

HARNESSING PRIVATE REGULATION

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In private regulation, private actors make, implement, and enforce rules that serve traditional public goals. While private safety standards have a long history, private social and environmental regulation in the forms of self-regulation, supply chain contracting, and voluntary certification and labeling programs have proliferated in the past couple decades. This expansion of private regulation raises the question of how it might be harnessed by public actors to build better regulatory regimes. This Article tackles this question first by identifying three forms of strong harnessing: public incorporation of private standards, public endorsement of self-regulation, and third-party verification. It then analyzes eight third-party verification programs established by six federal regulatory agencies to derive lessons about what makes a program successful and to develop recommendations to federal agencies about when and how they should use third-party verification.

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INTRODUCTION

Private regulation is a large and growing field of regulatory activity.¹ Industry associations set health and safety standards for their member companies. Companies with global supply chains establish codes of conduct for their foreign suppliers regarding treatment of workers and the environment. Companies join voluntary programs that certify and label their consumer products to indicate compliance with social and environmental criteria. Private auditors are hired to assess corporate compliance with rules and standards developed by both governments and private entities. In all these forms of private regulation, private actors engage in developing and implementing rules that serve the traditional social goals of public regulation, particularly health, safety, and environmental protection.²

Private regulation is often viewed as an alternative to public regulation.³ It tends to develop where there are gaps in public regulation.⁴ Private environmental governance has thrived in the United States, for example, in the absence of significant new legislation.⁵ Gaps may also be present because existing governmental institutions cannot reach certain activity. Economic globalization has been an important driver of private regulation because governmental actors lack sufficient authority to regulate against many of the negative social externalities of international economic activity.⁶

1. See Michael P. Vandenbergh, *Private Environmental Governance*, 99 CORNELL L. REV. 129, 140–41 (2013) (discussing the “large number of private environmental governance initiatives that have emerged”); see also *infra* notes 37–40 and associated text.

2. Vandenbergh, *supra* note 1, at 147 (referring to private governance as the “development and enforcement by private parties of requirements designed to achieve traditionally governmental ends”). On the distinction between social regulation and economic regulation, see Keith Hawkins, *Rule and Discretion in Comparative Perspective: The Case of Social Regulation*, 50 OHIO ST. L.J. 663 (1989) (distinguishing social regulation from other forms of regulatory control that seek to control markets or other aspects of economic life); Cass R. Sunstein, *Administrative Substance*, 1991 DUKE L.J. 607, 609 (identifying health, safety, broadcasting, discrimination, and the environment as areas of social regulation and distinguishing social regulation from economic regulation). While much of its analysis may also apply to economic regulation, this Article limits its focus to social regulation.

3. As others have discussed, the lines between public and private blur upon examination. See especially 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., 1999); Martha Minow, *Public and Private Partnerships: Accounting for the New Religion*, 116 HARV. L. REV. 1229, 1229 n.1 (2003). However, these terms continue to be useful as “shorthand for describing different kinds of regulatory actors.” Freeman, *supra*, at 334 n.13.

4. Cf. Michael P. Vandenbergh, *The New Wal-Mart Effect: The Role of Private Contracting in Global Governance*, 54 UCLA L. REV. 913, 919 (2007).

5. See Vandenbergh, *supra* note 1, at 133.

6. Cf. Fabrizio Cafaggi, *New Foundations of Transnational Private Regulation*, 38 J.L. & SOC’Y 20 (2011) (discussing drivers of transnational private regulation); Frederick Mayer &

Even when public actors have the power to regulate, companies or industries may develop private regulation in an attempt to address public concerns and preempt new governmental regulation.⁷ Commonly cited benefits of enabling private actors to exercise functions that would otherwise be carried out by public actors include enhancing pluralism, better representing interests, increasing expertise, and reducing governmental bureaucracy and cost.⁸

Less examined are the ways that private regulation may be coordinated and even integrated with public regulation.⁹ Public regulation suffers from many well-documented deficiencies. Rulemaking has been described as ossified.¹⁰ Regulatory implementation is subject to slippage.¹¹ Enforcement is unreliable and agencies lack data to assess compliance.¹² Regulatory agencies endure budget constraints and downsizing.¹³ In this context, an apt

Gary Gereffi, *Regulation and Economic Globalization: Prospects and Limits of Private Governance*, 12 BUS. & POL., no. 3, art. 11, 2010 at 1, 3 (explaining that private governance responds to the public governance deficit in the face of economic globalization); David Vogel, *The Private Regulation of Global Corporate Conduct: Achievement and Limitations*, 49 BUS. & SOC'Y 68, 72–73 (2010).

7. Responsible Care, which was established in the wake of the Bhopal disaster, has been viewed as an example of this. Thomas P. Lyon & John W. Maxwell, "Voluntary" *Approaches to Environmental Regulation: A Survey*, in ECONOMIC INSTITUTIONS AND ENVIRONMENTAL POLICY: PAST PRESENT AND FUTURE 75, 79 (Maurizio Franzini & Antonio Nicita eds., 2002); see also ROSS E. CHEIT, SETTING SAFETY STANDARDS: REGULATION IN THE PUBLIC AND PRIVATE SECTORS 179–80 (1990) (discussing private regulatory action taken with the intention of forestalling governmental regulation).

