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Submitted via: sp2000-02@nist.gov

February 26, 2018

Ms. Lisa Carnahan
Standards Coordination Office
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Ref: Intertek comments on the *"Draft Conformity Assessment Considerations for Federal Agencies"*

Dear Ms. Carnahan,

Intertek is pleased to provide comments on the *"Draft Conformity Assessment Considerations for Federal Agencies"*.

Intertek is a leading Total Quality Assurance provider to industries worldwide, and is a leading United States provider of quality and safety services for a wide range of industries around the world. Our network of more than 1,000 laboratories and offices and over 42,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains.

Intertek supports NIST's development of the *"Draft Conformity Assessment Considerations for Federal Agencies"* and looks forward to continuing to work with NIST to insure that the resulting document provides the necessary guidance and information that will be useful to Federal Agencies when developing their requirements.

Thank you for the opportunity to offer the following comments. If you have any questions regarding our submission please feel free to contact me at 202-255-0350 or at joan.sterling@intertek.com.

Sincerely,

J. E. Sterling

Joan E Sterling
Intertek
Vice President, Public & Government Affairs

Intertek fully supports NIST's efforts to consult stakeholders throughout the process of developing the "*Draft Conformity Assessment Considerations for Federal Agencies"* document, and is pleased to see language in the *"Draft Conformity Assessment Considerations for Federal Agencies"* document that stresses the **importance of transparency and stakeholder engagement** by federal Agencies as they are designing conformity assessment programs. Transparency and engagement at the earliest stage is integral to the development of an effective program that can help regulators achieve their goals.

We have divided our comments into two sections. The first are issues that we believe are overarching comments on the nature and content of the document. The second section provides specific comments and language changes to the current draft that support these principle issues.

Section 1: Overarching Comments

- Lack of **neutrality** regarding the different methods of conformity. This is reflected in the promotion of first-party conformity assessment over other methods;
- Lack of language reinforcing the **OMB A-119 policy** that Agencies should leverage the resources of private sector conformity assessment in lieu of developing duplicative public-sector conformity assessment whenever possible;
- Deviation and inconsistency with the globally accepted terminology in the ISO/IEC 17000 group of standards and principles related to conformity assessment;
- Emphasis regarding the use of government laboratories, which is in direct conflict with **OMB A 76** that prohibits government competition with private sector resources, unless there is a legitimate documented reason, such as national security.
- Lack of language regarding the need for **reciprocity** provisions with other economies when an agency chooses to accept results from non-domestic conformity assessment bodies ; and
- Duplication of concepts within the companion *"Draft ABCs of Conformity Assessment"* document.

Intertek recommends that the documents be rewritten reflect "method-neutral" language and remove any language that portrays one method as preferential or more "trade-friendly" than another. As a non-regulatory agency, NIST should strive to be "method-neutral" in its approach to providing guidance and coordinating conformity assessment in the United States.

Conformity Assessment and the demonstration of compliance itself does not have any impact on trade. The issue that is being implied is one of National Treatment, in other words are the requirements the same for domestic and non-domestic manufacturers or conformity assessment service providers. National Treatment is defined as:

"Each Party shall accord to conformity assessment bodies located in the territory of another Party treatment no less favourable than that it accords to conformity assessment bodies located in its own territory or in the territory of any other Party[1]."

This means that conformity assessment bodies in the exporting country should be authorized to test, inspect, and certify products, processes, or services in accordance with the legal and technical (standard-based) requirements that apply in the importing country. National treatment helps facilitate trade and time-to-market since manufacturers are free to use the appropriately accredited/recognized conformity assessment body of their choice, in the location most appropriate to their business model, instead of being limited to a restricted selection of conformity assessment bodies in the destination market only. National Treatment also gives regulators greater confidence that requirements are met because regulators would approve conformity assessment bodies and/or accreditation bodies directly, instead of via a Mutual Recognition Agreement that provides a decreased level of confidence.

Additionally, the language in the documents seem to confuse "methods of conformity" with "conformity assessment activities" and some of the descriptions are not based on the ISO/IEC 17000 definitions that apply to conformity assessment. Intertek recommends aligning the document with the vocabulary and definitions in the ISO/IEC 17000 series.[2]

Intertek recommends that NIST considers removing any overlap of content between the *"Draft Conformity Assessment Considerations for Federal Agencies"* document and the *""Draft ABCs of Conformity Assessment"* document, because the *"Draft ABCs of Conformity Assessment"* is an accompanying document to the *"Draft Conformity Assessment Considerations for Federal Agencies"* document. The *"Draft ABCs of Conformity Assessment"* should focus on providing a user-friendly overview of conformity assessment language and concepts in a neutral and purely educational manner.

The *"Draft Conformity Assessment Considerations for Federal Agencies"* document should not repeat those concepts, but focus instead on identifying the types of questions/criteria Agencies should consider when selecting methods of conformity and in designing a program or scheme. Please see Annex 1 with a comprehensive set of suggested questions for consideration that can help in selection of the method of conformity that help achieve the desired goals for design of a conformity assessment program or scheme.

Intertek recommends that both the *"Draft ABCs of Conformity Assessment"* and the *"Draft Conformity Assessment Considerations for Federal Agencies"* documents clearly convey that **there are different avenues for demonstrating compliance,** and **each of these avenues provide different levels of assurance** which are applied based on what is needed to manage risks and have the level of confidence needed for the specific situation.

Section 2: Specific Comments

Line 146-148 edit:

- *Agencies should also design conformity assessment programs with the objectives of furthering outcomes that are closely aligned with market dynamics and otherwise maximize net benefits to*

[1] Trans-Pacific Partnership (TPP) Technical Barriers to Trade Chapter: https://ustr.gov/sites/default/files/TPP-Final-Text-Technical-Barriers-to-Trade.pdf

[2] https://www.iso.org/obp/ui/#iso:std:iso-iec:17000:ed-1:v1:en:sec:3.1

society. ***In this context, Agencies should recognize the possible contribution of private sector conformity assessment activities. When properly conducted, conformity assessments conducted by private sector conformity assessment bodies can increase productivity and efficiency in government and industry, expand opportunities for international trade, conserve resources, improve health and safety, and protect the environment.***[3]

Lines 146-148 is an excerpt from OMB A-119, pg. 30; however, the language is out of context since NIST did not include the entire paragraph from A-119, which describes the possible contributions of private sector conformity assessment. Intertek recommends that NIST takes the opportunity throughout the document to reinforce that Agencies should follow OMB policy and leverage private sector conformity assessment activities whenever possible. Intertek recommends that NIST include the entire paragraph from OMB A-119.

