UNDERSTANDING COMFORMITY ASSESSMENT AND ITS RELATIONSHIP TO ENVIRONMENTAL HEALTH

James D. Dingman, R.E.H.S., D.A.A.S.
Underwriters Laboratories Inc.
Northbrook, Illinois, USA

Environmental Health professionals are familiar with requirements for “approved” products in many program areas such as drinking water additives and equipment, swimming pool equipment, and food service equipment. However, many are unfamiliar with what this “approval” really means. This presentation will provide the basic principles of product approval through conformity assessment by addressing major aspects of the certification process. These aspects include (1) what is conformity assessment and why it is important, (2) what are standards, and what is their relationship to conformity assessment, (3) the importance of certification, and (4) an example of how this certification process works.

What is conformity assessment?

Simply put, it is a process whereby a product, service, process, or system is evaluated against specific requirements. For the Environmental Health field, these requirements are based mainly on health-related criteria.

Where does conformity assessment come from?

It is a “need driven” process. A need to insure that products are safe to use, are not going to cause adverse health effects, or that the product is able to do what the manufacturer claims it can do.

Who initiates the conformity assessment need for a product?

The need for conformity assessment can be initiated by a variety of sources. A governmental agency, whether at a Federal, State, or Local level, can initiate this need. Code organizations, such as those dealing with plumbing and mechanical codes may also initiate a need for conformity assessment. A product manufacturer or group of manufacturers may want to provide a means for the consumer or regulator to verify that their product meets certain claims they have made. To insure this, the manufacturer(s) can also initiate a need for conformity assessment services. Finally, the general public can demand products meet specific requirements, and thereby initiate the need for conformity assessment services for the product.

Why is conformity assessment important?

There are product manufacturers that make claims about their products that may be misleading. Others may have products that do everything the manufacturer claims it will.

How can a regulator or consumer differentiate between these two types of manufacturers?
Conformity assessment will provide a means for the manufacturer to verify that the claims made can be substantiated. In other words, it provides a means to distinguish between conscientious manufacturers and disreputable ones.

As a consumer, for example a restaurant owner, conformity assessment is important in that it provides reliability. The consumer is receiving the correct product, which meets the applicable requirements, as verified through the conformity assessment process.

As a regulator, conformity assessment provides you with the assurance that the product meets all applicable requirements, thus making your job of enforcing regulations much easier. Without conformity assessment and organizations that conduct these assessments, you, as the regulator, would need to verify each product's compliance with the applicable standards. Most all health departments and similar regulatory authorities lack the personnel, expertise, equipment, and funds to conduct these product verifications.

What activities are included in the conformity assessment process?

This process involves numerous activities including sample testing, inspection of products, evaluation of the manufacturing process, certification of products, and possibly management system registration.

Why a third party?

In the Environmental Health field, most regulations that require product conformance with specific standards, specify that this conformance be verified by a third party conformity assessment organizations. This takes the burden of verification off of the regulatory authority, and provides an unbiased evaluation of the product.

In other instances, the consumer is the driving force behind third-party certification. The consumer wants the product evaluation to be conducted by a third party to assure them that the product will perform as expected, and that complete neutrality was used in making this determination. This only makes sense. If the evaluation of the product was conducted by the manufacturer or its representative, how can the consumer, or regulator for that matter, be assured that the evaluation was not influenced by the relationship between the manufacturer and the evaluator?

Along this same line, the manufacturer looks to a third party for conformity assessment services as a means of market differentiation. Which manufacturer would most likely sell their product – one with a third party certification product verification, or one who simply advertises compliance?

However, there are instances in which product certification is not required, nor are there standards available to evaluate products to. In these cases, both the consumer and

regulator are left to make their own choices of purchase or acceptance based on what information they are able to obtain from various sources.
It should be easy to see that conformity assessment services performed by a third party are the best way to go.

These third party conformity assessment organizations may seek accreditation of their programs as a declaration of competence.

Why do they seek accreditation? To distinguish themselves from other conformity assessment organizations by having an impartial evaluation of their competence based upon international recognized criteria. Accreditation assures the manufacturers, consumer, and regulators that the organization has the proper personnel, equipment, processes, and ability to conduct product evaluations in the proper manner.

