



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Third-Party Programs to Assess Regulatory Compliance Committee on Collaborative Governance – Draft Recommendation

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

A third-party program is just one of many approaches that may enhance regulatory compliance. In some areas of regulation, Congress has directed federal agencies to develop a third-party program; in others, regulatory agencies have developed programs under existing statutory authority. Two broad reasons support their growing use in federal regulation. First, regulatory agencies confront a variety of constraints in assessing compliance. In many areas of regulation, the number of regulated products and entities continues to grow without corresponding growth in agency resources. Third-party programs may have the effect of shifting some costs associated with compliance assessment to regulated entities and thereby conserving governmental resources. Second, third-party programs can extend the reach of federal regulators as third parties around the world can be authorized to undertake compliance assessment activities. Such programs may be particularly suitable when regulated products or processes are part of international chains of production.

Regulatory third-party programs raise a host of important questions. Representing a partial privatization of the public function of implementing and enforcing regulatory law, they are a form of “public-private governance,” in which private actors play roles that are traditionally viewed as governmental in nature.¹ While they may increase regulatory compliance and otherwise improve the performance of regulated entities and products, third-party programs also pose risks.² If they are not well-conceived and well-operated, they may both undermine the achievement of regulatory goals and impose unnecessary costs on agencies and regulated entities.

Frequently, regulatory third-party programs use the practices and terminology of an international conformity assessment framework that has been developed by private-sector standards organizations. “Conformity assessment” is defined in international standards as the “demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled.”³ International standards also set forth how the organizations that conduct conformity assessment – “conformity assessment bodies,” which are usually private organizations – should operate. International standards have been developed for various types of conformity assessment bodies, including testing bodies, certification bodies, and inspection bodies.

Recognizing the assessment of regulatory compliance as a form of conformity assessment, many federal agencies that have established third party programs have relied on conformity assessment standards and bodies. Agencies may require, for example, that third parties that certify conformity with regulatory requirements operate in accordance with the

¹ See 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); 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); 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)

² See Lesley K. McAllister, *Regulation by Third-Party Verification*, 53 B.C. L. REV. 1 (2012).

³ 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>.

international standards for certification bodies. Federal agencies may also require that the third parties be accredited by accreditation bodies that operate in accordance with international accreditation standards. Accreditation bodies are established in many countries, and they may be either private or governmental.

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

A key resource for agencies considering a regulatory third-party program is the National Institute of Standards and Technology (NIST), which has the responsibility under the National Technology Transfer and Advancement Act of 1995 to coordinate conformity assessment activities of governmental and private-sector entities with the goal of avoiding unnecessary duplication and complexity. Following Office of Management and Budget (OMB) Circular A-119, NIST published guidance for federal agencies on conformity assessment activities in 2000.⁴ NIST offers services to: (1) provide advice, solutions, and program support for development of technical standards and conformity assessment programs to support agency missions; and (2) develop and conduct customized standards-related workshops and educational events for government.

Recognizing the growing use of third parties and the issues it raises, the Administrative Conference is issuing this recommendation to assist federal agencies in determining whether and how to establish third-party programs to assess regulatory compliance. The recommendation first suggests that when considering a third-party program, agencies should

⁴ OMB Circular A-119 Revised §§ 8, 13(e) (Feb. 10, 1998); NIST, Guidance on Federal Conformity Assessment Activities, 65 Fed. Reg. 48894 (Aug. 10, 2000).

consult relevant governmental and nongovernmental resources. Next, agencies should compare the advantages and disadvantages of a third-party approach to a more traditional approach of direct governmental compliance assessment. Also, if an agency is considering a program in which regulated entities could choose whether to contract with a third party for regulatory compliance assessment, it should evaluate whether regulated entities will have adequate incentives to choose to contract with a third party.