Lines 230-231 edit:

Each agency should consider using terms that are consistent with ~~their stakeholders~~ ***ISO/IEC 17000 definitions****.*

Intertek recommends that NIST encourages Agencies to consider using terms and definitions consistent with ISO/IEC 17000 definitions. Consistent application of the globally accepted definitions for conformity assessment terms contained in ISO/IEC 17000 will reduce confusion for both stakeholders and for interagency coordination.

Lines 321- 326 edit:

~~*Understand the perspective with respect to their views on: the potential impact (positive and negative) conformity assessment activities may have on the market's ability to produce/deliver product to meet demand; the potential impact on demand (increase or decrease); and the potential impact on the use of the product/service.*~~

Intertek recommends that this be deleted. It is not clear what NIST is recommending; how does the **method** of compliance impact the market's ability to meet demand for the product or service? The agency should understand the markets that might be impacted by the regulations. Once the Agency determines that there is a need to regulate, industry must demonstrate compliance, and the Agency will need to determine how this demonstration will take place. The determination of the method should be based on the objectives and confidence needs of the regulator to fulfill its goals and mission. This will depend on various factors, such as the risks associated with products/processes/services, how likely is non-compliance, what is the industry's track record, how much trust there is in the supply chain, what are the societal costs of non-compliance, what are the Agency's resources and capabilities, etc.

Lines 337-338 edit:

Understand the capacity needs and requirements for conformity assessment programs. ~~Federal conformity assessment programs should not be a bottleneck in the private sector meeting demand.~~

and Line 867 edit:

[…] understanding capacity needs. ~~so that the model does not create built in bottle necks.~~

[3] https://www.nist.gov/sites/default/files/revised_circular_a-119_as_of_01-22-2016.pdf

Intertek recommends deleting the above language. It is not clear what NIST means when it states that Agencies need to "understand capacity needs" and ensure their programs are "not a bottleneck in the private sector meeting demand". If a program is well designed with the inputs of all stakeholders, including conformity assessment bodies, it is very unlikely that the program will create any bottleneck because the market forces for delivery of conformity assessment services has always demonstrated the ability to fulfill demand for capacity.

Lines 392-395:

> *OMB A-119 states that "Agencies should consult with the USTR on the relevant international commitments for conformity assessment, as well as to consider Executive Order 13609 "Promoting International Regulatory Cooperation" [OMB A-119, Pg. 32].*

Intertek supports NIST's reinforcement of OMB A-119 and the directive for Agencies to **consult** with USTR on "relevant international commitments for conformity assessment", but NIST should provide additional context or narrative to reinforce **why** it is a critical step in "understanding federal law, policies and rulemaking". Ultimately the decision of Agencies policies related to compliance is based on their goals and objectives.

Line 442 edit:

> *Testing is considered to produce definitive results in a test report* ***for the single item that has been tested.***

Intertek recommends addition the above language to clarify what is expected from the outcome of a specific conformity assessment activity.

Lines 444-449 edit:

> *Testing can be performed by laboratories differing widely in size, legal status, purpose, range of testing services offered, and technical competence. In the United States, ~~they may be government regulatory laboratories, government research laboratories, or government-supported laboratories - at the Federal, state or local levels.~~ ~~T~~testing laboratories can be ~~college/university laboratories,~~ independent private sector laboratories, laboratories affiliated with or owned by industrial firms or industry associations, or manufacturers' in-house laboratories.*

It is not clear why there should be an emphasis on government laboratories or subsidized laboratories in the document. OMB Circular A-76[4] clearly states that the government should not compete with the private sector, and should instead rely on **commercial** sources to supply the products and services it needs. Government laboratories, which rely on public funds, routinely compete with private sector laboratories in direct violation of A-76. Intertek recommends that NIST reinforce in the *"Draft Conformity Assessment Considerations for Federal Agencies"* the OMB A-76 policy and the need for Agencies to refrain from choosing State Owned Enterprises over the services provided by the private sector conformity assessment bodies in any conformity assessment activity (testing, inspection, certification, auditing, etc.). Conformity assessment bodies have: the ability to scale services, technical expertise, and innovative technologies to provide such services in a more cost-effective and efficient manner. Taxpayers should not have to finance duplicative activities that are more effectively provided by the private sector.

[4] https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A76/a076.pdf

Line 471 edit:

(…) cost of having an inspector present during production ~~may be restrictive~~ ***should be considered****.*

Intertek recommends that unsupported language be replaced with specific recommendations.

Line 564-568 edit:

These activities can be conducted by: (1) a first party, which is ~~generally~~ the supplier or manufacturer; (2) a second party, which is generally the purchaser or user of the product; (3) a third party, which is an independent entity that is ~~generally~~ ***always*** *distinct from the first or second party and has no interest in the transactions between the two parties~~.; and (4) the government, which has a unique role in these activities often related to regulatory requirements.~~*

Intertek supports the use of ISO/IEC 17000 definitions and suggests the removal of unnecessary and confusing modifying terms. Additionally, NIST includes government as one of the parties that can perform conformity assessment activities along with first, second and third-party. This is not aligned with ISO/IEC definitions. Intertek recommends adhering to the definitions in the ISO/IEC 17000 series. A note can be added (after the description of first, second and third-party) to elaborate that government has a unique role in conformity assessment activities related to establishing and enforcing regulatory requirements and that government is sometimes considered a second party in procurement applications. This change would be consistent with international standards definitions while still validating that government has a unique role in the area of conformity assessment.

Line 583 edit:

A listing function ~~is not in itself~~ ***may or may not be part of*** *an attestation.*

Attestations are issuance of a statement, based on a decision following review that fulfilment of specified requirements has been demonstrated. A listing function may be part of a specific program/scheme requirement.

