Design for Compliance:

It’s about time [and money!]

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Abstract—In the drive to reduce wireless product development cycle times and costs, one area often neglected or left to the eleventh hour is regulatory compliance. Focusing on this area early in the development process and establishing regulatory compliance as a critical parameter of a product’s design will reduce both time and costs prior to product release and drive a more rapid return on the R&D investment. This approach is termed Design for Compliance, and its benefits impact a company’s market, finances, and overall corporate viability.

Keywords—wireless; compliance; global; standards; product development; design for compliance

INTRODUCTION

To paraphrase Dickens in A Tale of Two Cities, wireless manufacturers are in the best of times and the worst of times. On the one hand, they are experiencing a time of catapulting innovations in personal and industrial wireless (i.e., radio frequency or RF-based) products, tools, devices, and network infrastructure equipment. Simultaneously, however, they are pressured by a shrinking economy, reduced resources, a global marketplace, and a highly competitive environment. In general, it is a time in which wireless product manufacturers need to meet time-to-market goals with precision as they conduct product development programs. Fig. 1 depicts an idealized scenario for a product development plan: develop the product; release it; realize sizable revenues.

In this scenario, being first to market is what enables the company to capture the rewards of the development program:

- Recognition, as early as possible, of the highest possible revenues from the new product
- Triumph over the competition
- Identification of the company with the technology of the new product
- Recognition of the company’s brand with innovation, technical excellence, and product delivery
- Increased shareholder satisfaction

- Increased customer loyalty
- Lowered costs of manufacturing
- Achievement of an ROI that will fund ongoing R&D, innovation, and future product successes

Inversely, not being first to market can have serious, negative impacts on a company:

- Limited sales volumes that make it impossible to implement manufacturing economies that would boost profit margins
- Lower-than-forecast revenues that impede achievement of corporate financial goals

Ensuring the coveted first-to-market win over the competition, and/or achieving a company’s stated time-to-market plan, require acknowledging and working through all the factors that govern the product development process. For wireless products planned for release, regulatory compliance is a gating factor that often is not considered until just before the product release date. This is a practice that can yield catastrophic results.

WHERE PROBLEMS LIE

In the world of regulatory compliance (and global sales), there is North America, and then there is Europe and the rest of the world (ROW). Failure to understand this dichotomy of regulatory environments can be one way in which a product release plan can fail. Failure to understand
and interpret the implications of existing standards and the potential impacts of any changes in the product or standards are other pitfalls.

Example A: A successful engineering company designed a commercial-market device that used an embedded RF transmitting chip to make the item easy to locate. During development, the company took care to make sure that the device would operate over the FCC-approved frequency band for that use. When readying the product for its introduction within Europe and the ROW, however, the company realized that the frequency of operation was not approved for the specific, intended product use in Europe and the ROW. The cost of taking the product into world markets escalated, and the time-to-market lengthened considerably.

Example B: A wireless manufacturer had a globally deployed product that had passed all standards requirements when tested for certification. At some point during the product life cycle, an oscillator vendor changed a specification, introducing faster rise times. Delighted with the increase in reliability, engineers incorporated the revised component through an engineering change order (ECO) process. Months after the revised product began shipping, a potential customer discovered that the product did not meet standards for radiated emissions. The improved product had become a noncompliant product.

Example C: Standards govern the use of radio equipment with external antennas. It was during product testing that a radio manufacturer discovered that standards in place in North America prohibited use of an external antenna in a particular frequency band. Redesign and retesting of the additional product variant prior to certification multiplied costs and delayed the product release. The desire and attempt to test and certify one product for global purposes was foiled.

THE COST OF GETTING IT WRONG

Fig. 2 presents a generalized picture of what happens when a product introduction process encounters problems as a result of not knowing, not understanding, and/or not designing with consideration of global regulatory compliance issues.

The situation can totally disrupt the time-to-market plan:

- The development process comes to a halt, project resources are redirected, and a redesign effort is launched
- Redirecting resources for continued work on this project delays progress in other development programs
- Investments increase as the company covers the costs of added research, planning, and development
- The date for product launch is pushed into the future, disappointing customers
- When released, the revenues generated are less than the original forecast in the project plan

Added to this disappointing scenario is the threat of long-term doom displayed in Fig. 3. In this situation, the competition initiates its product development program later than the first company, but, by leveraging regulatory compliance considerations early in its design phase, it speeds by to capture higher revenues (and, of course, the rewards of market recognition and market share).

Delays caused by not considering regulatory compliance issues early enough in a program can be extreme. There are citable instances where companies have discovered, at seemingly the last phase of product development, that regulatory standards do not yet address the technology about to be released in the new product. Correcting this situation can take months, or years, as the company engages in lobbying and involvement with standards-setting bodies to influence the adoption of applicable standards.

