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

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

Dear Ms. Carnahan,

The International Federation of Inspection Agencies ("IFIA") is pleased to provide comments on the "Draft Conformity Assessment Considerations for Federal Agencies".

IFIA is a trade federation that represents over 60 of the world's leading independent third-party testing, inspection and certification (TIC) companies. IFIA members offer conformity assessment services, including testing, inspection, certification, systems audits, advisory and training, technical and documentary support. These services help manufacturers gain global market access and help ensure that not only regulatory requirements are fulfilled, but also that reliability, economic value, environmental impact and sustainability are enhanced.

We appreciate the opportunity to offer the following comments and look forward to continuing the discussion and supporting NIST's efforts.

Sincerely,

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General comments:

IFIA applauds NIST's extensive efforts to consult stakeholders throughout the process of developing the "Draft Conformity Assessment Considerations for Federal Agencies". IFIA welcomes language in the Considerations 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 key for the success of a program. However, IFIA has some concerns with the current proposed document:

- lack of neutrality of methods of conformity and promotion of one method of conformity assessment over others;
- lack of language reinforcing OMB A-119 policy that agencies should, whenever possible, leverage private sector conformity assessment in lieu of public-sector conformity assessment;
- failure to encourage agencies to use terms/definitions consistent with ISO/IEC 17000 standards;
- unnecessary emphasis regarding government-run laboratories;
- lack of language regarding reciprocity in the acceptance of conformity assessment results; and
- duplication of concepts with the companion ABCs document.

IFIA recommends that NIST considers removing any overlap of content between the Considerations and the ABCs documents, since the ABCs is an accompanying document to the Considerations. The ABCs should provide a user-friendly overview of key conformity assessment concepts. The Considerations document should not repeat those concepts but focus instead on identifying the types of questions/criteria agencies should consider when selecting methods of conformity. Please see Annex 1 with full set of suggested questions and the answers depending on the method of conformity (first or third-party) for NIST's consideration.

IFIA recommends that both the ABCs and the Considerations documents clearly convey that **there are different avenues for demonstrating compliance,** and **each of these avenues deliver 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.

IFIA recommends that the documents be rewritten to 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 coordinating conformity assessment in the United States.

Also, the language in the documents seem to conflate methods of conformity with conformity assessment activities and some of the descriptions are not based on the ISO/IEC standards that apply to conformity assessment. IFIA recommends aligning the document with the vocabulary and definitions in the ISO/IEC 17000 series.[1]

Specific comments:

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 describe the possible contributions of private sector conformity assessment. IFIA 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. IFIA recommends that NIST include the entire paragraph from OMB A-119 to read as follow:

> *"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 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."***[2]

Lines 230-231: Replace "their stakeholders" with "ISO/IEC standards":

> *"Each agency should consider using terms that are consistent with* ***ISO/IEC standards****".*

IFIA recommends that NIST encourages agencies to consider using terms and definitions consistent with ISO/IEC definitions. There is no benefit to anyone - and it could become quite confusing and unproductive for stakeholders (and for interagency coordination) - if agencies are encouraged to use their own conformity assessment terms and definitions.

[1] https://www.iso.org/obp/ui/#iso:std:iso-iec:17000:ed-1:v1:en:sec:3.1
[2] https://www.nist.gov/sites/default/files/revised_circular_a-119_as_of_01-22-2016.pdf

Lines 321-324 states the following:

> *"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."*

It is not clear how does the method for demonstrating compliance impact the market's ability to meet demand for the product? Agencies should understand the markets that might be impacted by the regulations. Once the agency determines that there is a need to regulate, industry has to demonstrate compliance, and the agency has 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 mission. This will depend on various factors, such as the risks associated with the object of compliance, how likely non-compliance is, what the industry's track record is, how much trust there is in the supply chain, the societal costs of non-compliance, the agency's resources and capabilities, among others.

Lines 337-338:

> *"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:

> *"(…) understanding capacity needs so that the model does not create built in bottle-necks."*

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: This paragraph seems lost here. IFIA 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".

Lines 445-447: Similar to the ABCs, it is not clear the reason why there should be an emphasis on government laboratories in the documents. OMB Circular A-76[3] 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. IFIA recommends that NIST reinforce in the Considerations document (as well as in the ABCs; please see IFIA comments on the ABCs lines 360-363) the OMB A-76 policy and the need for agencies to refrain from competing with 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 shouldn't have to finance activities that can be more effectively provided by the private sector.

Line 471: Replace "may be restrictive" with "**should be considered**":

> *"(…) cost of having an inspector present during production **should be considered**".*

Line 566: Replace "generally" with "**always**":

> *"(…) third-party (…) is **always** distinct from the first or second-party (…).*

Lines 567-568: 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. IFIA recommends sticking to the definitions based on the ISO/IEC 17000 series (similar in the ABCs, please see IFIA comments on the ABCs lines 266-268, Fig 1.).