Lines 602-625 edit:

~~***Recognition***~~

~~*Recognition is a statement of equivalence and is generally made as a force-multiplier and to preclude the necessity of inefficient case-by-case approvals. Recognition is often used to acknowledge other conformity assessment programs as equivalent to the federal conformity assessment program. For example, an agency might recognize a foreign conformity assessment program whose outcomes demonstrate U.S. regulatory compliance. Recognition might also be used to confer authority or assign a role to a third-party organization that determines conformance in lieu of, or on behalf of, the program owner, such as by the use of phrases like "by a recognized organization." Recognition is often manifested through regulations, agreements between program owners, such as a Mutual Recognition Agreement (MRA), or acceptance of a conformity assessment body by the program owner through a Memorandum of Agreement (MOA). Recognition helps create opportunities in a global marketplace and gives consumers more choice by leveraging the expertise of other qualified conformity assessment bodies.*~~

~~*A Mutual Recognition Agreement between the United States and the European Commission on "Mutual Recognition Certificates of Conformity for Marine Equipment (US-EC MRA) allows a manufacturer to reach multiple markets on the basis of compliance with one set of regulatory requirements instead of multiple ones. […] only products having identical or equivalent requirements in each market were included in the scope of the agreement. The two MRA's product scope include the same forty-three products in three main categories: life saving equipment (e.g. visual distress signals, marine evacuation systems); fire protection equipment (e.g. fire doors, insulation); and navigational equipment (e.g., compasses, GPS equipment, echo-sounding equipment)"[20]. A second mutual recognition agreement between the US and European Economic Area (EEA) European Free Trade Association (EFTA) includes the same scope as the US-EC MRA.*~~

This section on recognition is duplicating the content of the *"Draft ABCs of Conformity Assessment"* and Intertek recommends that NIST consider streamlining the documents, leaving the description of the concepts to the *"Draft ABCs of Conformity Assessment"* while focusing the *"Draft Conformity Assessment Considerations for Federal Agencies"* document on how and when it is appropriate for Agencies to leverage such instruments.

If NIST **does** continue to include language on recognition in the documents, Intertek recommends that NIST include the edit to Line 619 below and also include the following language on National Treatment for conformity assessment bodies, which is an effective alternative to mutual recognition agreements (MRAs).

Line 619 edit:

[…] only products having identical or equivalent requirements, ***including method of conformity****, in each market were included in the scope of the agreement.*

Addition:

National Treatment

National Treatment is defined as:

> ***"Each Party shall accord to conformity assessment bodies located in the territory of another Party treatment no less favourable than that it accords to conformity assessment bodies located in its own territory or in the territory of any other Party[5]."***

Are the requirements the same for domestic and non-domestic manufacturers or conformity assessment service providers? Conformity assessment bodies in the exporting country should be authorized to test, inspect, and certify products, processes, or services in accordance with the legal and technical (standard-based) requirements that apply in the importing country. National treatment helps facilitate trade and time-to-market since manufacturers are free to use the appropriately accredited/recognized conformity assessment body of their choice, in the location most appropriate to their business model, instead of being limited to a restricted selection of conformity assessment bodies in the destination market only. National Treatment also gives regulators greater confidence that requirements are met because regulators would approve conformity assessment bodies and/or

[5] Trans-Pacific Partnership (TPP) Technical Barriers to Trade Chapter: https://ustr.gov/sites/default/files/TPP-Final-Text-Technical-Barriers-to-Trade.pdf

accreditation bodies directly, instead of via a Mutual Recognition Agreement that provides a decreased level of confidence.

For MRAs to be effective, they require the **same standards, the same methods of conformity assessment and the same accreditation requirements**. Past MRAs have had limited success facilitating trade due to the lack of trust in the trading partner's quality infrastructure (standardization, accreditation, conformity assessment, metrology) and, in some instances, have established a non-level playing field for the testing, inspection and certification industry by adding unnecessary and burdensome administrative procedures.

Line 627 edit:

*Program Owner**/Scheme Owner***

Intertek recommends consistency with ISO/IEC 17000 terminology. This could be achieved with adding the language Scheme Owner in addition to the title of Program Owner to indicate that NIST is considering these to be equivalent terms at this time.

Lines 628-630, footnote 21 edit:

[21] International standards (i.e., ISO/IEC 17000 and ISO/IEC 17067) use the term conformity assessment scheme owner or system owner. The context of these terms is often used in association with certification programs. In this document the term program owner/scheme owner is used in recognition of the varying types of conformity assessment programs operated by federal Agencies, ~~many of which do not rely on certification.~~

Intertek recommends deleting this as there is no reason for including in this altered definition.

Lines 734-737 edit:

Intertek recommends adding language to encourage Agencies to avoid choosing a specific edition of a standard and be more general so that the most recent edition of the standard is always applicable. Conformity assessment bodies are required to comply with the most recent editions of the standards by accreditation bodies and having a regulation require an older edition of the standard will cause inconsistency and inefficiencies.

Line 775 edit:

*[. . .] been achieved, weighing the risk of non-~~conformity~~**compliance***

Intertek recommends that the document be consistent with OMB A-119 terminology, therefore, replacing *"non-conformity"* with "***non-compliance".***

Lines 773-823 edits:

Addition:

Intertek recommends that in the discussion of "Determining the Confidence Point" that NIST also provide a comprehensive set of checklists with questions for Agencies to consider when evaluating deciding on a method of conformity that best meet their confidence needs. Some questions that Agencies should consider when deciding on the appropriate method of conformity include: how hazardous is the product?, how likely is non-compliance?, what is the industry's track record?, how

much trust is there is in the supply chain?, what are the societal costs of non-compliance?, what are the Agency's resources and capabilities?, how effective are the mechanisms for removing non-compliant products from the market?, what are the penalties and other deterrent mechanisms in place?, etc.

Intertek offers for NIST consideration (please see **Annex 1**) a full set of suggested questions and the responses that generally apply for selection of different methods of conformity.

Lines 796-800 edit:

~~*"Producers and supplier costs are relatively more easily determined in monetary terms since the potential direct costs for various conformity assessment activities can generally be estimated by the conformity assessment bodies and producers. In addition to the direct costs (i.e., the cost of testing, inspection, audit, SDoC, certification or surveillance) to producers and suppliers, there are indirect costs. These may include a time-to-market increase or potential cost increases in a supply chain."*~~

This paragraph implies that costs are derived from a particular method of conformity. Costs are driven by the regulatory requirements and not by the method of conformity. Once there is a requirement, there is a need to demonstrate compliance with the requirements. This demonstration can be done in multiple ways. It can be performed by the first party (where the manufacturer/supplier must build labs, hire/train engineers, buy/calibrate equipment, etc.) or by a third-party service provider. The costs to demonstrate compliance are about the same whether done by a first-party or by a third-party; in fact, many times it is less expensive to use a third-party due to economies of scale and technical expertise. This is the reason why organizations often rely on third-party conformity assessment service providers to meet their legal obligations, even when there is no mandatory requirement to do so. **The business cost is compliance and the only way to save costs is to not perform the required conformity assessment that supports demonstration of compliance.** In addition, there is no evidence to support the assumption that different methods of conformity have different impacts on time-to-market or increased costs in a supply chain. We ask that these types of statements which are not based on data or empirical evidence be removed.