8. David M. Lawrence, *Private Exercise of Governmental Power*, 61 IND. L.J. 647, 651–57 (1986); see also Minow, *supra* note 3, at 1242–46 (citing potential increases in quality of public services, incentives for improvement, pluralism, and new knowledge).

9. An important body of legal scholarship has recognized the many public functions that private actors fulfill, but there has been little work on how public and private regulation can be coordinated and integrated. Key works include Freeman, *supra* note 3; Jody Freeman, *Extending Public Law Norms Through Privatization*, 116 HARV. L. REV. 1285, 1286–87 (2003); Minow, *supra* note 3; WILLIAM J. NOVAK, *Public-Private Governance: A Historical Introduction*, in GOVERNMENT BY CONTRACT: OUTSOURCING AND AMERICAN DEMOCRACY (Jody Freeman & Martha Minow eds., 2009).

10. Jody Freeman, *Collaborative Governance in the Administrative State*, 45 UCLA L. REV. 1, 9 (1997); Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385 (1992).

11. Daniel A. Farber, *Taking Slippage Seriously: Noncompliance and Creative Compliance in Environmental Law*, 23 HARV. ENVTL. L. REV. 297 (1999).

12. Victor B. Flatt & Paul M. Collins, Jr., *Environmental Enforcement in Dire Straits: There Is No Protection for Nothing and No Data for Free*, 85 NOTRE DAME L. REV. 55, 86 (2010).

13. Sidney A. Shapiro & Rena Steinzor, *Capture, Accountability, and Regulatory Metrics*, 86 TEX. L. REV. 1741, 1756–59 (2008); Paul Verkuil, *Outsourcing and the Duty to Govern*, in GOVERNMENT BY CONTRACT: OUTSOURCING AND AMERICAN DEMOCRACY 310, 311 (Jody Freeman & Martha Minow eds., 2009).

question is whether public and private regulation can be combined to create more robust regulatory regimes.¹⁴ More specifically, this Article addresses whether and how private regulation can be leveraged—or harnessed—by public regulators to achieve the objectives of public law.¹⁵ By relying on the mechanisms and institutions of private regulation, public regulators may be able to regulate more effectively.¹⁶

Such harnessing has been recognized as a possibility by other scholars, but little analysis exists regarding how public regulators can design regulatory regimes that include significant roles for private actors.¹⁷ As one commentator has stated, “scholarship on new regulatory forms has produced far more empirical research on their rise and character than on their translation into practice.”¹⁸ To the extent that legal scholars have considered how private regulation can be leveraged to serve public goals, they have focused primarily on the constitutionality of private delegations and the incorporation of private standards.¹⁹ Much less has been written about designing

14. On the concept of a regulatory regime, see DAVID LEVI-FAUR, *Regulation & Regulatory Governance*, in HANDBOOK ON THE POLITICS OF REGULATION 13–14 (David Levi-Faur ed., 2011) (“The notion of a regulatory regime encompasses the norms, the mechanisms of decision making, and the network of actors that are involved in regulation.”); Colin Scott, *Regulating Everything: From Mega- to Meta-Regulation*, 60 ADMINISTRATION 61, 67 (2012) (“A regulatory regime is the aggregation of the activities of those whose actions shape behaviour within a particular set sector or policy domain.”).

15. Harnessing is used herein in the sense of leveraging or bringing into service or incorporating, cf. David Freeman Engstrom, *Harnessing the Private Attorney General: Evidence from Qui Tam Litigation*, 112 COLUM. L. REV. 1244, 1253 (pointing out that harnessing can be used in two senses: to mean either leveraging or constraining).

16. Cf. Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 549 (2000) (stating that administrative law needs to reorient “toward facilitating the effectiveness of public/private regulatory regimes”).

17. *Id.* (mentioning the “possibility of harnessing private capacity to serve public goals”); see also Tim Büthe, *Global Private Politics: A Research Agenda*, 12 BUS. & POL., no. 3, art. 12, 2010 at 1, 19 (stating that it is possible that private regulation can “strengthen public regulation, for instance if the former addresses problems that are inherently transnational and hence cannot be effectively regulated by any one state unilaterally”); Sidney A. Shapiro, *Outsourcing Government Regulation*, 53 DUKE L.J. 389 (2003) (discussing contractual standard setting and contractual enforcement); David M. Trubek & Louise G. Trubek, *New Governance & Legal Regulation: Complementarity, Rivalry, and Transformation*, 13 COLUM. J. EUR. L. 1 (2006) (suggesting that transformation in the law can be achieved by yoking private and public regulation together); see also *infra* notes 151–156 and associated text.