Conformity assessment organizations can obtain accreditation from a variety of sources. However, national accreditation is the most sought after. Examples of such accreditation would be the American National Standards Institute (ANSI), the United Kingdom Accreditation Services (UKAS), and the Japanese Ministry of Economy, Trade and Industry (METI).

Now that you have a general background of conformity assessment, let's turn our attention to the documents that are used to verify product compliance. These documents are called Standards. A standard is a formal, published collection of requirements for evaluating a particular product to class of products, for example, commercial cooking equipment.

Why are standards necessary?

When a need for a specific health or safety requirement is determined, standards provide an efficient resource to insure that these requirements are applied to all appropriate products.

In many instances, compliance with specific standards is required by codes, regulations, and laws.

How are standards developed?

The standard development process is a lengthy and costly process. The first step in this process is the identification of a need for a standard. Due to the time and cost involved in developing a standard, the need must be strong, and must be well documented. A standard that is not needed, is not important to and accepted by the regulatory community, or one that is poorly developed is of no use to anyone.

Most standard writing organizations, many of whom also conduct conformity assessment services, want their standard to be a national standard. The rationale behind this is simple. If more than one standard exists for a product, which one is the

best? Which one should the regulator choose to accept? In such a situation, the regulator assumes some unnecessary liability. Having only one national standard simplifies the process, and removes the liability from the regulator.

In order to develop a national standard in the United States, the developing organization obtains a Project Initiation Notification (PIN) from ANSI. There is only one PIN given out for any standard, insuring that there is no duplication of standards, and the situation cited as an example above should not occur.

Once the PIN has been obtained, the committee to work on the standard is developed. This committee is made up of all interested stakeholders: manufacturers, consumers, regulators, and other interested parties. The composition of the committee is such that all stakeholder groups are represented equally. No specific group is able to obtain an unfair advantage based on committee composition.

After the committee has developed the final draft of the standard, it is sent out for public comment. Any comment received must be considered. Finally, the standard is ready to be balloted by the group that overseeing the committee. Any negative ballots must be supported by proper documentation. It is not required that all negative ballots result in changes to the standard, however, the committee must answer all negative ballots, and support their answer.

Once a consensus has been reached, and all negative ballots answered, the standard is sent to ANSI. ANSI does not review the content of the standard, but rather reviews the process to insure that the standard was developed in accordance with their procedural requirements. Once ANSI has reviewed the standard and it complies with their requirements, it is designated as an ANSI national standard.

In order to insure that standards are uniform in their organization, most of the standards writing organization follow a similar outline in the organization of their own standards. In general, the following format is followed:

1. Forward: This section is the “legal” section of the standard. It essentially affords the standard writing organization a certain amount of legal protection with regard to use of the standard.

2. Introduction: The introduction contains general information needed to correctly apply the standard. Within the introduction are the scope, glossary, and installation and operating instructions.

   The scope explains what products are covered by the standard. It often refers to nationally recognized codes or regulations. It is important to check the scope to make sure the product being investigated is covered by the standard before applying the requirements in the standard to the product.

The glossary provides definitions of terms that are not commonly used, or terms that are used in a way that might not correspond with a generally accepted definition.

Installation and operating instructions are used as a guide for product investigation. These instructions shall also include appropriate items of concern to users and installers of the product.

3. Construction: This section describes the physical characteristics needed by covered products in order to comply with the standard. For example, a piece of food service equipment may require a specific thickness of stainless steel.

4. Performance: This part of the standard describes the various tests which the covered product might need to undergo and pass in order to comply with the standard. For example, plastic pipe may be subjected to various water pressures to insure that it will not rupture under conditions of normal use. This section also describes the type of equipment required to conduct the tests.

5. Manufacturing and Production Tests: In this section, the standard specifies the tests required to be conducted by the manufacturer on 100% of the production before it leaves the factory.

6. Rating: The rating section specifies the units of measurements to be used in rating the product, such as “ppm” or “cfs.”

7. Markings: The markings section specifies how the covered product needs to be marked. For example, the manufacturers name identifying symbol, or catalogue number. Any requirements for warning or cautionary markings also appear here, and often specify the text, location, and minimum letter height.

8. Other: Many standards also have a components section, or a clause about components. Its purpose is to clarify that if a component was evaluated by a different standard, it does not need to be reevaluated.

Two other important items to remember when dealing with standards concern the ownership and use of standards, and the “living” nature of them.