Still other costs occur if a fielded product is found noncompliant, as the company may need to redesign the product, handle field returns, and create corrective actions for all noncompliant products in the field. Increasingly, market surveillance audits—the practice of random compliance checks by regulatory agencies or customers on products being sold—are becoming commonplace. As shown in Example B, a simple design change to an existing product can render a compliant product noncompliant.

In addition, changing regulatory requirements can cause an existing product to become noncompliant, and so it is
critical to monitor the regulatory landscape over the entire life of the product. This criticality grows exponentially if the wily competition’s compliance efforts target incorporation of standards changes that exclude other manufacturers. A regulatory compliance program then becomes a company’s tool for protecting its investments.

*Getting it wrong* is thus very costly on several levels. It is difficult to know which cost is higher: the cost of the added investments for corrective actions, the cost of delayed revenues, or the cost of lost competitive advantage.

**The Reward for Getting it Right**

*An Environment of Regulatory Compliance*

Regulatory compliance is an interactive environment surrounding the full lifecycle of a product—from initial product discovery, planning, and development through product end of life. Understanding this fact is key to making regulatory compliance an effective tool for accelerating new product launches and supporting continued sales over the product’s life. As shown in Fig. 4, the compliance environment is interactive with every stage of the product development cycle:

- Product discovery
- Design
- Preproduction engineering
- Production

In addition, the environment of compliance continues as engineering change orders (ECOs) are reviewed and implemented to address product revisions that augment, replace, or update system components.

*Design for Compliance*

Design for Compliance as a term denotes both a philosophy and a practice that considers the compliance environment at every stage of a product lifecycle. This approach continuously asks key questions:

- What standards apply to the product and how do the standards vary among the countries in which the product is intended for sale?
- Are standards in the process of changing, and will the changes affect the ability to sell the product in different countries?
- Do new standards need to be introduced for the technology being applied in the product?
- Does the product design optimize or limit the ability to achieve certification in each country where it is planned to offer the product for sale?
- What is the compliance test plan required by this design?
- Would any design changes simplify compliance testing and approval requirements?
- Does our ECO process include a regulatory compliance review process?

Implementation of a Design for Compliance approach requires not only heightened recognition of the impact of regulatory compliance from initiation of a product development program throughout product deployment, but also adoption of a complete compliance management plan.

**Benefits**

As already seen, implementation of a Design for Compliance approach can accelerate a product development program, allowing a company to achieve new revenues, grow in customer loyalty and esteem, and diminish competition. A more detailed list of the rewards of adopting a Design for Compliance program is shown in Table I.

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<th>Category</th>
<th>Benefit</th>
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| **Financial** | • Accelerate revenue recognition from new products  
• Minimize need for costly redesign  
• Reduce costs of duplicative testing for multiple markets  
• Reduce retesting costs required by noncompliance  
• Reduce costs from irrelevant requirements  
• Minimize risk of manufacturing noncompliant products |
| **Market** | • Reduce time-to-market and potentially gain first-to-market position  
• Increase market acceptance  
• Enhance customer confidence  
• Improve branding opportunities |
| **Corporate** | • Reduce company liabilities from design changes and updates  
• Enhance corporate recognition  
• Increase stakeholder value |

Figure 4. Compliance as an interactive environment surrounding product development.
THE PATH TO SUCCESS

A Compliance Management Plan

Success with a Design for Compliance strategy and program requires performance to an effective compliance management plan. The plan can be implemented by internal staff, or it can be developed and implemented by a qualified external resource. With either approach, success requires commitment on the part of management to allocate resources so that the benefits listed in the table can be realized.

Elements of a comprehensive compliance management plan include the following:

- Discovery of relevant regulatory requirements
- Plan for compliance testing
- Processes and procedures for product compliance certification
- Plan for addressing on-going compliance considerations throughout the product lifecycle

Discovery of relevant regulatory requirements: This first step in the compliance management plan typically begins as a research project in either Marketing or Engineering, and it involves research of applicable standards for

- Electromagnetic compatibility (EMC/EMI)
- Product Safety (CE, NEBs, etc.)
- Radio frequency (RF)
- Specific absorption rate (SAR) for portable wireless devices

The result of the research is a comprehensive requirements list developed for the specific product and each intended market. Each requirement is interpreted for applicability, impact on the design of the product and possible product variants, and the ability of the product to operate within parameters listed in the standards. Mapping the requirements further ensures that the product design addresses the worst case requirements while allowing for cost-effective design alternatives if or when conflicts or obstacles arise.

The regulatory requirements list must be maintained, and the research must continue, throughout the product lifecycle. This will ensure continued compliance in the face of product changes or changing requirements. Knowing what is transpiring within the regulatory agencies (e.g., FCC, IC, Ofcom (UK), ANATEL, Ministry of Posts & Telecommunications (MPT) (China), etc.); the relevant standards bodies (e.g., IEEE, ETSI, IEC, and others); and Industry Groups (e.g., WiFi, WiLAN, WiMAX, etc.) can allow a company to plan for changes or possibly request delays or changes to impending requirement revisions.