18. Jodi L. Short & Michael W. Toffel, *Making Self-Regulation More Than Merely Symbolic: The Critical Role of the Legal Environment*, 55 ADMIN. SCI. Q. 361, 365 (2010) (citing Marc Schneiberger & Tim Bartley, *Organizations, Regulation, and Economic Behavior: Regulatory Dynamics and Forms from the Nineteenth to Twenty-First Century*, 4 ANN. REV. L. & SOC. SCI. 31, 50 (2008)).

19. On the constitutionality of private delegations, see especially Harold I. Abramson, *A Fifth Branch of Government: The Private Regulators and Their Constitutionality*, 16 HASTINGS CONST. L.Q. 165, 168 (1989); Harold J. Krent, *Fragmenting the Unitary Executive:*

public regulation to incorporate the implementation and enforcement mechanisms that are commonly used in private regulation.²⁰ By analyzing how major federal programs in the United States have been structured to enable third-party verifiers to assess the compliance of regulated entities, this Article helps fill that void. Moreover, the Article's broad analytical framework combines the insights of scholarship on private and public regulation in ways that suggest a set of criteria for designing public-private regulatory regimes and invite further theoretical and empirical research.

In its first part, this Article explains the concept of private regulation and analyzes the public harnessing of private regulation. This part begins by defining private regulation and identifying how private actors engage in standard setting, implementation, and enforcement in the most common forms of private regulation. It then conceptualizes harnessing and distinguishes weak forms from strong forms, in which a private regulatory function substitutes for a public regulatory function. Private standard setting, for example, is strongly harnessed when private standards are incorporated into public regulation. Private standard setting and private implementation are strongly harnessed when public law endorses self-regulation in various forms. And private implementation is strongly harnessed in third-party verification programs that rely on private inspectors to monitor and assess compliance with public law.²¹

The remaining three parts of the Article focus on third-party verification programs established by federal regulatory agencies.²² In these programs, federal agencies rely on private third parties that they have approved to provide information about the regulated entity's compliance with

Congressional Delegations of Administrative Authority Outside the Federal Government, 85 NW. U. L. REV. 62; Gillian E. Metzger, *Privatization as Delegation*, 103 COLUM. L. REV. 1367 (2003). On the incorporation of private standards, see Emily S. Bremer, *Incorporation by Reference in an Open Government Age*, 36 HARV. J.L. & PUB. POL'Y 131 (2013); Robert W. Hamilton, *The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety or Health*, 56 TEX. L. REV. 1329 (1978); Nina Mendelson, *Private Control Over Access to Public Law: The Puzzling Federal Regulatory Use of Private Standards*, 112 MICH. L. REV. 737 (2014); Peter L. Strauss, *Private Standards Organizations and Public Law*, 22 WM. & MARY BILL RTS. J. 497 (2013).

20. Cf. Colin Scott, *Beyond Taxonomies of Private Authority in Transnational Regulation*, 13 GERMAN L. J. 1329, 1330 (2012) (noting the need to "consider also the central importance of mechanisms of monitoring and enforcement").

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

22. These parts are closely based on a report that the author prepared for the Administrative Conference of the United States. See LESLEY K. MCALLISTER, *THIRD PARTY PROGRAMS TO ASSESS REGULATORY COMPLIANCE* (2012), available at http://www.acus.gov/sites/default/files/documents/Third-Party-Programs-Report_Final.pdf.

applicable standards.²³ While not an entirely new practice, third-party verification seems to be increasingly attractive to Congress and federal agencies in light of inadequate agency resources and other persistent barriers to reliably monitoring regulatory compliance.²⁴ The Article's objective in these parts is to analyze the design and performance of existing federal third-party programs and make policy recommendations for future programs based on this analysis. To gather information about existing programs, the author reviewed relevant statutes, regulations, guidance documents, and reports. She also conducted twenty interviews of agency staff and other experts.

Eight third-party verification programs developed by six different federal agencies are identified and described in the second part of the Article.²⁵ Congress directed agencies to use third-party verification in four of the programs. In the others, agencies chose third-party verification without specific Congressional authorization. In four of the programs, third parties are used by regulatory agencies to assess compliance with mandatory regulatory standards such as food and medical device safety standards. In the other four, third parties assess compliance with voluntary regulatory standards like those for U.S. Department of Agriculture's (USDA) organic food label and the Environmental Protection Agency's (EPA) Energy Star label. In all but two of the eight programs, the regulated entity has no choice but to contract with a third party if it wants to show compliance with the mandatory or voluntary standard. Four of the programs were established before 2003 (with one dating to the late 1980s), and four others have been established since 2008.

23. *Id.* at 7–8 (“Several types of programs that share some similarities but do not meet this description are outside the scope of this Article. Examples include (1) where a federal agency places responsibility for inspecting and providing information about compliance directly on regulated entities; (2) where a federal agency relies on state agency personnel to inspect and provide information about compliance [as in the USDA's Good Agricultural Practices/Good Handling Practices (GAP/GHP) Audit Program]; (3) where a federal agency takes into account whether a regulated entity is certified as meeting an [International Organization for Standardization/International Electrotechnical Commission (ISO/IEC)] standard or other similar privately-established standard in determining its inspection priorities; and (4) where an agency uses private third parties to assess compliance with its own procurement or federal assistance policies.”).