Lines 802-810 edits:

There are resource costs for the agency in operating a conformity assessment program. ***Fully funded*** ***r~~R~~****esources are necessary:*

- *To perform the conformity assessment program owner role;*
- *To directly conduct any other conformity assessment activities (e.g., testing, certification, listing, surveillance);*
- *To perform oversight activities when using private sector organizations or leveraging other program results;*
- *To manage any legal agreements, recognition agreements, or equivalency agreements if appropriate (i.e., resources are necessary for processing the agreements, monitoring, renewals, etc.)*

When evaluating cost estimates to determine the appropriate conformity assessment model, Intertek recommends that NIST **add** language reinforcing OMB A-119 policy that Agencies should leverage private sector conformity assessment instead of directly providing conformity assessment whenever possible. Reliance on private sector allows for Agencies to leverage scarce resources and focus its role on oversight and supervision of a market-based approach.

In addition, Agencies need to **evaluate all the benefits and avoided costs of different models** to all stakeholders, including the Agencies, business, and consumers. For instance, Agencies should account for the ssocietal costs (injuries, death, property damage, loss of production, loss of salary, cost of hospitalization, etc.) that may be avoided or mitigated with a more robust approach that relies on third-party conformity assessment.

Agencies should also account for all costs associated with a post-market approach which include: **fully funded market surveillance program**, investigations, recalls, penalties, criminal charges, etc. Depending on the risks and levels of confidence needed these post-market related costs may be considerably reduced if an agency leverages third-party conformity assessment. For instance, in 2008, OSHA estimated that implementing a first-party system, in lieu of the current use of accredited third parties, would cost the agency approximately $360 million annually, compared to the approximate $1 million annually required to operate the third-party Nationally Recognized Testing Laboratory (NRTL) program[6]. This differences in potential costs to OSHA are largely driven by OSHA having to fund/conduct surveillance activities versus reliance on the current structure that is provided in the NRTL certification program.

Line 867 edit:

> *[…] understanding capacity needs. ~~so that the model does not create built in bottle-necks.~~*

Intertek recommends deleting the above language. It is not clear what NIST means when it states that Agencies need to "understand capacity needs" and ensure their programs does "not create built in bottle-necks". If a program is well designed with the inputs of all stakeholders, including conformity assessment bodies, it is very unlikely that the program will create any bottleneck because the market forces for delivery of conformity assessment services has always demonstrated the ability to fulfill demand for capacity.

Lines 872-878 edits:

> *5. Determine the role of the agency in performing conformity assessment activities. The program owner role and the program oversight role are activities unique to the agency and should be considered. The agency may also serve as an approval authority (i.e., maintains a list of approved products/services or allows an approval mark). Consider whether the agency has the resources* ***or the true need*** *to perform the conformity assessment activities* ***internally, or whether private sector providers are appropriate****. Too little resource and the agency could become a bottle-neck in the ability of the program to meet demand.*

Intertek recommends that the additional clarification language be added to support the use of private sector resources where appropriate as specified in OMB A119.

[6] https://www.regulations.gov/document?D=OSHA-2008-0032-0099

Lines 880-881 edits:

> ~~*Note that generally, a requirement for independence add costs to stakeholders and overall program*~~

Intertek recommends that NIST cover cost aspects in a comprehensive and neutral manner. As discussed above, a requirement for independent third-party conformity assessment (which should be based on risks of non-compliance and level of confidence needed) will, in general, save Agencies resources compared to a post-market approach, where the Agency has to **fully fund** market surveillance activities to ensure that a first-party model can be successful. Similar to comments above on lines 796-800, what may impact "costs" to stakeholders are the regulatory requirements, not the conformity assessment method.

Line 901-903 edits:

> *In conformity assessment, the use of the most independent and most robust model does not always lead to a program that is optimally effective and/or efficient for achieving conformity assessment program goals and meeting broader objectives,* ***nor does the use of the least robust model always lead to program that is optimally effective and efficient for achieving conformity assessment program goals and meeting broader objectives****.*

Intertek suggests that NIST adds the following sentence: **"nor does the use of the least robust model always lead to program that is optimally effective and efficient for achieving conformity assessment program goals and meeting broader objectives",** or remove this section as it does not provide a complete portrayal of appropriate considerations.

Lines 939-94 edits:

> *8. Develop the conformity assessment model graphically and validate that the model, when implemented, can meet* ~~*all*~~ ***requirements needed to fulfill the Agency's mandate to all stakeholders in the most effective and efficient manner.***~~*goals, expectations, etc. at an acceptable cost to all stakeholders.*~~ ~~*Validate that the model can be supported by its participants, especially those of the private-sector from a business perspective.*~~ *Private-sector organizations in the model make business or financial decisions to participate. Agencies often reiterate this process to develop a model that gives the highest probability of a program that is effective, efficient and meets Agency objectives.*

Intertek recommends that the above changes to the language. There is no method proposed to evaluate this idea. How does NIST define acceptable? And to whom? **Any conformity assessment program should be developed to meet the Agency's need to fulfill their mandate in the most effective and efficient manner to all stakeholders.**

Lines 951-955 edits:

> *An SDoC is generally used when:*
>
> - *the risk associated with non-conformity is low;*
> - *there are adequate penalties for placing non-conformant products on the market; and*
> - *there are adequate mechanisms to remove non-conformant products from the market.*
> - ***there is a fully funded post market surveillance system, typically funded by government***

Intertek recommends adding the new bullet: **"market surveillance activities are fully funded".** In addition to risk being low, adequate capacity to impose penalties, and ability to remove product from the market, a fully funded market surveillance is key for a successful SDoC model. The lack of a fully funded market surveillance in an SDoC model will lead to a high incidence of non-compliant products on the market, which can contribute to health and safety issues and other socio-economic costs. For example Europe, which relies on a first-party conformity assessment (SDoC) model for consumer products, has acknowledged the need to "**strengthen controls by national authorities and customs officers to prevent unsafe products from being sold to European consumers":**

> *"There are still too many unsafe and non-compliant products sold on the EU market: as many as 32%of toys, 58% of electronics, 47% of construction products or 40% of personal protective equipment inspected do not meet the requirements for safety or consumer information foreseen in EU legislation. This endangers consumers and puts compliant businesses at a competitive disadvantage".*[7]

The high levels of non-compliance identified by the Europeans Commission (EC) studies is corroborated by IFIA (International Federation of Inspection Agencies) market survey from 2014-2016[8]. The survey, which reviewed small household appliances on the U.S. and EU markets, have found that products which were self-declared (mostly in Europe) presented a much higher percentage of non-compliance as compared to products that were third-party certified (mostly in the U.S.): 17% of self-declared products had safety-critical failures (high risk or fire or permanent injury), compared to less than 1% for products with third-party certification.

