



Agency Use of Third-Party Programs to Assess Regulatory Compliance

Committee on Collaborative Governance

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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 new
10 roles in coordinating and overseeing these third-party 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.¹ Regulatory objectives may, for example, be adequately
15 served by requiring regulated entities to self-assess and report their compliance (sometimes

¹ 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. 10, 1989); and Recommendation 78-4, Federal Agency Interaction with Private Standard-Setting Organizations, 44 Fed. Reg. 1357 (Jan. 5, 1979).

16 referred to as “first-party certification”). Also, statutory restrictions on information disclosure
17 or other legal restrictions may preclude the agency from using third parties to conduct
18 inspections and other compliance assessment activities. Some compliance assessment
19 activities may be inherently governmental, and thus require performance by government
20 personnel.²

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. Representing a
31 partial privatization of the public function of implementing and enforcing regulatory law, they
32 are a form of “public-private governance,” in which private actors play roles that are
33 traditionally viewed as governmental in nature.³ While they may increase regulatory
34 compliance and otherwise improve the performance of regulated entities and products, third-
35 party programs also pose risks.⁴ If they are not well-conceived and well-operated, they may

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

³ 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).

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

36 both undermine the achievement of regulatory goals and impose unnecessary costs on
37 agencies and regulated entities.

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

47 Recognizing the assessment of regulatory compliance as a form of conformity
48 assessment, many federal agencies that have established third-party programs have relied on
49 conformity assessment standards and bodies. Agencies may require, for example, that third
50 parties that certify conformity with regulatory requirements operate in accordance with the
51 international standards for certification bodies. Federal agencies may also require that the
52 third parties be accredited by accreditation bodies that operate in accordance with
53 international accreditation standards. Accreditation bodies are established in many countries,
54 and they may be either private or governmental.

55 Agencies that establish third-party programs generally cannot or do not delegate their
56 regulatory authority to conformity assessment bodies. Rather, agencies authorize conformity
57 assessment bodies to perform certain technical tasks to assess conformity, and regulatory
58 agencies rely on these assessments in their own enforcement of regulatory requirements. The
59 goal is to leverage expertise and resources in the private sector to serve regulatory objectives.

⁵ 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>.

60 Because the regulatory agency must remain ultimately responsible for achieving regulatory
61 objectives, it is vital to provide public oversight of third-party assessment activities.

62 A key resource for agencies considering a regulatory third-party program is the National
63 Institute of Standards and Technology (NIST), which has the responsibility under the National
64 Technology Transfer and Advancement Act of 1995 to coordinate government conformity
65 assessment activities with similar activities of private-sector entities, with the goal of avoiding
66 unnecessary duplication and complexity. Following Office and Management and Budget (OMB)
67 Circular A-119, NIST published guidance for federal agencies on conformity assessment
68 activities in 2000.⁶ NIST offers services to: (1) provide advice, solutions, and program support
69 for development of technical standards and conformity assessment programs to support
70 agency missions; and (2) develop and conduct customized standards-related workshops and
71 educational events for government.

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

82 The recommendation then sets forth considerations for agencies after they have decided
83 to establish a third-party program. An agency should design conformity assessment programs

⁶ 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).

84 to be proportional to the risks associated with regulatory noncompliance. When regulatory
85 noncompliance implies serious risk to public health, safety, or other important values, third-
86 party program rules should guarantee a high degree of rigor and independence. When
87 possible, the agency should incorporate existing conformity assessment standards, which may
88 avoid unnecessary duplication and otherwise create efficiencies for both agencies and
89 regulated entities. The agency should also ensure that the government and the public have
90 appropriate access to information about program operation. Finally, the agency should
91 undertake appropriate oversight activities to ensure that the third-party program is fulfilling its
92 regulatory purpose.