24. Congress has required the use of third-party verification in two recent major reforms of regulatory legislation: the Food Safety Modernization Act of 2011, *see infra* Part II.A.1; and the Consumer Product Safety Improvement Act of 2008, *see infra* Part II.A.2.

25. The author's research showed these eight programs to be the most significant and well-documented examples of third-party verification in federal environmental, health, and safety regulation. *See supra* note 23 and associated text for specification of types of programs that fell outside the scope of the research.

The third part develops a set of metrics of success for third-party programs. While a variety of forces are leading public regulators to consider third-party programs, there has been little analysis and discussion of what a successful program looks like. The metrics of success identified and discussed include the reliability of the compliance assessments made by third-party verifiers, the rates at which regulated entities comply with standards when third-party verification is used, the sufficiency of agency resources for establishing and maintaining a third-party program, and the acceptance of the program by the public and by industry. In the case of programs that allow but do not require regulated entities to use third-party verifiers, the rate at which regulated entities do so is another relevant metric of success.

The fourth and final part consists of policy recommendations to federal agencies about whether and how to establish a third-party program. The first set of recommendations pertains to federal agencies that are considering whether to establish a third-party program. Agencies are advised, for example, to consult available public and private resources, consider the suitability of the regulatory problem for third-party verification, and compare this approach with others. The second set of recommendations is directed toward those agencies that have already decided to establish such a program, whether required by law or on their own initiative. Here, agencies are advised to calibrate the program to the risks presented, rely on existing conformity assessments standards and activities, ensure agency and public access to appropriate program information, and undertake necessary oversight. The recommendations contained in this part were the basis for a formal Recommendation issued by the Administrative Conference of the United States (ACUS) in December 2012.²⁶ The text of the ACUS Recommendations is included in an appendix.

I. PRIVATE REGULATION AND ITS HARNESSING

Regulation is typically understood by lawyers to refer to the rules that administrative agencies promulgate to implement statutes.²⁷ In a slightly broader view, regulation encompasses not just rulemaking, but also the implementation and enforcement of rules.²⁸ In current academic parlance,

26. Agency Use of Third-Party Programs to Assess Regulatory Compliance, 78 Fed. Reg. 2939, 2941-45 (Jan. 15, 2013).

27. Cf. Vandenberg, *supra* note 1, at 134 (describing the “standard model” of environmental law in which it is assumed that “the actor is the government and the action is some form of positive law”). For a broad survey of various meaning and uses of the term regulation, see LEVI-FAUR, *supra* note 14, at 3–11.

28. LEVI-FAUR, *supra* note 14, at 4 (“Some contend that regulation comprises mostly rule making while others extend it to include rule monitoring and rule enforcement.”).

however, a much broader understanding of regulation has prevailed that includes not just rules made by governmental actors but also those made by private actors: regulation is “the promulgation of prescriptive rules as well as the monitoring and enforcement of these rules by social, business, and political actors on other social, business, and political actors.”²⁹ Regulation is “decentred”: government does not have a monopoly on it, and it can occur within and between other social actors without the government’s involvement.³⁰

Notably, in this broader understanding, regulation can still be said to have three aspects.³¹ First is rule creation, in which regulatory objectives—often referred to as standards—are established.³² Second is rule implementation, wherein mechanisms are developed and deployed to monitor for compliance. And third is rule enforcement, through which deviations are corrected. Regulation accordingly refers to “any process or set of processes by which norms are established, the behavior of those subject to the norms monitored or fed back into the regime, and for which there are mechanisms

29. *Id.* at 9.

30. Julia Black, *Decentering Regulation: Understanding the Role of Regulation and Self-Regulation in a “Post-Regulatory” World*, 54 CURRENT LEGAL PROBS. 103, 103 (2001); see also Colin Scott, *Regulatory Governance and the Challenge of Constitutionalism*, in THE REGULATORY STATE: CONSTITUTIONAL IMPLICATIONS 15, 21 (Dawn Oliver et al. eds., 2010) (stating that regulation is fragmented, “within the state and beyond the state, substantial involvement of supranational and non-state organizations at every stage, including the making, monitoring and enforcement of norms”).