This survey sheds light on the value of third-party conformity assessment in providing higher levels of confidence in compliance with safety standards and regulations and reinforces how different avenues for demonstrating compliance deliver different levels of assurance.

Lines 960-962 edits:

> ~~*Reliance on an SDoC is considered to be a trade-friendly approach to conformity. From a manufacturer's perspective, the SDoC allows flexibility in choosing where to have a product tested and reduces associated testing costs and time to market.*~~

Intertek recommends that this statement be removed. This document should be "method neutral" in relation to conformity assessment and not be promoting a specific perspective that one method of determining conformity is better than another. **All methods of conformity assessment are trade friendly as long as national treatment is provided for conformity assessment bodies**.

National treatment can be defined as:

> *"Each Party shall accord to conformity assessment bodies located in the territory of another Party treatment no less favourable than that it accords to conformity assessment bodies located in its own territory or in the territory of any other Party*[9]*."*

[7] http://europa.eu/rapid/press-release_IP-17-5301_en.htm

[8] http://www.ifia-federation.org/content/wp-content/uploads/IFIA_CIPC_239_2014-2016_Market_survey_report.pdf

[9] Trans-Pacific Partnership (TPP) Technical Barriers to Trade Chapter: https://ustr.gov/sites/default/files/TPP-Final-Text-Technical-Barriers-to-Trade.pdf

For example CABs in the exporting country should be authorized to test, inspect and certify products, processes, or services in accordance with the legal and technical (standard-based) requirements that apply in the importing country. National treatment helps facilitate trade and time-to-market because manufacturers are free to use the appropriately accredited/recognized conformity assessment body of their choice, in the location most appropriate to their business model, instead of being required to select from a restricted list of CABs in the destination market only.

National Treatment also gives regulators greater confidence that requirements are met because regulators would approve conformity assessment bodies and/or accreditation bodies directly, instead of via a Mutual Recognition Agreement that provides a decreased level of confidence.

In addition, the statement that SDoC is trade-friendly is not consistent with the language on OMB policy Circular A-119, Revised, which states that *"(…)* ***conformity assessments conducted by private sector conformity assessment bodies can increase productivity and efficiency in government and industry, expand opportunities for international trade, conserve resources, improve health and safety, and protect the environment"***.

Lines 966-968 edits:

> *For other equipment, such as personal computers and attachments thereto, the FCC allows the equipment declared conformant by the supplier, under a process called Declaration of Conformity, provided supporting test results are obtained from an FCC-approved laboratory.* ***This places additional requirements on the first party to utilize recognized third party laboratories to support the attestation (Declaration).***

While the attestation is first-party, the testing is conducted by an accredited and FCC recognized laboratory. Therefore, this program is not a 100% SDoC as the language implies. Intertek recommends that this language be separated from the previous sentence and revised as recommended above to reflect that this is not equivalent to the standard sDoC process that is mentioned in the previous sentence as independent testing is required.

Line 968-974 edits:

> ~~*This program benefits manufacturers in two ways -- reducing costs and time to market while maintaining a high level of protection of health and safety.*~~
>
> ~~*While the SDoC can save costs, such an approach to conformity assessment may not always be appropriate, particularly where technical infrastructure is lacking or it would compromise health, safety or environmental protections.*~~

Intertek recommends that this language be removed. This paragraph implies that costs are derived from a particular method of conformity. Costs are driven by the regulatory requirements and not by the method of conformity. Once there is a requirement, there is a need to demonstrate compliance with the requirements. This demonstration can be done in multiple ways. It can be performed by the first party (where the manufacturer/supplier must build labs, hire/train engineers, buy/calibrate equipment, etc.) or by a third-party service provider. The costs to demonstrate compliance are about the same whether done by a first-party or by a third-party; in fact, many times it is less expensive to use a third-party due to economies of scale and

technical expertise. This is the reason why organizations often rely on third-party conformity assessment service providers to meet their legal obligations, even when there is no mandatory requirement to do so. **The business cost is compliance and the only way to save costs is to not perform the required conformity assessment that supports demonstration of compliance.** In addition, there is no evidence to support the assumption that different methods of conformity have different impacts on time-to-market or increased costs in a supply chain. We ask that these types of statements which are not based on data or empirical evidence be removed. This document should be method-neutral and not promote the perspective that one method of conformity is "better" than another.

Many manufacturers seek conformity assessment bodies' services to demonstrate assurance that products are compliant across various markets at the design stage of the supply chain, which significantly reduces costs, liability and reputational risks while allowing smooth international trade flow and global market access. Many government Agencies across the globe rely on third-party certification requirements when higher levels of confidence and assurance are needed to protect health and safety, which at the same time reduce the amount of resources needed to properly staff and fund market surveillance, import inspections, and recall activities.

> NIST does rightly point out that there are challenges to the use of first party conformity assessment ***where technical infrastructure is lacking or it would compromise health, safety or environmental protections*** that should be taken into consideration by Agencies when making decisions on conformity assessment programs and requirements and should be incorporated in an appropriate place in this document.

Line 978 edits:

> ~~*Third-party certification programs can differ greatly from one another.*~~

Intertek recommends deleting this sentence. Not only third-party programs can differ greatly from one another; **all** programs irrespective of the conformity assessment method (first, second or third-party) will differ greatly from one another due to different objectives and confidence levels needed.

Lines 979-985 states:

> *"The degree of confidence that can be placed in a particular certification program depends on many factors, such as the adequacy of the product standards used; the program's comprehensiveness (the number and types of testing and inspection methods used within the program to assess conformity); the size of the sample and the type(s) of sampling process(es) used; the use of quality management system requirements; the competence of the personnel involved in the program; the adequacy of the facilities and equipment; and the nature and extent of any surveillance or follow-up procedures used to assure that product continues to conform. For an agency choosing to perform as a certification body, these factors should all be addressed and implemented by the agency."*

Intertek recommends that the document be revised to clarify that many of these factors apply to **any** program (first, second or third-party) and not only to third-party certification program, as it currently implies.

Lines 1014-1015 edits:

*[. . .] quality management approach (whether it be validated through third party certification or by regulatory **or third-party** inspection) [. . .]*

Intertek recommends the addition of "or third-party inspection" reinforcing OMB A-119 policy that Agencies should leverage private sector conformity assessment instead of directly providing conformity assessment whenever possible. Reliance on private sector allows for Agencies to leverage scarce resources and focus its role on oversight and supervision of a market-based approach.

