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Director, Center for Compliance Studies
Loyola University Chicago School of Law

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by Laurie Burgett, CCEP

Product integrity: Some compliance principles for engineering organizations

» Market competition is driving faster engineering cycles and pressure for innovation.

» Decreased cycle times and business pressures may inhibit product realization that meets promises to consumers and regulatory requirements.

» ISO standards or engineering processes may not be enough to prevent fraudulent behavior or misleading promises about a product's capability.

» Diligence in reviewing engineering designs includes the concept of a separation of duties.

» An environment where engineers and technicians can and will express concerns in meeting promises to customers or regulations is critical.

In today's market, the drive to be the first company with a new product or a product enhancement is vital. Engineering cycles are now faster than ever, with less time to assess concepts and perform comprehensive testing. This can place engineering groups and individual engineers under great pressure to produce results. Without oversight and controls in place, this situation may lead to exaggerations in performance capability or even fraud and potential regulatory issues. Worse yet, promises made to customers by the business will not be fulfilled.

Burgett

Volkswagon's unfulfilled promises

The premier case for this is the Volkswagen emissions scandal, where software with a "defeat device" was used in the design verification process to manipulate data that made emissions appear to meet specifications on diesel cars. The situation at Volkswagen was complicated with a strong and ambitious managerial structure (often described as "empire-like" and without diversity) trying to break into the North American market, pressure for success from German government officials due to Volkswagen's huge financial impact to their economy, and labor pressures for profitability. To top it off, the culture at Volkswagen was one where management was known to terrify and intimidate engineers with termination to get results. These external pressures for results influenced a small team of engineers to make bad decisions to adjust the software used to track emissions. They were able to do this undetected for many years.

Even after the realization of misdeeds within the company, Volkswagen management did not take action until tests performed by third parties exposed data contrary to Volkswagen's performance promises. The details of the case are still being unraveled,

because not just one, but two groups of engineers at different sites appear to have created or used a software program to fraudulently make emissions seem within specification. As *Fortune* magazine describes:

> "…instead of telling management that they couldn't meet the parameters, the decision was taken to manipulate. No one had the courage to admit failure. Moreover, the engine developers felt secure because there was no way of detecting the deceit with the testing technology that existed at the time. It was, the whistleblower said, "an act of desperation."[1]

Engineering groups are not immune to enabling or reacting to the "seven deadly sins" that are often precursors to unethical behavior.

Volkswagen is blaming a team of rogue engineers, but there is strong evidence that the Volkswagen culture from the top was one of success at any price and an unwillingness to copy known technologies, thus putting serious pressure on their engineering staff for difficult technological breakthroughs.

The role of culture

Even in large companies, many Engineering departments are somewhat insular, especially in business sectors where design verification, such as qualification testing, may be determined by the same organization involved with creating the design. Issues may be undetected due to the nature of the beast where the staff on the business end is often unable to interpret highly technical engineering processes or results. There may even be product already promised or sold to customers with a new technology that is actually still in development, thus putting the expectation on technical staff to perform rapidly. It is, however, important that this rush to perform does not compromise the product integrity.

Engineering groups are not immune to enabling or reacting to the "seven deadly sins"[2] that are often precursors to unethical behavior. A few of the dangers in the engineering environment are that some engineering groups perceive themselves as state of the art or best in class, and some are eager to be seen as innovators. This can lead to "conceit" and "cult" qualities in engineering organizations where arrogance can lead to exaggeration of accomplishments rather than objective results based on statistically sound data. In companies, such as Volkswagen, where there is strong pressure to perform, "dread" and "desperation" may be felt by individual engineers who know about or participate in abuses or short cuts, because they feel they can't speak up or even that they may lose their jobs. They may falsify information or kludge the design or testing in extreme cases. Other engineers may know that something is wrong or doesn't make sense, but they keep silent due to fear of retaliation or reaction from the greater group. Perhaps they are never asked by management as to their opinion about the quality of the design parameters, the design itself, or the testing quality and assume their opinion would not be valued. Sales and other management structures may promote "cronyism" for their supporters in the

technical world who are prematurely willing to say that the design is great and ready to go to market. "Disregard" or perhaps "distain" may be shown for those who disagree that the product has been shown to meet requirements when there is an eager market waiting.

So, as compliance professionals, what can we do to understand risks in meeting our company's code of conduct and our promises of integrity and quality regarding product performance? Although many companies follow ISO standards or other basic processes in fulfilling designs, this may not be enough to ensure compliance, because evaluating designs relies on human interaction and evaluation. Therefore, a deeper scrutiny may be mandated of the engineering process, including assurance of a distinct separation of duty in reviewing and validating designs.

Many companies have robust engineering processes, but it is important for the sake of speed that these are not shortchanged.

As in most topics regarding compliance, process is king. Risk is greatly reduced if critical thought and oversight are exercised throughout the design cycle(s). Designing a product is a complex process, because engineering a new innovation or product, even if based on an existing product design, is iterative. Knowledge is gained through cycles of requirement development, design proposals, modeling/prototyping, and testing to refine a design; through those, the product is advanced and improved. A Compliance function, working with the business, can oversee and periodically audit that a documented process with appropriate separation of duty is in place and followed for product realization. Ideally, the designers and design reviewers would have enough separation that an independent review of the design, unfettered by politics, expectations, or relationships, would be ongoing at points along the design journey.