31. Scott, *supra* note 20, at 1333 (stating that regulation comprises norm creation, detection of deviation, and correcting deviation). The regulatory process can be defined into more stages, but the terms rule making, implementation and enforcement are intended to encompass the whole. See, e.g., Tim Büthe, *Private Regulation in the Global Economy: A (P)Review*, 12 BUS. & POL., no. 3, art. 2, 2010 at 1, 1 n.1 (specifying as regulations components: “agenda-setting, rule-making, implementation, monitoring, adjudication, and enforcement”); see also Kenneth W. Abbott & Duncan Snidal, *The Governance Triangle: Regulatory Standards Institutions and the Shadow of the State*, in THE POLITICS OF GLOBAL REGULATION 44, 63 (Walter Mattli & Ngaire Woods eds., 2009) (setting forth components of regulation as agenda, negotiation, implementation, monitoring, enforcement, with discussion about overlap among them); Errol Meidinger, *Private Import Safety Regulation and Transnational New Governance*, in IMPORT SAFETY: REGULATORY GOVERNANCE IN THE GLOBAL ECONOMY 233, 237 (Cary Coglianese et al. eds., 2009) (“Regulatory programs can be broken down into several basic functions, including standard-setting and rule-making, adoption, implementation, inspection and monitoring, and sanctioning.”).

32. The term standard is broadly defined as “[c]ommon and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices.” OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, CIRCULAR NO. A-119, REVISED, MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES: FEDERAL PARTICIPATION IN THE DEVELOPMENT AND USE OF VOLUNTARY CONSENSUS STANDARDS AND IN CONFORMITY ASSESSMENT ACTIVITIES (1998).

for holding the behavior of regulated actors within the acceptable limits of the regime.”³³

With this broad definition, one can speak of public regulation, private regulation, or a combination of the two, which is sometimes referred to as co-regulation.³⁴ As used in this Article, public regulation refers to the exercise of public authority to make, implement, and enforce rules.³⁵ Private regulation means that private actors play a major role in one or more of these elements of regulation.³⁶ The first part of this section further explains the concept of private regulation and how private regulators perform standard setting, implementation, and enforcement functions in common forms of private regulation. The second part of this section analyzes the interaction of public and private regulation, with a focus on how public regulation can harness private regulation.

A. Elements of Private Regulation

Private regulation is long-standing, widespread, and varied.³⁷ Organizations like the American Society for Testing Materials (now ASTM International) and professional societies like the American Society of Civil

33. Colin Scott, *Analysing Regulatory Space: Fragmented Resources and Institutional Design*, PUB. L., Summer 2001, at 329, 331.

34. See, e.g., Edward J. Balleisen & Marc Eisner, *The Promise and Pitfalls of Co-Regulation: How Governments Can Draw on Private Governance for Public Purpose*, in NEW PERSPECTIVES ON REGULATION 129 (David Moss & John Cisternino eds., 2009); NEIL GUNNINGHAM & PETER GRABOSKY, SMART REGULATION: DESIGNING ENVIRONMENTAL POLICY 55 (1998) (stating that in co-regulation, “[g]overnment may directly engage in the self-regulatory process by jointly negotiating targets and strategies, and providing, if necessary, external verification and/or ratification”); Lesley K. McAllister, *Co-Regulation in Mexican Environmental Law*, 32 UTAH ENVTL L. REV. 181 (2012).

35. Public regulation thus encompasses the “standard model” of regulatory law. Cf. Vandenbergh, *supra* note 1, at 131. Notably, this standard model is “already co-regulatory” in the sense that it “relies significantly on private participation in implementation, even though this is largely hidden from public view.” Freeman, *supra* note 3, at 350–51.

36. Büthe, *supra* note 31, at 1 n.1 (“Private regulation in a broad sense entails private actors playing a major role—at one or more stages beyond implementation or compliance . . .”).

37. A variety of terms have been used for private regulation. For example, Vogel defines global civil regulation as “voluntary, private, nonstate industry and cross-industry codes that specify the responsibilities of global firms for addressing labor practices, environmental performance, and human rights policies.” Vogel, *supra* note 6, at 68. Transnational private regulation is an active area of scholarship among international law scholars. See especially Cafaggi, *supra* note 6. Private regulation can be understood as an aspect of private governance, namely that part of private governance that is about “steering the flow of events and behavior, as opposed to providing and distributing [public goods and services].” John Braithwaite et al., *Can Regulation and Governance Make a Difference?*, 1 REG. & GOVERNANCE 1, 3 (2007).

Engineers have been writing safety standards for over a hundred years.³⁸ By the early 1920s, Underwriters Laboratory (UL) had established itself as the primary regulator of fire safety, with the largest fire-testing laboratory in the world and over 500 million products stamped with the UL label each year.³⁹ The Orthodox Union established a rigorous certification system for Kosher food in the 1950s and 1960s, such that by 1970 it employed more than 750 supervisors to certify more than 2,500 products for 475 companies.⁴⁰

Private regulators have been called a fifth branch of government.⁴¹ Like their counterparts in public agencies, private regulators essentially “make laws and adjudicate disputes.”⁴² While some private regulators specialize in setting standards or assessing compliance, others perform functions that span the regulatory process. This section explains how private regulators of different types carry out the three elements of regulation: setting, implementing, and enforcing standards.

1. Standard Setting

In line with the diversity of private regulation, private regulators of various types set private standards of various types. As described below, standards development organizations (SDOs) at the national and international levels have set tens of thousands of private standards. Standards are also often set by firms, industry associations, and non-governmental organizations (NGOs) in the form of voluntary codes to guide their own behavior and that of other organizations with which they conduct business.