The recommendation then sets forth considerations for agencies after they have decided to establish a third-party program. An agency should design conformity assessment programs to be proportional to the risks associated with regulatory noncompliance. When regulatory noncompliance implies serious risk to public health, safety, or other important values, third-party program rules should guarantee a high degree of rigor and independence. When possible, the agency should incorporate existing conformity assessment standards, which may avoid unnecessary duplication and otherwise create efficiencies for both agencies and regulated entities. The agency should also ensure that the government and the public have appropriate access to information about program operation. Finally, the agency should undertake appropriate oversight activities to ensure that the third-party program is fulfilling its regulatory purpose.

RECOMMENDATION

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

1. *Resources.* When considering whether to develop a third-party program to assess regulatory compliance, the agency should consult governmental and non-governmental resources relating to third-party conformity assessment. These include, but are not limited to, the National Institute of Standards and Technology (NIST) and private standards and related organizations, in particular, the conformity assessment standards of the International Organization for Standardization (ISO).

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

- (a) whether third-party conformity assessment is likely to be technically effective for the applicable regulatory standards and context;
- (b) the costs and potential delay that may result from developing and establishing a third-party program;
- (c) the capacity of the agency to perform effective oversight and its related costs;
- (d) the potential for the agency to achieve efficiencies through reducing its direct compliance assessment costs and resource needs;
- (e) the costs to regulated entities of paying third parties to perform conformity assessment activities, which are likely to be of particular concern to small businesses; and
- (f) the benefits that may accrue to regulated entities by, for example, receiving regulatory approval to market their products more quickly or simultaneously satisfying the regulatory requirements of other agencies to which they are subject, including state agencies or agencies in other countries. (See Administrative Conference of the United States, Recommendation 2011-6, International Regulatory Cooperation, 77 Fed. Reg. 2,257, 2,259 (Jan. 17, 2012); Exec. Order 13,609 (May 1, 2012); Exec. Order 13,563 (Jan. 18, 2011)).

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

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

B. Considerations for Federal Agencies When Establishing a Third-Party Program to Assess Regulatory Compliance

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

- (a) accreditation rules that set high standards of competence for the accreditation of third parties;
- (b) selection rules that pertain to how regulated entities select third parties, requiring, for example, that third parties disclose conflicts of interests or that regulated entities contract with a different third party after a specified number of assessments;
- (c) performance rules that require third parties to perform a rigorous set of assessment activities; and

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

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

(a) When an agency incorporates existing conformity assessment standards into its program requirements, important concerns may arise about the public availability of those standards due to the costs of obtaining copyrighted materials. When an agency considers incorporating copyrighted material by reference, the agency should ensure the material will be reasonably available to regulated entities and other interested parties. (See Administrative Conference of the United States, Recommendation 2011-5, Incorporation by Reference, 77 Fed. Reg. 2,257 (Jan. 17, 2011));

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

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

(d) Agencies should also be aware that existing conformity assessment standards may include confidentiality provisions that apply to information collected during the assessment. Agencies should consider when disclosure is necessary and when confidentiality may be justified. Program-specific reporting rules, as discussed in section 6

below, may be necessary to enable appropriate governmental or public access to such information.

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

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

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

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

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

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

- (a) Beyond conducting direct oversight, an agency can require third parties to conduct additional assessment activities that provide further information to the agency about program operation. For example, an agency may require accreditation bodies to annually audit a certain number of conformity assessments or it may require conformity assessment bodies to conduct particular types of surveillance on products they assess;
- (b) The agency should establish procedures for receiving and responding to public complaints regarding potential noncompliance or other aspects of program operation. The agency could, for example, require a third party that has assessed the conformity of a regulated product or entity to investigate a related complaint of noncompliance. However, the agency should ensure that complaints are resolved in an appropriate and timely manner; and
- (c) The agency should make clear the possible adverse actions that it may take against third parties that do not comply with program rules. A key adverse action is removing third parties from the program. Third parties may be removed temporarily through a suspension of recognition or accreditation, or permanently through a withdrawal of recognition or accreditation.