



## Agency Use of Third-Party Programs to Assess Regulatory Compliance

### Committee on Collaborative Governance

Proposed Recommendation | December 6-7, 2012

#### Proposed Amendments

*This document displays manager's amendments (with no marginal notes) and additional amendments from Conference members (with the source shown in the margin).*

1 | Federal agencies in diverse areas ~~of regulation~~ have developed third-party programs to  
2 | assess whether regulated entities are in compliance with regulatory standards and other  
3 | requirements. Through these programs, third parties ~~are charged with assessing~~ the safety of  
4 | imported food, children's products, medical devices, cell phones and other telecommunications  
5 | equipment, and electrical equipment used in workplaces. Third parties also ensure that  
6 | products labeled as organic, energy-efficient, and water-efficient meet applicable federal  
7 | standards. In these regulatory third-party programs, regulated entities generally contract with  
8 | third parties to carry out product testing, facility inspections, and other regulatory compliance  
9 | assessment activities in the place of regulatory agencies. Regulatory agencies ~~take on then~~  
10 | ~~adopt~~ new roles in coordinating and overseeing these ~~third-party~~ ~~ies~~ ~~actors~~.

11 | In some areas of regulation, Congress has directed federal agencies to develop a third-  
12 | party program; in others, regulatory agencies have developed programs under existing  
13 | statutory authority. A third-party program is just one of many regulatory approaches that  
14 | Congress and agencies may adopt.<sup>1</sup> Regulatory objectives may, for example, be adequately

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<sup>1</sup> The Administrative Conference has addressed various approaches in prior recommendations. See, e.g., Recommendation 94-1, The Use of Audited Self-Regulation as a Regulatory Technique, 59 Fed. Reg. 44,701 (Aug. 30, 1994); Recommendation 89-1, Peer Review and Sanctions in the Medicare Program, 54 Fed. Reg. 28,965 (Jul.

15 | [served met](#) by requiring regulated entities to self-assess and report their compliance  
16 | (sometimes referred to as “first-party certification”). Also, statutory restrictions on information  
17 | disclosure or other legal restrictions may preclude [the an](#) agency from using third parties to  
18 | conduct inspections and other compliance assessment activities. Some compliance assessment  
19 | activities may be inherently governmental, and thus require performance by government  
20 | personnel.<sup>2</sup>

21 | Several broad reasons support the growing use of third-party programs in federal  
22 | regulation. In many areas, federal regulatory agencies are faced with assuring the compliance  
23 | of an increasing number of entities and products without a corresponding growth in agency  
24 | resources. Third-party programs may leverage private resources and expertise in ways that  
25 | make regulation more effective and less costly. In comparison with other regulatory  
26 | approaches, third-party programs may also enable more frequent compliance assessment and  
27 | more complete and reliable compliance data. Because agencies can authorize third parties  
28 | located in other countries to undertake assessment activities, third-party programs may be  
29 | particularly effective when regulated products or processes are international in scope.

30 | Regulatory third-party programs raise a host of important questions. [Because third-party](#)  
31 | [programs represent Representing](#) a partial privatization of the public function of implementing  
32 | and enforcing regulatory law, they are a form of “public-private governance,” in which private

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10, 1989); [and](#) Recommendation 78-4, Federal Agency Interaction with Private Standard-Setting Organizations, 44  
Fed. Reg. 1357 (Jan. 5, 1979).

<sup>2</sup> Office of Mgmt. & Budget, OMB Circular No. A-76 (Revised (May 29, 2003)).

33 actors play roles that are traditionally viewed as governmental in nature.<sup>3</sup> While ~~they third-~~  
34 ~~party programs~~ may increase regulatory compliance ~~and or~~ otherwise improve the performance  
35 of regulated entities and products, ~~third-party~~~~these~~ programs also pose risks.<sup>4</sup> If they are not  
36 well-conceived and well-operated, they may both undermine the achievement of regulatory  
37 goals and impose unnecessary costs on agencies and regulated entities. Whatever option is  
38 chosen, either the agency or the regulated entity must bear the costs of assuring compliance  
39 with the applicable standard. For that reason, the issue of cost allocation should be considered  
40 openly by the agency in deciding which option to pursue.

**Comment [CMA1]:** Alan Morrison Proposed Amendment

41 Frequently, regulatory third-party programs use the practices and terminology of ~~an~~  
42 ~~international~~ conformity assessment framework that has been developed by ~~international~~  
43 private-sector standards organizations. “Conformity assessment” is defined in international  
44 standards as the “demonstration that specified requirements relating to a product, process,  
45 system, person, or body are fulfilled.”<sup>5</sup> International standards also set forth how the  
46 organizations that conduct conformity assessment – “conformity assessment bodies,” which  
47 are usually private organizations – should operate. International standards have been  
48 developed for various types of conformity assessment bodies, including testing bodies,  
49 certification bodies, and inspection bodies.