Just in the United States, there are hundreds of private SDOs with diverse institutional characteristics.⁴³ Most are industry or trade associations like the American Petroleum Institute; scientific or professional societies like the Society of Automobile Engineers; or membership organizations

38. *Notable Milestones*, ASTM INT'L, <http://www.astm.org/HISTORY/milestones.html> (last visited Nov. 25, 2013); *History of ASCE*, AM. SOC'Y OF CIVIL ENG'RS, <http://content.asce.org/history/150/150years.html> (last visited Nov. 25, 2013).

39. SCOTT GABRIEL KNOWLES, *THE DISASTER EXPERTS: MASTERING RISK IN MODERN AMERICA* 122 (2011).

40. Timothy D. Lytton, *Competitive Third-Party Regulation: How Private Certification Can Overcome Constraints that Frustrate Government Regulation*, 15 *THEORETICAL INQUIRIES L.* (forthcoming 2014).

41. Abramson, *supra* note 19, at 168.

42. *Id.*; see also Henry H. Perritt, Jr., *Towards a Hybrid Regulatory Scheme for the Internet*, UNIV. CHI. LEGAL F. 215, 250 (2001) (“Private regulatory regimes are a form of government . . . Private legislators make the rules, private judges apply them to concrete situations, and private sheriffs enforce the rules against violators.”).

43. *Standards Development in the United States*, NAT'L INST. OF STANDARDS & TECH., <http://gsi.nist.gov/global/index.cfm/L1-5/L2-44/A-165> (last visited Nov. 8, 2013).

specifically established to set standards, such as ASTM.⁴⁴ Writing private standards is costly, so an important question regards why private standard setting occurs.⁴⁵ Industry associations may set standards in the expectation of private gains, as their standards may lower their compliance costs or create barriers to entry in ways that enhance their profits.⁴⁶ Professional societies and membership organizations may establish standards to position themselves as experts in a given regulatory field and derive revenues from selling their copyrighted standards.⁴⁷ Not uncommonly, private actors compete to establish the dominant standards.⁴⁸

Many SDOs seek to establish standards that will be considered “voluntary consensus standards” based on their adherence to certain procedures.⁴⁹ In the United States, American National Standards Institute (ANSI) accredits SDOs that meet its requirements for developing voluntary consensus standards.⁵⁰ Accreditation requires, for example, that SDOs open standards development to all directly affected persons, notify the public in suitable media, ensure a balance of participation from diverse interests and a lack of domination by a single interest, promptly consider the written views and objections of all participants, and maintain an appeal process.⁵¹ In addition, accredited SDOs must use consensus voting. Instead of a unanimity requirement, consensus voting refers to a process that seeks the greatest possible agreement by hearing and responding to negative votes that are

44. TIM BÜTHE & WALTER MATTLI, *THE NEW GLOBAL RULERS: THE PRIVATIZATION OF REGULATION IN THE WORLD ECONOMY* 148 (2011) (stating that the U.S. private-sector standards consists of about 300 trade associations, 130 professional societies, 40 general membership organizations, and 150 consortia); Cheit, *supra* note 7, at 23–24; *see also* OFFICE OF TECH. ASSESSMENT, U.S. CONG., *OTA-TCT-512, GLOBAL STANDARDS: BUILDING BLOCKS FOR THE FUTURE* 49–51 (1992).

45. Büthe, *supra* note 31, at 12.

46. *Id.* at 13.

47. *Id.*; *see* OFFICE OF TECH. ASSESSMENT, *supra* note 44, at 50–51.

48. Büthe, *supra* note 31, at 14–15 (discussing competition among industry actors and between industry and civil society NGOs); BÜTHE & MATTLI, *supra* note 44, at 148 (describing how SDO’s in the United States have been spurred by competition to develop high quality standards).

49. OFFICE OF MGMT. & BUDGET, *supra* note 32.

50. BÜTHE & MATTLI, *supra* note 44, at 150 (discussing ANSI and the American system of standardization); AM. NAT’L STANDARDS INST., *ANSI ESSENTIAL REQUIREMENTS: DUE PROCESS REQUIREMENTS FOR AMERICAN NATIONAL STANDARDS* 4–5 (2013), *available at* http://publicaa.ansi.org/sites/apd/Documents/Standards%20Activities/American%20National%20Standards/Procedures,%20Guides,%20and%20Forms/2013_ANSI_Essential_Requirements.pdf.