The engineering process

Many companies have robust engineering processes, but it is important for the sake of speed that these are not shortchanged. In fact, it's not uncommon to overrun the design cycle schedule and then compress the schedule as other functions such as tooling, manufacturing, and testing, are engaged to do their part of the build and verification cycle. With full system testing at the end of the cycle, it's critical that some minimum standards are adhered to with a subsequent, thorough design review. There are many philosophies on successful design processes, but the following are some fundamental steps that should be included in any design process.

Requirements

Clear and detailed requirements and criteria are the basis for any good design. What is the problem that the company is solving through the design and what will customers ultimately be promised if they buy a company's solution?

Test plan

From the detailed requirements, a qualification test plan should be designed to evaluate the ability of the product to meet those objectives. Depending on the type of product, this test plan should be statistical in nature and show that the product works to specification within any promised environmental tolerances (e.g., temperature, humidity, altitude). Once in production, an acceptance test criteria may

be necessary to show that the product still meets design requirements as manufacturing variations are introduced.

Design review process

Evaluations held through design reviews are needed at various intervals throughout the design process. As the design progresses, assumptions, calculations, logic, and other factors should be reviewed periodically but, at minimum, through a preliminary and final (or end state) design review. It's important for engineering groups to validate that individual engineers did their homework, that they performed necessary calculations upon which to base assumptions, and that they did not guess or blindly copy other designs. Especially in insular engineering groups, exuberance or pressure to perform can be a potential conflict of interest that leads to an overly positive and optimistic interpretation of a small data set or single test.

As the design progresses, assumptions, calculations, logic, and other factors should be reviewed periodically but, at minimum, through a preliminary and final (or end state) design review.

This is where a second set of eyes by technical experts who do not work directly on that project are critical. For a more complex product, different types of engineers may need to evaluate the thoroughness of the design at interfaces and throughout different systems. This would also include the ability to physically build the design into a viable product and may include suppliers. Companies should do their best to find knowledgeable but neutral third parties to oversee major reviews. Where the government is the customer or in highly regulated industries, such as aerospace, this separation of duties is usually a robust part of the process. In commercial markets where due diligence is internally developed, neutral reviews will need to be built into the design process to ensure the product's ability to meet requirements—no more and no less. Some body of test results will likely need review as well.

Documentation

Detailed documentation by engineering should be kept of assumptions, calculations, and tests— both qualification and acceptance tests. This is especially important in companies that tend to replicate or scale elements of designs for new designs.

There should be an organized configuration management structure to the product. Configurations should be tracked in some manner, such as by serial number or by production date, so that any product issues may be resolved with a fix or a recall, especially if product safety is a factor. If a part number is called out in an assembly, then any part with that part number should be interchangeable in that assembly, if it meets the specifications of the engineering drawing. If a part does not meet the engineering drawing specification and is used in a product, there should be additional documentation by a qualified internal organization as to why the part was acceptable for use (i.e., a material review process). This insures the design intent will be preserved for customer satisfaction.

Raising concerns

Although it may be difficult with business pressures, as well as other cultural aspects, there should be a means for engineers or technicians who feel the design does not meet regulations or performance promises to customers to feel comfortable raising their concerns. This may include reservations about the quality of the design requirements, the design, or the testing quality. Management must make these engineers and technicians feel their opinion is being solicited and is valued by the business and, at minimum, their concerns will be answered or addressed. This essential element is another reason why a diverse group should be invited to design reviews, which should be a forum for such items to be considered. Design reviews should be documented and open items tracked for follow up.

If an engineer or technician is not comfortable speaking up in a public setting, private meetings, hotlines, or other means should be encouraged. The third-party aspect of working through the Compliance function may help facilitate honest feedback if the environment in a company has cultural qualities that inhibit employees from speaking up. It is essential to make sure there is follow up and response to any concerns.

Conclusion

The financial effects of the fraud at Volkswagen are currently estimated at $20 billion to compensate consumers and for fines and, clearly, Volkswagen's business and reputation have sustained ongoing negative publicity and public outrage. It's also clear that, while a set of rogue employees is blamed for the problems, the whole culture, starting at the top, was a factor in this situation. Volkswagen says they are taking steps to change the culture away from blind obedience and have brought in new outsider executives to promote dialog and alternative points of view.

Although a compliance organization should not be a watchdog for engineering a product, it can facilitate review and audit of engineering processes and documentation in order to evaluate process integrity and adherence.

Although a compliance organization should not be a watchdog for engineering a product, it can facilitate review and audit of engineering processes and documentation in order to evaluate process integrity and adherence. Compliance organizations can validate that there is segregation of duty for those reviewing the design versus those creating or validating the design. It can also provide a forum for whistleblowers if the corporate culture does not allow public discussion. Risk of not meeting customer and regulatory expectations can be reduced with a strong and inclusive process so that all critical aspects of the design are considered and verified. ✳

1. Geoffrey Smith and Roger Parloff: "Hoaxwagon: How the massive diesel fraud incinerated VW's reputation" *Fortune* magazine, March 7, 2016. Available at http://bit.ly/vw-diesel-fraud
2. John Cross: "The seven deadly sins of unethical organizations" *Compliance & Ethics Professional*, April 2014, pp. 19-23

Laurie Burgett *(GoldenHillConsulting@gmail.com) is owner of Golden Hill Consulting Incorporated in San Diego, CA.*