50 Recognizing the assessment of regulatory compliance as a form of conformity  
51 assessment, many federal agencies that have established third-party programs have relied on

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<sup>3</sup> See William J. Novak, *Public-Private Governance: A Historical Introduction*, in GOVERNMENT BY CONTRACT: OUTSOURCING AND AMERICAN DEMOCRACY (Freeman and Minow, eds., Harvard University Press, 2009); Martha Minow, *Public and Private Partnerships: Accounting for the New Religion*, 116 HARV. L. REV. 1229, 1230 (2002-2003); Jody Freeman, *Extending Public Law Norms through Privatization*, 116 HARV. L. REV. 1285, 1286-87 (2002-2003); Jody Freeman, *Private Parties, Public Functions and the New Administrative Law*, in RECRAFTING THE RULE OF LAW: THE LIMITS OF LEGAL ORDER 331 (David Dyzenhaus ed., Hart, 1999).

<sup>4</sup> See Lesley K. McAllister, *Regulation by Third-Party Verification*, 53 B.C. L. REV. 1 (2012).

<sup>5</sup> American National Standards Institute (ANSI), National Conformity Assessment Principles for the United States, 3, available at <http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/NCAP%20second%20edition.pdf>.

52 conformity assessment standards and bodies. Agencies may require, for example, that third  
53 parties that certify conformity with regulatory requirements operate in accordance with the  
54 international standards for certification bodies. Federal agencies may also require that the  
55 third parties be accredited by accreditation bodies that operate in accordance with  
56 international accreditation standards. Accreditation bodies are established in many countries,  
57 and they may be either private or governmental.

58 Agencies that establish third-party programs generally cannot or do not delegate their  
59 regulatory authority to conformity assessment bodies. Rather, agencies authorize conformity  
60 assessment bodies to perform certain technical tasks to assess conformity, and regulatory  
61 agencies rely on these assessments in their own enforcement of regulatory requirements. The  
62 goal is to leverage private expertise and resources in the private sector to serve regulatory  
63 objectives. Because the regulatory agency must remain ultimately responsible for achieving  
64 regulatory objectives, it is vital to provide public oversight of third-party assessment activities.

65 A key resource for agencies considering a regulatory third-party program is the National  
66 Institute of Standards and Technology (NIST), which has the responsibility under the National  
67 Technology Transfer and Advancement Act of 1995 to coordinate government conformity  
68 assessment activities with similar activities of private-sector entities, with the goal of avoiding  
69 unnecessary duplication and complexity. Following Office and of Management and Budget  
70 (OMB) Circular A-119, NIST published guidance in 2000 for federal agencies on conformity  
71 assessment activities in 2000.<sup>6</sup> NIST offers services to: (1) provides s advice, solutions, and  
72 program support for development of technical standards and conformity assessment programs  
73 to support agency missions; and (2) develops s and conducts s customized standards-related  
74 workshops and educational events for government.

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<sup>6</sup> OMB Circular A-119 Revised §§ 8, 13(e) (Feb. 10, 1998); NIST, Guidance on Federal Conformity Assessment Activities, 65 Fed. Reg. 48,894 (Aug. 10, 2000).

75 Recognizing the growing use of third parties and the issues it raises, the Administrative  
76 Conference ~~is issuing~~ ~~makes~~ this recommendation to assist federal agencies in determining  
77 whether and how to establish third-party programs to assess regulatory compliance. The  
78 recommendation first suggests that, when considering a third-party program, agencies should  
79 consult relevant governmental and nongovernmental resources. Next, agencies should  
80 compare the advantages and disadvantages of a third-party approach to a more traditional  
81 approach of direct governmental compliance assessment. Also, if an agency is considering a  
82 program in which regulated entities could choose whether to contract with a third party for  
83 regulatory compliance assessment, it should ~~evaluate whether first determine that~~ regulated  
84 entities will have ~~adequate sufficient~~ incentives to choose to contract with a third party.

85 The recommendation then sets forth considerations for agencies after they have decided  
86 to establish a third-party program. An agency should design conformity assessment programs  
87 to be proportional to the risks associated with regulatory noncompliance. ~~Agencies should be~~  
88 ~~cautious about using third parties w~~ when regulatory noncompliance implies serious risk to  
89 public health, safety, or other important values. ~~If the agency decides to use third parties in~~  
90 ~~such cases, third party~~ program rules should guarantee a high degree of rigor and  
91 independence. When possible, the agency should incorporate existing conformity assessment  
92 standards, which may avoid unnecessary duplication and ~~otherwise~~ create efficiencies for both  
93 agencies and regulated entities. The agency should also ensure ~~appropriate that the~~  
94 government and ~~the~~ public ~~have appropriate~~ access to information about program operation.  
95 Finally, the agency should undertake appropriate oversight activities to ensure that the third-  
96 party program ~~is fulfilling~~ its regulatory purpose.