Ownership of a standard is reserved for the organization that wrote the standard. Although anyone wishing to test products to a standard may do so, only the owner of a standard can make revisions to the standard. If anyone using a standard has questions about how to do something in the standard, only the owner of the standard can provide the required interpretations. This helps to insure that the standard remains virtually unchanged, unless or course, revised by the owner.

Standards are living documents. Once a standard is written, it is revised as new technologies, processes, or other applicable information is available. Most standards are reviewed on a regular basis and revised if needed.

Now that you have a basic background in Conformity Assessment and Standards, let's look at an example of the certification process for a product that might be used in the Environmental Health field. As with the discussion on standards, this example is a general one, and may vary somewhat between conformity assessment organizations.

The certification process begins with a preliminary meeting (or meetings) between the conformity assessment organization and the manufacturer, or its representative(s). At this meeting, all blueprints, prototypes, data, and anything else of importance are reviewed. A determination is made as to the applicable standard(s) and tests needed for certification. Depending upon the type of tests needed, a determination will be made as to the number of samples required. Finally the cost of the evaluation, and the timeline for completion will be determined. Once all parties involved agree upon these items, the actual equipment investigation can begin.

The equipment investigation may require the efforts of chemists, engineers, laboratory technicians and others. This investigation will include a construction review, a materials analysis, performance testing (if applicable), and the preparation of a report.

The construction requirements of the standard are applied to the product under evaluation. Some of these requirements might include the location of any zones, and the acceptability of corners, joints, seams, fasteners, and other similar items. In the case of products used in many of the Environmental Health fields, there are also requirements that the product is cleanable and does not provide harborage for vermin.

An analysis of the materials used in the product is also conducted. These materials shall not impart any toxic substance, odor, color, or taste to the product. The submitter must supply a list of all materials used in the product. Additional tests are conducted to insure that the product is corrosion resistant and nonabsorbent. Any coating that might be on the product are also evaluated.

This analysis of the materials is conducted following detailed procedures which include applicable certification polices for the specific product by the owner of the standard. Also, Federal regulations, toxicological resources, and other standards are also frequently used in these analyses.

Performance testing is required by some standards. If such requirements exist, the product is tested to insure that it performs as required. Some of this testing may be conducted at the manufacturing facility instead of at the conformity assessment organizations facilities.

Once the product has completed all of the required tests, and the test results have passed the criteria required in the standard, a report of the evaluation is prepared. This report includes any significant construction features and materials identification.

The report is used in numerous ways. It is used by the conformity assessment organization during field inspection at the manufacturing facility to insure that the products currently manufactured are identical to the product(s) submitted for evaluation. The manufacturer also uses it for the same purposes. Additionally, it provides a record of the tests performed on the product. This information is important in helping to provide answers to inquiries from regulatory authorities. As a note …. this information is the property of the manufacturer and therefore cannot be given to anyone, including regulatory authorities, without the permission of the manufacturer.

Once the certification process has been completed and the product has complied with all of the requirements in the standard, the product is then considered to be certified. Depending upon the conformity assessment organization conducting the evaluation, the name “certified” may be replaced by other wording such as “Listed” or “Classified.”

It is important to remember that conformity assessment organizations **do not** “approve” products. They **verify** compliance to applicable standards.

Once the product has been certified, information concerning the product is usually published in a directory by the conformity assessment organization. Although these directories are useful for activities such as plan reviews and field inspections, it is important to remember that they may not contain completely accurate information due to additions or deletions of manufacturers or products. In order to be sure that the product is currently certified, you must either contact the conformity assessment organization or see the certification mark on the product.

In order to insure that the product leaving the factory for sale is the same product as the one evaluated in the laboratory; in other words, the product is in compliance with the standard, many conformity assessment organizations conduct follow-up factory inspections as part of their certification process. These inspections are usually unannounced visits; very similar in nature to inspections regulatory authorities conduce on their regulated facilities. During these visits, production controls are checked, samples are selected as needed, testing is witnessed, and a general inspection if the facility is conducted.

As you can see, the certification process can be an expensive and time-consuming venture. However, the time, effort, and cost that a manufacturer puts into developing a product and obtaining certification pays off when it comes to acceptance by the regulatory authority. The presence of the conformity assessment organization’s mark on the product is the regulatory authorities’ assurance that the product complies with requirements of the applicable standard.