Lines 1024-1026 edits:

*The goal of performing surveillance is to have confidence in the ongoing conformity to requirements. ~~Often~~ ~~s~~**S**urveillance is used by the **certification** organization ~~issuing an attestation (either supplier declaration or certification)~~ to maintain confidence that the product or service conforms to requirements on an ongoing basis.*

As stated earlier, Intertek recommends that the document be revised to clearly convey that **there are different avenues for demonstrating compliance,** and **each of these avenues deliver different levels of assurance**. Supplier declaration does not typically include surveillance and therefore should not be portrayed as similar to the third-party certification surveillance activity. The agency (or regulator) is generally responsible for insuring the surveillance activity is carried out either by the government or through the use of a private sector independent third party. In a certification model certification bodies generally conduct extensive review of a product, process, or service and makes a determination that the product, process, or service complies with applicable standards. The certification process generally includes periodic testing, inspection, market surveillance, and factory auditing. It provides assurance of ongoing compliance throughout the entire [production] process with corrective actions in place if non-conformities or issues are identified during the process. Third party surveillance activities may also include surveillance of any Marking used as a protection against counterfeiting of Marks.

Surveillance requirements as it relates to first party sDoC is addressed below in lines 1063-1067.

Lines 1063-1067 edits:

If the Federal agency conformity assessment program relies on an SDoC issued by the supplier, the program owner should develop surveillance requirements (analogous to the surveillance requirements that certification bodies have). Requirements can be focused ~~on the supplier performing surveillance activities;~~ on the agency performing surveillance activities; or by another organization performing surveillance activities on behalf of the agency.

NIST states that an agency can set surveillance requirements "focused on the supplier performing their surveillance activities". This means that a first-party is surveilling first-party results and that there is no independent review involved in the compliance process, and therefore should be deleted. It is the responsibility of the agency for this oversight to assure compliance. NIST should clearly state in this document the need for a **fully funded market surveillance system** to be in place as the mechanism to support first-party (sDoC) attestation. When an agency puts in place such mechanisms, it needs to rely on regulatory or third-party surveillance, which are impartial and independent.

Lines 1076-1081 edits:

Addition:

Intertek recommends that the OSHA NRTL example be further elaborated. The program is a successful example of public-private partnership that relies on independent third-party certification to ensure that certain types of equipment are tested to consensus standards and certified for their safe use in the workplace. The program helps the agency to fulfill its mission while leveraging the agency resources. In 2008, the agency estimated that implementing a first-party system, in lieu of the current use of accredited third-party conformity assessment bodies, would cost OSHA approximately $360 million annually, compared to the estimated $1 million annually required to operate the third-party NRTL program[10]. The differences in potential costs to OSHA are largely driven by the fact that OSHA would have to fund/conduct surveillance activities instead of relying on the NRTLs themselves.

Lines 1083-1096:

Addition:

The CPSC example demonstrates how the agency has to combine different policy tools and invest resources in a post-market surveillance system to fulfill its mission to protect consumer safety. Differently from the OSHA NRTL program, which relies on third-party certification (with the surveillance activities conducted by the certification bodies allowing OSHA to focus on oversight), the CPSC allocates resources to conduct ongoing market surveillance not only in the ports but also after the products have entered the market. CPSC also invests resources to manage a recall system, all of which are important measures that need to be in place and fully funded if there is no requirement for third-party certification in place.

NIST should clarify that the CPSC does have in place third-party testing requirements for children's products, which can be appropriate tool **when used in combination with other non-compliance deterrence measures**, such as civil and criminal penalties, education of the supply chain on CPSC requirements, fully funded market/import surveillance, and a recall system (as described above). Other market-driven aspects such as product liability and retailers' programs also provide further incentive for compliance.

Lines 1135-1136 edits:

The agency should consider accepting test results or attestations that are considered ~~*beyond*~~***to provide a higher level of assurance than*** *what is required (e.g., accepting a* ***third party*** *certification if SDoC is the requirement).*

Intertek supports such approach, and recommends the clarifying language added above. Many organizations go beyond the mandatory requirements and use certifications and other conformity assessment activities as means to meet consumers' expectations, protect their brands and reputation, and mitigate risks across the supply chain. These companies should be able to fully leverage their certifications beyond what is mandated without being required to provide additional demonstrations of compliance.

Line 1138 edits:

[10] https://www.regulations.gov/document?D=OSHA-2008-0032-0099

*4. Conformity assessment program**s and** policies should **be designed to meet the needs of the agency without exceeding those needs with unnecessary*** ~~*limit to those conformity*~~ *assessment activities* ~~*necessary to meet conformity assessment program goals and agency objectives, and no more*~~*. Policies should **also require only necessary*** ~~*limit*~~ *participant information* ~~*requirements to only those necessary as well*~~*.*

Intertek suggests the above clarifying language to achieve the necessary objectives.

Line 1151 edit:

*6. **When designing conformity assessment programs/schemes** Agencies should consider* ~~*using caution if adding requirements*~~ *if policies* ~~*to the conformity assessment program that*~~ *may conflict, or otherwise cause inconsistencies, with other conformity assessment programs/**schemes** with similar scopes or that are leveraged.*

The goal of this document is to provide a framework for Agencies when they are considering implementing programs. Intertek believes this revised language provides a clear recommendation for consideration.

Lines: 1194-1196 editorial:

*The program owner should consider requiring the decision **maker** of the appeal to be higher in the organizational hierarchy than the decision maker of the approval.*

This is an editorial comment – we believe the writers meant to use the word maker instead of make.

Lines 1212-1213 editorial:

- *any management systems requirements such as documented processes, training, record keeping, improvement processes, conformance and appeals processes,* ~~*and record keeping*~~

This is an editorial comment regarding removal of duplicative language.

Lines 1228-1229 edits:

- *Penalties stated in regulation, Federal policy, agency policy or procurement policy; these **penalties should be designed for a deterrent effect on non-compliances***

Intertek recommends that above addition to clarify intent.

Line 1246:

*Addressing international obligations, equivalency**,*** ~~*or*~~ *recognition, **and reciprocity***

Intertek recommends that NIST include language on reciprocity, and reinforce that Agencies should establish baseline requirements for acceptance of conformity assessment bodies including, accreditation bodies.

Specifically in regard to accreditation bodies we strongly recommend that Agencies fully evaluate accreditation bodies to determine if they have the necessary abilities and technical expertise to assess third-parties to U.S. regulatory requirements and the appropriate standards. It is therefore the responsibility of the regulatory agency to investigate, review, and verify the qualifications of each accreditation body prior to acceptance as this will have a significant effect on the qualifications of the conformity assessment service providers.