51. AM. NAT’L STANDARDS INST., *supra* note 50, at 8–9 (setting forth requirements for “[e]vidence of consensus and consensus body vote”).

accompanied by related comments.⁵² In 2012, there were over 200 ANSI accredited SDOs, collectively responsible for approximately 10,000 voluntary consensus standards.⁵³ ASTM, the largest developer of consensus standards in the United States, with over 12,000 standards promulgated by 2013, has similar procedural requirements.⁵⁴

The International Organization of Standards (ISO) and the International Electrotechnical Commission (IEC) are major SDOs at the international level.⁵⁵ ISO alone has developed more than 18,000 standards, and together ISO and IEC account for about 85 percent of all known international standards.⁵⁶ Founded in 1946, the ISO's membership consists of the one body from each country that is most responsible for coordinating private standard setting in that country.⁵⁷ ISO members in developing countries are often governmental departments, whereas ISO members in developed countries tend to be "non-governmental organizations recognized by their government as the entity responsible for such voluntary standardization."⁵⁸ In the United States, the non-governmental ANSI is the ISO member body.⁵⁹

52. *Id.*; see also BÜTHE & MATTLI, *supra* note 44, at 145–46 (explaining that consensus-based standard setting means that the process tries to incorporate negative opinions "striving for the greatest feasible agreement"); CHEIT, *supra* note 7, at 176 (noting the rule in consensus decisionmaking that there be no "unresolved negatives").

53. *Domestic Programs (American National Standards) Overview*, AM. NAT'L STANDARDS INST., http://www.ansi.org/standards_activities/domestic_programs/overview.aspx?menuid=3#UcikGZxuuJs (last visited Nov. 8, 2013). No estimate of the number of standards set by all private SDOs is available, but twenty-five years ago, it was estimated that 400 SDOs had promulgated over 30,000 private standards. MAUREEN A. BREITENBERG, NAT'L INST. OF STANDARDS & TECH., NISTIR 6014, THE ABC'S OF THE U.S. CONFORMITY ASSESSMENT SYSTEM 3 (1997). Also, a 1996 study by the National Institute of Science and Technology counted 49,000 private standards. OFFICE OF STANDARDS SERV., NAT'L INST. OF STANDARDS & TECH., SPECIAL PUBLICATION 806, STANDARDS ACTIVITIES OF ORGANIZATIONS IN THE UNITED STATES 2 (Robert B. Toth ed., 1996), available at <http://gsi.nist.gov/global/docs/SP%20806.pdf>.

54. Robert W. Hamilton, *Prospects for the Nongovernmental Development of Regulatory Standards*, 32 AM. U. L. REV. 455, 462–64 (1983) (discussing how standard setting by ASTM requires balance of participation, consensus adoption, special procedure for no votes, written procedures, and an appeal mechanism); *Annual Book of ASTM Standards*, ASTM INT'L, http://www.astm.org/BOOKSTORE/BOS/standard_track1.htm (last visited Nov. 8, 2013) (stating that ASTM's Annual Book of Standards contains over 12,000 ASTM standards).

55. BÜTHE & MATTLI, *supra* note 44, at 5.

56. *Id.* at 137.

57. *Id.* at 131, 138.

58. INT'L ORG. FOR STANDARDIZATION, INTERNATIONAL STANDARDS AND "PRIVATE STANDARDS" 4 (2010), available at www.iso.org/iso/private_standards.pdf; see also BÜTHE & MATTLI, *supra* note 44, at 138–39 (stating that such bodies are often private-sector organizations funded largely by industry).

59. David A. Wirth, *The International Organization for Standardization: Private Voluntary Standards as Swords and Shields*, 36 B.C. ENVTL. AFF. L. REV. 79, 81 (2009).

ISO standard setting is coordinated by a secretariat in Geneva and carried out by tens of thousands of experts organized into hundreds of technical committees and subcommittees, and thousands of associated working groups.⁶⁰ Seeking to establish international consensus standards, ISO purports to abide by principles of transparency, openness, impartiality, and consensus set out in World Trade Organization (WTO) agreements.⁶¹ As explained by ISO, other SDOs at the international level such as private consortia in the fields of information and communications, agri-food industry organizations, and retailers that develop private standards relating to social and environmental aspects often do not adhere to the WTO principles of international standardization.⁶²

Many standards developed by private bodies are technical standards designed to ensure that parts or products made by one manufacturer function with those of others. They generally “regulate uniformity or interchangeability,” with limited relevance for health, safety, and environmental protection.⁶³ Economic actors generally have strong incentives to comply with such standards because they enhance the market for their products and services.⁶⁴ Industry has a long history of establishing and promoting these uniformity and interchangeability standards. For example, the pharmaceutical, automotive parts, railroad, and aviation industries have adopted such standards.⁶⁵

Other private standards, however, can be considered to be regulatory standards that “have significant implications for the public interest.”⁶⁶ They may, for example, regulate the maximum age of pilots, the level of pesticide residues in agricultural products, and the level of cadmium and other heavy

60. INT’L ORG. FOR STANDARDIZATION, *supra* note 58, at 5; BÜTHE & MATTLI, *supra* note 44, at 139.

61. INT’L ORG. FOR STANDARDIZATION, *supra* note 58, at 2, 8 (particularly mentioning annex 3 of the WTO TBT Agreement Code of Good Practice for the preparation, adoption and application of standards).

62. *Id.* at 6–7.