If it is determined that the essential requirement standards limit or preclude the approval of the technology being implemented in the product, then it is necessary to generate and implement a standards lobbying strategy to update or introduce relevant requirements.

A successful compliance test plan: An appropriately developed compliance test plan captures all relevant pretest requirements and ensures that all members of the product development team understand their roles in the overall test program. A test program’s content can vary depending on which requirements need to be met and the type of product being tested. A well-planned test program should include

- Identification of all product variants
- Compilation of the documentation package (product description; development and manufacturing drawings and related documentation; technical and operations manuals)
- Formulation of test configurations and system setups
- Testing schedule
- Definition of pretest, environmental, and customized software testing requirements
- Definition of product readiness (approval test units and pretesting)
- Plan for handling compliance failures during testing

Certification processes and procedures: With the conclusion of compliance testing and resolution of outstanding compliance issues, the test reports, together with a signed Declaration of Conformity (DoC), become integral components of the product documentation package. This is used in the application for product compliance certification. Many countries recognize requirements developed by technical standards bodies such as ETSI or IC and FCC. Others develop an independent set of compliance requirements. The requirements in each country targeted for product sales govern the processes and procedures used in the certification application process.

Ongoing compliance plan: The plan for compliance maintenance over the life of the product is in many ways a risk assessment plan. It must be an integral part of the ECO process, and it must address how the company responds to component obsolescence or changes in component specifications. As a minimum, the plan for ongoing compliance needs to address

- Potential effects of ECOs on regulatory compliance
- Parameters at risk
- Retesting plan
- Cost analysis and budget

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• Plan for monitoring and assessing changes in compliance standards

WHEN TO OUTSOURCE?

A qualified, accredited compliance laboratory can reduce recurring and nonrecurring costs associated with many steps in the compliance management plan. In startup environments or in companies with downsized staffs, the benefits of a relationship with a qualified compliance partner are immediately apparent. For all companies, however, there are savings to be realized in the heightened efficiencies of an experienced consulting organization. In addition, there are less measurable benefits to be realized in the focused use of engineering’s time.

Product innovation is the vehicle that elevates companies from market followers to market leaders. By outsourcing responsibility for compliance management to a qualified external organization, internal design teams can focus on core competencies in innovative product development. This ability to maintain effective, consistent innovation practices can propel a company to higher revenues and higher profits.

Benefitting from a Compliance Partner

A qualified compliance laboratory that can work with a company as a compliance partner will typically be thoroughly familiar with the regulatory environment and with wireless product development. As such, it is appropriate to expect that the laboratory maintains comprehensive lists of regulatory requirements and that it has established relationships with most regulatory agencies. Costs associated with using a compliance laboratory’s comprehensive list of regulatory requirements are substantially less than the funding required to join specific standards groups or the cost of the research and maintenance of such a list by internal staff. With experience in the applicability of many standards in place throughout the world, the laboratory compliance partner is able to select only the requirements that are relevant to the specific product approvals.

A competent compliance partner organization also can drive the compliance test program from development of the plan through testing and report generation. Based on experience, the laboratory can limit the amount of testing to only what is relevant, ensuring that testing is completed in a timely manner—maintaining project schedules. When the internal design team works with a qualified laboratory partner in developing and executing the testing plan, testing surprises and noncompliant test results should be minimized, if not eliminated.

A qualified compliance partner may also provide other services such as periodic product testing, maintenance of compliance histories for products, and other valuable services. Periodic product testing throughout the product lifecycle can verify internal processes as well as continued compliance to regulatory requirements and to published product specifications. Whether a risk is from a surveillance audit conducted by a customer or by a regulatory agency, the financial impact of failing such an audit is difficult to absorb. The right compliance partner can minimize this risk and provide valuable support to the success of a Design for Compliance program.

CONCLUSION

The global marketplace and innovative environment of commercial and industrial wireless product and equipment development are mandating that companies achieve on-time approval and delivery of new products in many countries throughout the world. A Design for Compliance approach to product compliance testing and certification elevates regulatory compliance as a mechanism for ensuring that product developments stay on schedule. Design for Compliance, successfully implemented with a well developed compliance management plan, heightens awareness of the impact of regulatory compliance on every phase of the product lifecycle.

Whether conducted by an internal team or by a qualified external compliance laboratory partner, Design for Compliance impacts the financial, market, and corporate strengths of the company and accelerates revenues realized from new and existing products over the entire product lifecycle. Design for Compliance accelerates time-to-market and reduces costs. It is about time and money.

ABOUT THE AUTHORS

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