RECOMMENDATION

93 **A. Considerations for a Federal Agency When Deciding Whether to Develop a Third-Party** 94 **Program to Assess Regulatory Compliance**

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

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

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

- 107 (b) the costs and potential delay that may result from developing and establishing a
108 third-party program;
- 109 (c) the capacity of the agency to perform effective oversight and its related costs;
- 110 (d) the potential for the agency to achieve efficiencies through reducing its direct
111 compliance assessment costs and resource needs;
- 112 (e) the costs to regulated entities of paying third parties to perform conformity
113 assessment activities, which are likely to be of particular concern to small businesses;
- 114 (f) the potential for development of a well-functioning market in third-party conformity
115 assessment services; and
- 116 (g) the benefits that may accrue to regulated entities by, for example, receiving
117 regulatory approval to market their products more quickly or simultaneously satisfying
118 the regulatory requirements of other agencies to which they are subject, including state
119 agencies or agencies in other countries. (See Administrative Conference of the United
120 States, Recommendation 2011-6, International Regulatory Cooperation, 77 Fed. Reg.
121 2257, 2259 (Jan. 17, 2012); Exec. Order 13,609 (May 1, 2012); Exec. Order 13,563 (Jan.
122 18, 2011)).

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

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

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

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

141 (a) accreditation rules that set high standards of competence for the accreditation of
142 third parties;

143 (b) selection rules that pertain to how regulated entities select third parties, requiring, for
144 example, that third parties disclose conflicts of interests or that regulated entities contract
145 with a different third party after a specified number of assessments;

146 (c) performance rules that require third parties to perform a rigorous set of assessment
147 activities; and

148 (d) reporting rules that require third parties to provide sufficient information to the
149 agency about the process and outcomes of assessment activities.

150 5. *Use of Existing Conformity Assessment Standards.* The agency should consider relying
151 on existing conformity assessment standards, particularly international standards that set forth
152 requirements for conformity assessment bodies and accreditation bodies. Incorporating
153 existing standards may reduce costs for the agency and for the regulated entities. The agency
154 should take into account the following considerations:

155 (a) When an agency incorporates existing conformity assessment standards into its
156 program requirements, important concerns may arise about the public availability of
157 those standards due to the costs of obtaining copyrighted materials. When an agency
158 considers incorporating copyrighted material by reference, the agency should be
159 cognizant of issues relating to incorporation by reference. (See Administrative Conference
160 of the United States, Recommendation 2011-5, Incorporation by Reference, 77 Fed. Reg.
161 2257 (Jan. 17, 2012));

162 (b) An agency that anticipates the use of conformity assessment bodies in other countries
163 may particularly benefit by recognizing accreditation bodies that operate in accordance
164 with international standards rather than the agency itself accrediting conformity
165 assessment bodies;

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

171 (d) Agencies should also be aware that existing conformity assessment standards may
172 include confidentiality provisions that apply to information collected during the
173 assessment. Agencies should consider when disclosure is necessary and when
174 confidentiality may be justified. Program-specific reporting rules, as discussed in section 6
175 below, may be necessary to enable appropriate governmental or public access to such
176 information.

177 6. *Access to Information.* The agency should ensure that both the government and the
178 public will have appropriate access to information about program operations. An agency's
179 development of third-party program rules and guidance should include notice and an
180 opportunity for public participation. Also, the agency should provide information to the public

181 about the roles and identities of the third parties associated with a regulatory program. Finally,
182 the agency should establish reporting rules that require third parties to provide information to
183 the agency based on the following considerations:

184 (a) The reporting rules should facilitate transparency. Information about the compliance
185 of regulated entities should be available to the public, comparable to what would be
186 available in the absence of a third-party program. Agencies may also be able to provide
187 additional compliance information to the public that was not available before the third-
188 party program;

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

193 (c) Where necessary or appropriate, the agency might design reporting rules that
194 enhance the degree to which conformity assessment bodies answer directly to the
195 agency. For example, a conformity assessment body can be required in certain
196 circumstances to send its assessment results directly to the agency; and

197 (d) The agency might require program actors to report electronically, which may facilitate
198 the provision of information to the public.

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

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

210 (b) The agency should establish procedures for receiving and responding to public
211 complaints regarding potential noncompliance or other aspects of program operation.
212 The agency could, for example, require a third party that has assessed the conformity of a
213 regulated product or entity to investigate a related complaint of noncompliance.
214 However, the agency should ensure that complaints are resolved in an appropriate and
215 timely manner; and

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