A note can be added (after the description of first, second and third-party) to elaborate that governments have 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 conformity assessment.

Line 583: IFIA recommends replacing *"A listing function is not in itself an attestation"* with "*A listing function **may or may not be** an attestation".*

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

Lines 602-625: This section on recognition is duplicating the content of the ABCs and IFIA recommends that NIST consider streamlining the documents, leaving the description of the concepts to the ABCs and focusing the Considerations on how and when is appropriate for agencies to leverage such instruments.

If NIST does include language on recognition in the documents, IFIA recommends that NIST also include language on national treatment for conformity assessment bodies, which is an effective alternative to mutual recognition agreements (MRAs).

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*[4]*."* That means that CABs in the exporting country should be authorized to test, inspect and certify certain products 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 conformity assessment body of their choice and location most appropriate to their business model, instead of having to select from a restricted list of CABs in the destination market only. National treatment also gives regulators greater confidence that requirements are met since regulators would approve CABs and/or Accreditation Bodies directly instead of via a MRA approach.

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.

Lines 628-630, footnote 21: IFIA recommends deleting *"many of which do not rely on certification*" since there is no reason for adding this sentence.

Lines 734-737: IFIA 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.

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

Line 775, footnote 24: IFIA recommends that the document be consistent with OMB A-119 terminology, therefore, replacing *"non-conformity"* with "***non-compliance".***

Lines 773-823 on "Determining the Confidence Point": IFIA recommends that NIST also provide a comprehensive set of checklists with questions for agencies to consider when 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: 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. IFIA offers for NIST consideration (please see Annex 1) a full set of suggested questions and the answers that generally apply for different methods of conformity (first or third-party).

Lines 802-810 states: *"resource costs for the agency in operating a conformity assessment program".*

When discussing cost estimates to decide on the appropriate conformity assessment model, IFIA 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 save 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 societal 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 costs associated with post-market approach: fully funded market surveillance, 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[5]. This differences in potential costs to OSHA

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

are largely driven by OSHA having to fund/conduct surveillance activities versus reliance on the NRTLs themselves.

Lines 880-881 currently reads as follows:

> *"generally, a requirement for independency add costs to stakeholders and overall program"*

IFIA recommends that NIST cover cost aspects in a comprehensive manner. As discussed above, a requirement for independent third-party conformity assessment (which should be based on risks 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 to ensure that a first-party model can be successful.

Lines 875-877: IFIA suggests adding "**or the true need**" after "resources" and **"internally, or whether private sector providers are appropriate"** after "activities":

> *"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**"*

Line 901-903: After objectives, IFIA 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":**

> *"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**."*

Lines 939-94 currently reads: *"Develop the conformity assessment model (…) at an acceptable cost to all stakeholders".* IFIA recommends that this be deleted since there is no method addressed to evaluate what these terms mean. How does NIST define acceptable? And to whom? **Any conformity assessment program should be developed to meet agency's need to fulfill their mandate in the most effective and efficient manner to all stakeholders.**

Lines 951-955: "SDoC is generally used when…" add after the last bullet the following new bullet: **"market surveillance activities are fully funded".**

In addition to risk being low and there being adequate capacity to impose penalties and remove product from the market, fully funded market surveillance is key for a successful SDoC model. The lack of a fully funded market surveillance in a 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 instance, in 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".*[6]

The high levels of non-compliance identified by the Europeans Commission (EC) studies is corroborated by IFIA's market survey from 2014-2016[7]. The survey, which reviewed small household appliances on the U.S and EU markets, have found that products that were self-declared (mostly in Europe) presented much higher percentage of non-compliance 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 state:

> *"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".*

IFIA recommends that this statement be removed. This document should be neutral and not be promoting a specific perspective that one method of conformity is better than another. **Any method of conformity is**

[6] http://europa.eu/rapid/press-release_IP-17-5301_en.htm
[7] http://www.ifia-federation.org/content/wp-content/uploads/IFIA_CIPC_239_2014-2016_Market_survey_report.pdf

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*[8]*."* That means that CABs in the exporting country should be authorized to test, inspect and certify certain products 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 conformity assessment body of their choice and location most appropriate to their business model, instead of having to select from a restricted list of CABs in the destination market only.

In additional, 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"***.

Line 961-962 and lines 969-970:

> *"SDoC (…) reduces associated testing costs and time to market"*

IFIA recommends that this line be removed. This document should not be promoting a specific perspective that one method of conformity is better than another. A manufacturer may have higher costs and time-to-market regardless of which conformity assessment method is used (SDoC or third-party). In fact, many manufacturers rely on third-party to reduce in-house compliance costs and time-to-market and gain global market access due to economies of scale and technical expertise of conformity assessment bodies.

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.

