Chemicals Management Programs & Management Systems Standards

A White Paper by Tim Cassidy

Introduction

Companies are struggling to find an effective way to manage chemicals and develop good chemicals management programs (CMPs). While regulatory requirements must be met, and normally the Product Safety and Compliance teams are charged with assuring they do, today's consumers are concerned with chronic exposure to presumed-hazardous substances that go beyond regulated chemicals. Corporations desire to satisfy customer needs and answer their concerns. Typical approaches used today do a poor job of assuring the full spectrum of chemicals management. These typical methods are often expensive and inefficient for companies. This paper suggests another, less typical option – a management systems standards (MSS) approach that addresses these concerns and leads to an alternative that may be a better fit for many companies.

Executive Summary

Typical chemicals management approaches, either restricted substances lists pushed up the supply chain, or chemicals content declarations coming down the supply chain, are unreliable and lead to additional expensive, complex, time-consuming testing to provide the level of assurance desired. While these typical methods have their place, an MSS approach is both more efficient, more proactive, and based on continual improvement and trust building between vendors and customers leading to a reliable level of assurance. Further, implementation of the MSS helps resolve issues companies confront regarding inter-organizational responsibilities for CMPs generally. Finally, the MSS approach derives efficiency by integrating the existing quality management system with CMP allowing for seamless assessment of both with the same resources, as well as reducing the need for expensive testing by increasing trust and competence across the supply chain.

Typical Approaches to CMP

There are generally two approaches typically relied on by companies today. The first is the RSL (restricted substances list). This approach has merit if the products' design documentation can restrict or ban the use of certain chemicals, particularly during the materials procurement phase where the vendors agree to provide materials complying with the specifications, including restrictions. The second approach is an informational declaration (ID) approach where the chemical composition of materials is declared and the declaration travels down the supply chain to (usually) the original equipment manufacturer and its customers. In effect the RSL travels one direction in the supply chain (customers stating requirements to vendors) while the ID travels in the other (vendors telling costumers what the composition of their materials are). But since both rely on representations requiring trust, testing is used to validate claims. This testing is usually duplicative at various locations in the supply chain.

Testing itself, has two main drawbacks. First is the determination of specifically *what to test*. What are the exposed parts? Is it the consumer, the repairer, the recycler, or the final disposal we need to consider? The choices made here would inform us what parts to test and considering testing is needed to overcome a lack of trust between parties in the supply chain. Testing all parts may not be viable depending on the complexity of the product (imagine the number of components and materials used in an automobile or a washing machine!). Furthermore, testing is a snapshot in time. We may test parts today and the parts used tomorrow are not precisely the same or are from an alternate source.

The second drawback is determining *what to* test *for*. That is, which specific chemicals should we test for? Different materials or components will be composed of different chemicals, so knowing which RSL chemicals are applicable to each is no easy task. This means companies need to have chemicals experts to help decide, or go to test houses and seek their help. Both are expensive propositions and must be considered carefully. Obviously, the more testing, the greater the expense.

Another Approach to CMP

MSS (management systems standards) have been around for a long time and most companies engage them. Probably the oldest and best known is ISO 9001, the quality management standard. Because these standards are general in nature, many industries have created their own versions to cover issues unique to their industry needs. Examples include aerospace, automotive, telecommunications, medical devices, food industries, and others. Beyond industry versions, many companies have developed their own specific addenda to these standards to meet with their unique corporate methods, procedures, cultures, etc. It's in this context that consideration to another MSS may be a fit for your specific CMP. That MSS is named IECQC 080000 (I call it "Q80"). Q80 is the ISO 9001 of CMP. It changes the CMP to a systems assessment approach aimed at discovering how the company is organized, trained, and otherwise capable to manage the chemicals used in its products.

Q80 Anatomy

Q80 was designed to align with ISO 9001. Its clauses relate to each ISO 9001 clause header. Like ISO 9001, Q80 asks the fundamental questions "Do you know what you're doing"? and "Can you demonstrate it to an auditor"?

Beyond the fundamental questions of demonstrated capability, Q80 has two key requirements: You must meet all *regulatory requirements* for your products and factories; and you must meet your *customers' requirements*. But Q80 is focused on the *processes* by which you know that you meet both. Customer requirements differ from regulatory requirements when your customer has special rules, bans, or restrictions that you contractually agree to comply with, while regulatory requirements are legal mandates applicable in all cases. As an example, a customer company may restrict the use of specific chemicals when there is no regulation that prohibits their use. Your regulatory team may have special customer requirements also, such as particular reporting requirements (e.g. to aggregate data and report to a government under a specific brand or class of product, or to file specific jurisdictional reports). Q80 would seek to determine how you understand what the customer required, and what systems, processes, or procedures you have in place to guarantee meeting those requirements.

Based on this anatomy (regulatory + customer requirements), a company may use Q80 to manage vendors by expressing their unique customer requirements, and then auditing the vendor processes to validate they are capable to comply. Q80, like ISO 9001, is a continuous improvement model. This

means audits are in part gap assessments that identify opportunities for improvement and show a commitment to business relationships designed to increase trust between parties. As mentioned above, RSLs and IDs leave all parties in a position lacking trust, and therefore testing is practically a mandate. Q80 overcomes these issues over time.