While Intertek recognizes that the mission of regulatory Agencies does not include trade policy issues, it is necessary for Agencies to take into account when accepting conformity assessment results from non-domestic conformity assessment bodies, whether there is a system of equal recognition and equivalent market access in their country for the acceptance of the work of properly accredited U.S. based conformity assessment bodies. **This principle of reciprocity provides equivalent market access and will help insure equal treatment while fostering a level playing field for conformity assessment bodies and manufacturers across the globe.**

Lines 1250-1252 edits:

> *"to accept the results of conformity assessment procedures in other WTO member countries, provided it is satisfied that those procedures offer an assurance of conformity equivalent to its own procedures". **Agencies should evaluate many factors when determining their policy regarding equivalency since different conformity assessment procedures and application provide different levels of assurance.***

In applying the OMB A-119 guidance as stated above, Intertek recommends that NIST adds language that reinforces that Agencies need to **ensure equivalence of the method of conformity when accepting results from other countries**, since different methods provide different levels of assurance. Many factors are involved in the decisions as to the appropriate standards and the confidence level of the type of conformity assessment used to demonstrate compliance. These include seemingly unrelated issues such as individual legal systems and the ability to enforce requirements.

If a higher confidence level of conformity assessment has been applied using the adopted/recognized standard, then it would make sense to accept this more rigorous form to reduce duplicative testing and burdens on manufacturers. Conversely, it would not be prudent for regulatory Agencies to accept compliance as being equivalent if the method of conformity was less rigorous. For example, if a Federal agency required the use of testing by accredited laboratories, but the industry is currently using accredited product certification, then the agency should be allowed to accept product certification to fulfill its regulatory requirements. However, acceptance of testing from accredited laboratories would continue to meet the minimum regulatory requirements.

Lines 1266-1267 edits:

> *These include potential ~~costs~~**impacts** to**:** consumers or users, supplier**s** ~~cost and development time~~, and conformity assessment organization**s**~~capacity~~.*

Intertek recommends the above editorial changes to address more clearly the potential impacts.

Line 1275 editorial:

> *Requirements for conformity assessment organizations generally fall into three categories: management systems; technical ~~and~~ competence; and programmatic.*

This is an editorial comment to remove the unnecessary word.

Line 1310 edit:

> *[…] without additional assessment, **or accreditation**, of the organizations performing the conformity assessment activities.*

Intertek recommends addition the word *accreditation* to prevent duplicative accreditation requirements.

Line 1372 editorial:

> *Conformity assessment programs**/schemes** ~~have a liveness to them~~**should be considered as "living" programs/schemes that can evolve and be modified based on regulatory needs**.*

Intertek suggests the above editorial changes to clarify the intent of the language.

Line 1382 editorial:

> *What is the **impact**~~cost and benefits~~ of the path;*

Intertek suggests the above editorial change to clarify the intent of the language.

Lines 1446-1451 edits:

> *Metrics and data that indicate ~~how~~ **if the accreditation process for** conformity assessment organizations **is**~~are~~ **providing the expected results**~~performing~~. For example: Are conformity assessment organizations consistent in pass/fail results, attestation decisions, etc.? Are the conformity assessment organizations applying program guidance or requirement interpretations consistently? Is any single organization an outlier and if so, why? As the market changes, are conformity assessment organizations still meeting requirements and operating effectively?*

Intertek recommends changes to this paragraph to reflect that these metrics are assessments undertaken as part of any accreditation program. Therefore, it is imperative that Agencies define accreditation requirements that meet their confidence levels.

Lines 1464-1465 edit:

> *Agency (EPA) reviews the results of all post-market verification testing conducted on ENERGY STAR® certified products to ensure the Agency's oversight goals are met **in an efficient and effective manner** ~~without overburdening manufacturers,~~ and makes any necessary adjustments.*

Intertek recommends the above editorial changes to clarify the intent of supporting the Agency's overall goals.

ANNEX 1

<u>"Draft Conformity Assessment Considerations for Federal Agencies" document in Selecting Methods of Conformity as Part of Regulatory Scheme Framework</u>

1. Questions for Agencies to consider when deciding on a method of conformity that best meet their confidence needs

When a decision has been made to regulate (or recognize/reference standards) to address a specific hazard or risk, how to choose the appropriate method of conformity? How does the role of government change under each method?

In general, the requirement for a particular level of rigor in the conformity assessment process is determined by the risks associated with the product, process, or service and its scope of use. The appropriate conformity assessment mechanism is also determined by other market factors, such as the legal system and the general philosophy of pre-market conformity assessment versus a fully funded post-market surveillance system. The confidence level needed is based on the risk of non-compliance and what market-driven mechanisms exist as mitigation tools for non-compliance. Part of a full analysis would include the pre-market and post-market structure that would be required. The choice of that structure has implications for costs of related government infrastructure, socio-economic costs, costs of establishing and sustaining technical competency levels, and capacity of those providing the service.

Below is a table that summarizes a few questions that Agencies should consider when deciding on a method of conformity that best meet their confidence needs with the answers depending on the method of conformity. **The answers below are not always this clear cut, but represents what is <u>generally</u> the case for each method of conformity**.

QUESTIONS:	FIRST-PARTY	THIRD-PARTY
1. Is a high level of confidence required?	No	Yes
2. Is the perceived risk high?	No	Yes
3. Are products regulated primarily manufactured in countries with a history of risk factors and other issues?	No	Yes
4. Are products manufactured in complex and fragmented supply chains?	No	Yes
5. Is there a documented history of industry compliance?	Yes	No
6. Is there a documented history of industry non-compliance?	No	Yes
7. Is there evidence that product liability is an effective deterrent?	Yes	No
8. Do regulatory authorizing/statutory provisions provide severe penalties and an effective deterrent?	Yes	No
9. How strong is the need for impartiality and independence?	Low	High
10. Are there voluntary, market driven schemes that address confidence needs?	Yes	No
11. Are there relied upon accepted international schemes that can be leveraged?	Yes, and sufficient to meet confidence needs	Yes, but insufficient
12. What are the societal risks of non-compliant products?	Low	High
13. Who bears the costs of market surveillance?	Primarily governments	Private sector
14. How likely is the need for recall or corrective action?	More likely	Less likely
15. How effective is the model in supporting anti-counterfeiting enforcement?	Low	High

2. Methods of conformity Agencies can choose to satisfy their confidence needs

In general, there are three approaches to conformity assessment: **First-Party** (manufacturer), **Second-Party** (purchaser or user) and **Third-Party** (independent entity).

First-Party Conformity Assessment: "Performed by the person or organization that provides the object" [11], that is, the **supplier or manufacturer demonstrates that a product or service fulfils specified requirements,** and it is typically used when there is a lower level of risk associated with non-compliance and with the product. In First Party Conformity Assessment, the resulting statement of conformity is commonly referred to as the Supplier's Declaration of Conformity (SDoC).