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

Costs are driven primarily 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 either in-house (where the manufacturer has to outfit labs, hire/train engineers, buy/calibrate equipment, etc.) or by a third-party service provider. The costs to demonstrate compliance are generally about the same whether done in-house or by a third-party. 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, the claim that different methods of conformity have different impacts on time-to-market or increased costs in a supply chain should be based on data or empirical evidence or be removed from the document.

Lines 964-970: 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. IFIA recommends that this language be revised to reflect how the FCC program actually operates.

Line 978 notes that *"Third-party certification programs can differ greatly from one another".* 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 state:

> *"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."*

IFIA 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 1025-1026 states that *"Often surveillance is used by the 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, IFIA 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. Certification bodies generally conduct extensive review of a product's manufacturing process and make a determination that the product 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. Third party surveillance activities may also include surveillance of any Marking used as a protection against counterfeiting of Marks.

Lines 1063-1067 currently reads as follows:

> *"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". When relying on such approach, NIST should recommend that agencies put in place mechanisms to ensure that the supplier surveillance is actually happening. If an agency does not put in place such mechanisms, it needs to rely on regulatory or third-party surveillance, which are impartial and independent.

Lines 1076-1081: IFIA recommends that the OSHA NRTL example be further elaborated. The program is a public-private partnership that relies on third-party certification to ensure products entering the market are safe, reliable and efficient. The program helps the agency to fulfill its mission while saving 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[9]. This 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: 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.

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

Differently from the OSHA NRTL program, which relies on third-party certification (and all the surveillance activities are conducted by the certification bodies with OSHA focusing 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 if there is no requirement for third-party certification in place.

The CPSC does have in place third-party testing requirements for children's products, which is an 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 notes that *"The agency should consider accepting test results or attestations that are considered beyond what is required (e.g., accepting a certification if SDoC is the requirement)."* IFIA supports such approach. Many companies go beyond the mandatory requirements and use certifications 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 addition demonstrations of compliance.

In addition, IFIA recommends that NIST includes language encouraging agencies to consider creating systems that reward manufacturers for utilizing third-party, even if the conformity assessment mechanism does not require them to do so. Examples of such rewards might include "green-lighting" products with a third-party certification mark during the import surveillance screening, thereby allowing the agencies to more effectively target shipments, or reducing/eliminating facility inspections/audits if a company has third-party certification or inspection, etc.

Lines 1228: Add "**these penalties should be designed for a deterrent effect on non-compliances**" after "policy" so that the sentence reads as follows:

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

Line 1246: IFIA recommends that NIST includes language on reciprocity and reinforce that agencies should establish baseline requirements for acceptance of accreditation bodies to determine if they have the necessary abilities and technical expertise to assess third-parties to US 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 IFIA 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 states:

> *"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".*

In applying the OMB A-119 guidance as stated above, IFIA recommends that NIST 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 requirements 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 accredited testing but the industry is already using accredited product certification, then the agency should be allowed to accept product certification to fulfill its regulatory requirements. However, accrediting testing would still remain the floor and still meet regulatory requirements.

Lines 1266-1267: Remove "costs", "development time" and "capacity"' so the revised sentence would read as follows:

> *"These include potential impacts to consumers or users, supplier and conformity assessment*

organizations".

Line 1310: Add "**or accreditation**" after "assessment":

> *"(…) without additional assessment, **or accreditation**, of the organizations performing the conformity assessment activities."*

Lines 1446-1451:

> *"Metrics and data that indicate how conformity assessment organizations are 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?"*

All these metrics are assessments undertaken as part of an accreditation program. Agencies must define accreditation requirements that meet their confidence levels.

Lines 1464-1465: Replace "without overburdening manufacturers" with "in an efficient and effective manner":

> *"oversight goals are met in an **efficient and effective manner**".*

ANNEX 1

Considerations in Selecting Methods of Conformity as Part of Regulatory Scheme Framework

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 generally 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" [10], 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:[11]

- 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,

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

- 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" [12], 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 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."[13]

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[14]:

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

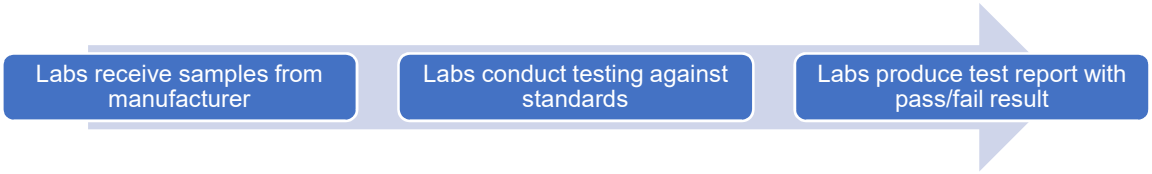
- There may be a **higher risk associated with non-compliance;**
- There may be a **higher risk from products;**
- There is need for an **independent** demonstration to the supply and demand chain such as consumers, manufacturers and regulators that a product fulfils specified requirements;
- There is 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.

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: