members can easily trace the links between requirements and their resulting risks, it is difficult to ensure those risks are controlled in the final product. Unfortunately, manually linking safety hazards to product requirements and downstream product artifacts becomes a maintenance nightmare as requirements and corresponding risks change in response to market needs and design trade-offs over the course of the project. In addition, coming up with unique identifiers for requirements can be a tedious and error-prone process.

Automated Traceability Improves Risk Visibility

Automated traceability can solve most of these issues. Automating the linking process can reduce the chances for error and provide an audit trail all team members can follow, whether they've been there since Day One or they just joined. When traceability exists between harms, hazards, and causes, it is much faster and easier to determine any impacted hazards when a requirement changes. With traceability back to the safety analysis and risks, the team can demonstrate that their test suites directly verify their risk mitigation strategies.

Traceability greatly benefits from automation and built-in linking between the systems managing requirements, hazards, test cases, and other development artifacts. Some product development lifecycle management tools include the ability to define and link requirements with corresponding risks and downstream artifacts, such as test cases and defects. This ability helps development teams ensure that identified risks are successfully controlled in the resulting product.

A Successful Product Development Lifecycle

Teams developing safety-critical products know they must include risk management as part of their development strategy to help reduce project risks. The next evolutionary step is improving the traceability between requirements and risk controls.

The most successful product teams work together with subject matter experts on requirements and safety risks, and manage them in an integrated way. Product and safety experts work directly from requirements, analyzing potential hazards and resulting harms to determine the best ways to control risk. These teams use product development lifecycle management tools to help them easily manage the traceability between risk controls and requirements.

Traceability between requirements and risks, as well as other product artifacts such as test cases, improves the likelihood of product development success by ensuring that risks are identified, controlled, and verified throughout the development process.

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Teams that use automated traceability to identify and manage risk have a greater confidence level in their ability to address regulatory requirements and demonstrate that risks have been controlled throughout the development process. The products produced by these teams are more likely to pass audits the first time and meet customer expectations of quality and safety, giving their organizations the ability to release better products to market more quickly and at a lower cost.

Helix ALM Automates Traceability to Simplify Risk Management

Helix ALM is an Agile project planning and management solution that makes risk management easier by automating traceability across all work items and data — from requirements capture and risk analysis through testing and defect resolution.

Helix ALM also helps reduce product development risk by increasing visibility into project health and enabling collaboration across disparate teams and departments.

Learn more at https://www.perforce.com/products/helix-alm.

About Perforce

Enterprises across the globe rely on Perforce to build and deliver digital products faster and with higher quality. Perforce offers complete developer collaboration and agile project management tools to accelerate delivery cycles – from agile planning tools to requirements, issues and test management, which then link to all source code, binary assets and artifacts for full build and release tracking and visibility. The company's version control solutions are well known for securely managing change across all digital content – source code, art files, video files, images, libraries - while supporting the developer and build tools your teams need to be productive, such as Git, Visual Studio, Jenkins, Adobe, Maya and many others. Perforce is trusted by the world's most innovative brands, including NVIDIA, Pixar, Scania, Ubisoft, and VMware. The company has offices in Minneapolis, MN, Alameda, CA, Mason, OH, the United Kingdom, Finland, Sweden, Germany, and Australia, and sales partners around the globe. For more information, please visit www.perforce.com