For a First-Party conformity assessment model to work:[12]

- The risk of noncompliance must be low;
- The risk of the product must be low;
- There is confidence that manufacturers understand the technical, regulatory and market requirements and has satisfactory control over their supply chain;
- There are adequate penalties for placing noncompliant products in the market, which include - but are not limited - to:
    - civil and criminal penalties
    - product recall, and/or
    - product bans; and
- There is a **fully-funded** post market surveillance system in place that quickly and effectively removes noncompliant products from the market in order to avoid injury and societal costs. A post market surveillance system should consist of:
    - mechanism for customer complaints,
    - marketplace surveillance and testing,
    - factory surveillance and testing, and
    - regular independent audits of individual manufacturers' declarations of conformity.

A **fully-funded** post market surveillance system is a key requirement for a first-party conformity assessment model to be successful and avoid a high incidence of non-compliant products on the market that can contribute to health and safety issues and other socio-economic costs.

Second-Party Conformity Assessment

"Performed by a person or organization that has a user interest in the object" [13], that is, the end user or entity acting in the interests of the end user, or an individual or group whose primary interest is in fulfilment of requirements demonstrates for itself that specified requirements are fulfilled.

Second parties may not always have business models that allow them to maintain the infrastructure, processes and technical competence to cost-effectively take advantage of this approach. Also, costs of goods and services

[11] https://www.iso.org/standard/29316.html
[12] ACIL: https://c.ymcdn.com/sites/www.acil.org/resource/resmgr/imported/ACILsDoCPositionPaper.pdf
[13] https://www.iso.org/standard/29316.html

can increase if suppliers face a high number of demands from individual second parties each carrying out their own conformity assessment. Therefore, second parties often rely on third-party conformity assessment to fulfil their confidence needs in a cost-effective manner.

Third-Party Conformity Assessment

Performed "by a person or body whose interests in the product are independent from those of first parties and whose interests in fulfilment of requirements are independent from those of second parties."[14]

Independent third-party conformity assessment bodies (CABs) may be accredited and regularly assessed by accreditation bodies as proof of qualification (competence) to provide services as a result of accreditation to international ISO/CASCO standards such as: ISO/IEC 17025 for testing, ISO/IEC 17020 for inspection and ISO/IEC 17065 for certification. This accreditation also includes an in-depth review of their documented management systems used to assure ongoing compliance with these international standards. The accreditation bodies may be either government bodies, recognized accreditation bodies operating under international guides, or a combination of both.

Third-party is widely relied upon in many markets when[15]:

- There may be a **higher risk associated with non-compliance;**
- There may be a **higher risk from products;**
- There is need for an **independent** demonstration to the supply and demand chain such as consumers, manufacturers and regulators that a product fulfils specified requirements;
- There is need for **higher levels of confidence and assurance of compliance** with safety, health or environmental requirements;
- Manufacturers seek to **reduce in-house compliance costs** or apply third-party as an added value to their own quality and conformity assessment procedures to gain global market access and protect their brands and reputation; and/or
- There are **limited government resources to fully fund market surveillance systems.**

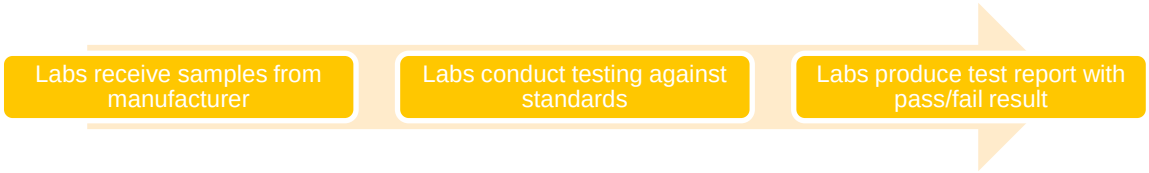
3. Third-party conformity assessment

Within third-party there are various options; in some cases there will be a need for a full certification and others third-party testing only. Sometimes the agency may need only facility audits or inspections or a combination of different procedures. Again, it will depend on various factors and the levels of confidence needed will drive the decision. For instance, if the agency has no resources for funding post-market surveillance and the risks associated with the product and with non-compliance are high, the agency might consider full certification. If the risks of non-compliance are low, there are liability laws and penalties that function as effective deterrents, and there is adequate post-market surveillance, then the agency might consider SDoC. If the situation is somewhere in between, perhaps third-party testing requirements might be an effective tool.

[14] https://www.iso.org/standard/29316.html
[15] ACIL: http://c.ymcdn.com/sites/www.acil.org/resource/resmgr/imported/The%20Value%20of%20Third%20Party%20Certification.pdf

Below are a few examples to illustrate third-party testing and third-party certification:

Third-party Testing:



When conducting testing only, the laboratory role is limited to receiving samples, testing against standards and reporting pass/fail results. Labs have no control of, nor information about:

a. Whether manufacturers are testing “golden samples”;

b. Any material changes by the manufacturers when receiving a request from manufacturers to transfer data from old test reports or from reports issued by other labs;

c. Whether the sample is representative of the entire production;

d. Whether manufacturers have reasonable testing programs in place;

e. Whether labs meet the applicable accreditation requirements when receiving test results from reports issued by other labs;

f. Whether manufacturers’ supply chains ensure traceability and there are documentation controls in place; and

g. Whether there is a system to offer testing to maintain continuing compliance

The U.S. Consumer Product Safety Commission (CPSC) third-party testing requirements for children’s products is an example of the use of third-party testing as one of the tools in the regulator’s toolbox to ensure products are safe. It is used in combination with other non-compliance deterrence measures, such as civil and criminal penalties, market and import surveillance, education of the supply chain on CPSC requirements, and a product recall system. Other market-driven aspects such as product liability and retailers’ programs also provide further incentive for compliance.

Third-party Certification:

Certification bodies conduct extensive review of a product’s manufacturing process and make a determination that the product (or system, process, person) complies with applicable standards. The certification process includes periodic testing, inspection, market surveillance and factory auditing. It provides assurance of ongoing compliance throughout the entire production process with corrective actions in place if non-conformities or issues are identified during the process.

The Environmental Protection Agency (EPA) Energy Star program is an example of a voluntary public-private partnership that relies on independent third-party certification to ensure ongoing compliance and the integrity of the Energy Star label. Third-party requirements were introduced after high levels of non-compliance were identified by an investigation from the Government Accountability Office (GAO). Reliance on third-party certification helps maintain consumer trust in the Energy Star designation and improve oversight of the

program while allowing the agency to save scarce resources since evaluation and market surveillance is performed by the private sector.

Below is an overview of the certification process: