

# Third-Party Programs to Assess Regulatory Compliance

Comments on Draft Recommendation (ACUS DRAFT 9-17-12)

Submitted 9-20-12 on behalf of the National Institute of Standards and Technology (NIST) by:

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## General Comments

The draft needs a preamble that provides context on regulatory conformity assessment and the limited scope of the ACUS recommendations. There are a wide variety of effective approaches to regulatory conformity assessment systems including first, second and third party conformity assessment systems as well as systems that only use premarket and/or post market activities. The ACUS recommendations are focused only on third party conformity assessment systems. Some readers may perceive that ACUS is recommending that only third party conformity assessment systems are effective for all regulatory needs without the needed context and scope statements.

The draft needs a discussion of the roles and responsibilities of regulatory agencies and third party conformity assessment bodies in regulatory conformity assessment. Regulators generally do not and cannot delegate their regulatory authority to conformity assessment bodies in these systems. Conformity assessment bodies (CAB) assess conformity and/or attest to the conformity of the object of assessment. Regulators enforce regulatory requirements.

## General Choice of Wording Comments

Use the term “conformity assessment bodies” in place of private actors. It is a more accurate description of these organizations.

Remove the word “private” as an adjective to third party conformity assessment bodies. In some countries and in certain circumstances in the U.S. the third party conformity assessment bodies are part of governments.

Consider using “rigor and independence” as a phrase to discern the level of technical conformity assessment activity and the demonstrated lack of conflict of interest of the third party CAB throughout the document.

## Specific Comments

Page 2, 1st par. – Clarify what “to do so” is referring to. We believe it is for regulated entities to choose to use third parties.

Page 3, 2nd par. – In most systems the accreditation bodies do not “approve” the CAB. They accredit the CAB. If there is CAB “approval,” the regulator approves the CAB based in whole or part on the accreditation.

Page 4, 1. (ii) - End sentence after the “use.” ANSI is involved in accreditation activities in a competitive environment and this mention may be perceived to provide a competitive advantage.

Page 4, 2 – Effectiveness of third party conformity assessment, perhaps the most important consideration for agencies is missing. Recommend that it be the first (i).

Page 4, 2. (iii) – End sentence after “savings.”

Page 5, (b) (i) – Delete (i). This recommendation is true of all conformity assessment and regulatory systems and not limited to third party systems.

Page 5, (b) (iii) – Delete (III) - there may be very important economic impacts of these types of programs.

Page 6, 3 (a) (i) – Consider deleting. This is unusual some government programs do not have fees and many third party programs have fees.

Page 6, 3 (a) (ii) - Add “in one conformity assessment” to the end of the sentence.

Page 6, 3 B 1 (a) - Replace "users" with "regulators."

Page 7, (ii) - Delete "or minimize the third party's reliance on subcontractors." Subcontracting does not correspond to a lower level freedom from conflict of interest.

Page 8, (b) last sentence - Replace "may still use" with "should consider using."

Page 11, (a) - Consider re wording "guarding the guardians." This phrase implies that the regulator is protecting CABs.

Page 12, (d) - Delete "backstop."

Page 12, (f) - Delete 2nd to last sentence.