**Comment [CMA2]:** Alan Morrison Proposed Amendment (See also Morrison Amendment in section 2)

## RECOMMENDATION

### 97 **A. Considerations for a Federal Agency When Deciding Whether to Develop a Third-Party** 98 **Program to Assess Regulatory Compliance**

99 1. *Resources*. When considering whether to develop a third-party program to assess  
100 regulatory compliance, the agency should consult governmental and non-governmental  
101 resources relating to third-party conformity assessment. These include, but are not limited to,  
102 the National Institute of Standards and Technology (NIST); private conformity assessment  
103 standards, particularly the standards of the International Organization for Standardization (ISO);  
104 and conformity assessment bodies, ~~as appropriate,~~ for practical input on feasibility and the  
105 impacts on the regulated entities.

106 2. *Compare Regulatory Approaches*. The agency should compare a third-party approach  
107 with direct governmental assessment of compliance. In choosing between them, the agency  
108 should evaluate the advantages and disadvantages of these approaches, with consideration of:

109 (a) whether regulatory noncompliance implies serious risk to public health, safety, or  
110 other important values;

111 (b) whether third-party conformity assessment is likely to be effective in practice and as  
112 a technical matter for the applicable regulatory standards and context;

113 (c) the costs and potential delay that may result from developing and establishing a  
114 third-party program;

115 (d) the capacity of the agency to perform effective oversight and its related costs;

116 (e) the potential for the agency to achieve efficiencies through reducing its direct  
117 compliance assessment costs and resource needs;

118 (f) the costs to regulated entities of paying third parties to perform conformity  
119 assessment activities, which are likely to be of particular concern to small businesses;

120 (g) the potential for development of a well-functioning market in third-party  
121 conformity assessment services; and

**Comment [CMA3]:** Alan Morrison Proposed Amendment (See also Morrison Amendment in the final paragraph of the Preamble)

122 | (gh) the benefits that may accrue to regulated entities by, for example, receiving  
123 regulatory approval to market their products more quickly or simultaneously satisfying  
124 the regulatory requirements of other agencies to which they are subject, including state  
125 agencies or agencies in other countries. (See Administrative Conference of the United  
126 States, Recommendation 2011-6, International Regulatory Cooperation, 77 Fed. Reg.  
127 2257, 2259 (Jan. 17, 2012); Exec. Order 13,609 (May 1, 2012); Exec. Order 13,563 (Jan.  
128 18, 2011)).

129 3. *Evaluate Incentives.* If an agency is contemplating a third-party program in which  
130 regulated entities would have the choice of either contracting with third parties or being  
131 assessed directly by the agency, the agency should evaluate whether sufficient incentives exist  
132 or can be created to attract the participation of regulated entities in the third-party program.  
133 Incentives for regulated entities to utilize third parties may include:

- 134 | (a) exemption from a governmental user-fee that would otherwise be applicable; or  
135 (b) the ability to satisfy the regulatory requirements of multiple jurisdictions through a  
136 single third-party conformity assessment engagement.

137 **B. Considerations for a Federal Agency When Establishing a Third-Party Program to Assess**  
138 **Regulatory Compliance**

139 4. *Proportionality to the Risk.* An agency that has decided to establish a third-party  
140 program to assess regulatory compliance, or is directed by statute or other provision of law to  
141 do so, should design its conformity assessment program to be proportional to the risks  
142 associated with regulatory noncompliance. When the risks are high, a conformity assessment  
143 program should be characterized by high degrees of rigor and independence. When the risks  
144 associated with noncompliance are lower, the regulatory objective may be achievable with less  
145 rigor and independence. Types of rules that may be established by the agency to help ensure  
146 rigor and independence include:

- 147 (a) accreditation rules that set high standards of competence for the accreditation of  
148 third parties;
- 149 (b) selection rules that pertain to how regulated entities select third parties, requiring, for  
150 example, that third parties disclose conflicts of interests or that regulated entities contract  
151 with a different third party after a specified number of assessments;
- 152 (c) performance rules that require third parties to perform a rigorous set of assessment  
153 activities; and
- 154 (d) reporting rules that require third parties to provide sufficient information to the  
155 agency and the public about the process and outcomes of assessment activities.