Q80 does not preclude the use of RSLs or IDs (in fact they may be customer requirements audited by Q80), but it instead enhances their use by focusing on how we know if we can rely on claims being made. If my vendor says he can meet my RSL, Q80 gives me a way to validate that my vendor is truly capable and operating in a way I can rely on.

Q80 Deployment

Applicability

Q80 was developed by IEC, so some may think it is only useful in the electrical or electronic sectors. Perhaps it should have been developed by ISO, but the standard is generally applicable across many (if not all) industry sectors. It is both *general* and *comprehensive* covering all relevant aspects of operations for controls needed for a top-quality CMP.

Q80 can be assessed either by 3rd party audit firms (thus registration or certification is attainable), or it can be used for assessment purposes when integrated to existing QA audit programs. The choice of certification versus assessment depends on where a company sits in the supply chain and what their customers most need. Assessment may be virtually cost neutral if integrated with existing quality audits and using existing audit resources.

Upstream Deployment

If your company already assess your vendors for quality assurance, you are most of the way to implementation in your vendor base. Two additional steps are needed. See figure 1 below for an illustration of this process. First, map Q80 into your ISO 9001 (or whatever quality standard you assess to). Make sure any audit questions you ask comprehensively cover the Q80 clauses. Since Q80 is designed to relate specifically to ISO 9001, it is not difficult to do this mapping.

The second step may be more difficult. You will need to define your customer requirements and determine the best way, in the context of your organization, to express the requirements to your vendors. This step is completely independent of the ISO 9001 mapping. But until you express *your CMP requirements* to your vendors, you cannot audit the "customer requirements" part (for CMP). These requirements may vary by company from simple to complex. They should consider what if anything, you want reported to you; when these reports should be made; what frequency they should be; and what reporting formats you may need, among other considerations.

Now that you have both mapped Q80 to your quality system, and expressed your customer requirements to your vendors, you are ready to use your quality system to assess your vendors, identify gaps, and set corrective actions. You also should have a good idea of which vendors you cannot rely on and which must be watched more carefully, as well as those who you can immediately trust. From that assessment, you can direct your resources efficiently and begin improving your supply chain.

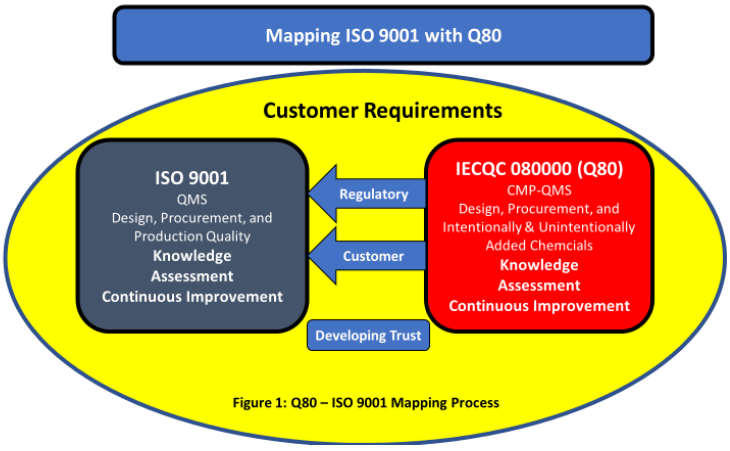

Figure 1: Q80 – ISO 9001 Mapping Process

Internal Deployment

Internal deployment looks a lot like upstream deployment, except that you need to determine what your customers are requiring of you and be sure those requirements are understood and complied with. The same gap assessment can be made internally, and the same continuous improvement model will apply.

Whose Job Is It Anyway?!

The act of creating your requirements so that they can both be expressed well to vendors, and assessed properly by the quality assurance audits, brings teams together and overcomes inter-organizational barriers to execution. Safety and Compliance are concerned with all regulatory elements. These may include proper marking or labeling of products, or governmental reporting for certain chemical regimes or jurisdictions. Social Accountability is concerned with chemicals that may extend beyond regulated chemicals. Well crafted "customer requirements" take both these functions into account. This allows the Quality Assurance teams to evaluate and assess vendor performance against the requirements and assure processes and procedures lead to fulfillment of vendor commitments and customer confidence and satisfaction. In the end each specific teams' needs are built into the CMP and validated with each Quality Assurance audit.

Conclusions

Integrating Q80 into quality management systems has advantages over typical CMP approaches. It allows assessments that direct the use of resources efficiently. It clarifies which vendors know how to manage their chemicals and which need improvements, and which simply cannot be trusted. Q80 works on a continuous improvement model and is designed to build greater trust in the supply chain so that companies can better rely on representations made by vendors. Q80 does not preclude RSLs or DIs and testing may well be a part of a vendor's demonstration of compliance. But Q80 also should reduce the need for testing overall, and therefore reduce expenses. Finally, deploying Q80 involves all inter-organizational stakeholders in developing customer requirements for your unique CMP.

Tim Cassidy is a seasoned product safety professional and instructs students at the Advanced Product Safety Management Course at St. Louis University. If you have comments or questions regarding this topic, please contact Tim by email at Cassidy.Tim@outlook.com