156 5. *Use of Existing Conformity Assessment Standards.* The agency should consider relying  
157 on existing conformity assessment standards, particularly international standards that set forth  
158 requirements for conformity assessment bodies and accreditation bodies. Incorporating  
159 existing standards may reduce costs for the agency and for the regulated entities. To evaluate  
160 the suitability of using existing standards, the agency should take into account the following  
161 considerations:

- 162 (a) When an agency incorporates existing conformity assessment standards into its  
163 program requirements, important concerns may arise about the public availability of  
164 those standards due to the costs of obtaining copyrighted materials. When an agency  
165 considers incorporating copyrighted material by reference, the agency should be  
166 cognizant of issues relating to incorporation by reference. (See Administrative Conference  
167 of the United States, Recommendation 2011-5, Incorporation by Reference, 77 Fed. Reg.  
168 2257 (Jan. 17, 2012));
- 169 (b) An agency that anticipates the use of conformity assessment bodies in other countries  
170 may particularly benefit by recognizing accreditation bodies that operate in accordance



171 with international standards rather than the agency itself accrediting conformity  
172 assessment bodies;

173 (c) When an agency incorporates existing standards into its requirements for third  
174 parties, it can supplement those standards with program-specific rules. An agency may  
175 require, for example, that in addition to being accredited to an international standard, a  
176 conformity assessment body must satisfy accreditation rules specific to the third-party  
177 program; and

178 (d) Agencies should also be aware that existing conformity assessment standards may  
179 include confidentiality provisions that apply to information collected during the  
180 assessment. Agencies should consider when disclosure to agencies and/or the public is  
181 necessary and when confidentiality may be justified. Program-specific reporting rules, as  
182 discussed in section 6 below, may be necessary to enable appropriate governmental or  
183 public access to such information.

184 6. *Access to Information.* The agency should ensure that both the government and the  
185 public will have appropriate access to information about program operations. An agency's  
186 development of third-party program rules and guidance should include notice and an  
187 opportunity for public participation. Also, the agency should provide information to the public  
188 about the roles and identities of the third parties associated with a regulatory program. Finally,  
189 the agency should establish reporting rules that require third parties to provide information to  
190 the agency based on the following considerations:

191 (a) The reporting rules should facilitate transparency. Information about the compliance  
192 of regulated entities should be available from the agency to the public, comparable to  
193 what would be available in the absence of a third-party program. Agencies may also be  
194 able to provide additional compliance information to the public that was not available  
195 before the third-party program;

196 | (b) The reporting rules should facilitate appropriate agency oversight. For example,  
197 | conformity assessment bodies can be required to report to the agency potential conflicts  
198 | of interest before performing a conformity assessment, or provide the dates of their  
199 | assessment activities so that the agency can conduct site visits;

200 | (c) Where necessary or appropriate, the agency might design reporting rules that  
201 | enhance the degree to which conformity assessment bodies answer directly to the  
202 | agency. For example, a conformity assessment body can be required to In certain  
203 | circumstances, the agency might have reporting rules that require conformity assessment  
204 | bodies to send its assessment results directly to the agency; and

205 | (d) The agency might require conformity assessment bodies and/or regulated entities  
206 | program actors to report electronically, which may facilitate the provision of information  
207 | to the public.

208 | 7. *Agency Oversight.* The agency should exercise oversight to ensure that the third-party  
209 | program is fulfilling its regulatory purpose. An agency should, to the extent possible, set forth  
210 | how it intends to conduct such oversight. It may, for example, annually audit a certain number  
211 | of accreditations or conformity assessments, or carry out a market surveillance program to test  
212 | regulated products off-the-shelf. In exercising oversight, the agency should also take into  
213 | account the following considerations:

214 | (a) Beyond conducting direct oversight, an agency can require third parties to conduct  
215 | additional assessment activities that provide further information to the agency about  
216 | program operation. For example, an agency may require accreditation bodies annually to  
217 | audit a certain number of conformity assessments, or it may require conformity  
218 | assessment bodies to conduct particular types of surveillance on products they assess;

219 | (b) The agency should establish procedures for receiving and responding to public  
220 | complaints regarding potential noncompliance or other aspects of program operation.

221 The agency could, for example, require a third party that has assessed the conformity of a  
222 regulated product or entity to investigate a ~~related~~ complaint of noncompliance.  
223 ~~However~~In any event, the agency should ensure that complaints are resolved in an  
224 appropriate and timely manner; and

225 (c) The agency should make clear the possible adverse actions that it may take against  
226 third parties that do not comply with program rules. A key adverse action is removing  
227 third parties from the program. Third parties may be removed temporarily through a  
228 suspension of accreditation, or permanently through a withdrawal of accreditation.