63. See CHEIT, *supra* note 7, at 5; *cf.* Strauss, *supra* note 19, at 499 (stating that SDOs have “long existed to create voluntary private standards by which to declare or measure the characteristics of goods on the marketplace”). Even technical standards, however, may have negative public interest impacts if they, for example, create barriers to market entry, freeze technological innovation, or reduce consumer choices. *Cf.* OFFICE OF COMMERCIAL SPACE TRANSP., U.S. DEP’T OF TRANSP., VOLUNTARY INDUSTRY STANDARDS AND THEIR RELATIONSHIP TO GOVERNMENT PROGRAMS 9 (1993), available at <http://www.strategicstandards.com/files/GovernmentStandards.pdf>.

64. See Büthe, *supra* note 17, at 17.

65. OFFICE OF COMMERCIAL SPACE TRANSP., *supra* note 63, at 3–4 (describing the history of standard setting in various industries).

66. See CHEIT, *supra* note 7, at 23.

metals in the surface coating of toys.⁶⁷ In contrast to technical standards that address network externalities, regulatory standards address social and environmental externalities.⁶⁸ Economic actors are less likely to have market incentives to privately create and enforce regulatory standards because such standards make them internalize the negative externalities of their activities.⁶⁹ Of ANSI standards that had been developed by 1990, roughly 10 percent related to the health and safety of industrial products and processes.⁷⁰ ISO has increasingly promulgated standards relevant to the environment and health and safety, including: standards for environmental management, environmental labeling, lifecycle assessment, greenhouse gas measurement, drinking water and wastewater services, and social responsibility.⁷¹

Aside from consensus standards, a wide variety of voluntary codes have been promulgated by industries, firms, and NGOs to regulate themselves or those with whom they establish business relationships.⁷² Voluntary codes setting forth responsible business practices “now exist for virtually every global industry and internationally traded commodity, including forestry, fisheries, chemicals, computers and electronic equipment, apparel, rugs, coffee, cocoa, palm oil, diamonds, gold, toys, minerals and mining, energy, tourism, financial service, and athletic equipment.”⁷³ They primarily address labor and environmental practices, often focusing on high-profile issues like sweatshops and sustainability.⁷⁴

67. Hamilton, *supra* note 54, at 455 (mentioning the rule that pilots be under a certain age). The test method ASTM F963-08, *Standard Consumer Safety Specification for Toy Safety*, places limits on the amount of antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium in toys. *FAQs: Lead In Paint (And Other Surface Coatings)*, U.S. CONSUMER PROD. SAFETY COMM’N, <http://www.cpsc.gov/en/Business--Manufacturing/Business-Education/Lead/FAQs-Lead-In-Paint-And-Other-Surface-Coatings/> (last visited Jan. 26, 2014).

68. Abbott & Snidal, *supra* note 31, at 45; *see also* Hamilton, *supra* note 54, at 455 (“Creating a regulatory standard requires an estimate of acceptable levels of risk Regulatory standards thus almost always involve social or political as well as technological issues.”).

69. Büthe, *supra* note 17, at 17.

70. *Cf.* CHEIT, *supra* note 7, at 22 (stating that 900 out of 8,500 ANSI standards in 1990 were considered to relate to health and safety).

71. INT’L ORG. FOR STANDARDIZATION, *supra* note 58, at 7. On ISO’s environmental management systems standard, *see especially* Wirth, *supra* note 59, at 82.

72. Stepan Wood, *Voluntary Environmental Codes and Sustainability*, in ENVIRONMENTAL LAW FOR SUSTAINABILITY 230 (Benjamin J. Richardson & Stepan Wood eds., 2006) (using the term code “in its ordinary sense as ‘a set of rules on any subject’”).

73. Vogel, *supra* note 6, at 71–72.

74. David Vogel, *Private Global Business Regulation*, 11 ANN. REV. POL. SCI. 261, 269 (2008).

Voluntary codes are often developed by industry associations and NGOs.⁷⁵ For example, the International Chamber of Commerce's Business Charter for Sustainable Development, endorsed by more than 2,000 global firms, sets out sixteen principles for environmental management.⁷⁶ The chemical industry's Responsible Care requires chemical companies "to recognize and respond to community concerns," "to develop and produce chemicals that can be manufactured, transported, used and disposed of safely," and "to report promptly to officials, employees, customers and the public, information on chemical-related health or environmental hazards."⁷⁷ The Forest Stewardship Council (FSC) established sustainable forestry goals for forest management operations that included, inter alia, complying with applicable laws, respecting the rights of indigenous peoples, and conserving biodiversity.⁷⁸

Other private standards are established by individual firms to regulate themselves. Standards for self-regulation often seek to accomplish objectives that are not legally required, and they may be embodied in a corporate code of conduct.⁷⁹ Examples discussed in the literature include ARCO's voluntary development of standards for reformulated cleaner gasoline in the late 1980s and voluntary codes adopted by the Body Shop, the Shell Group, and Interface Flooring.⁸⁰ Other self-regulatory standards involve the development of a management system. For example, some companies have established environmental management systems, which include policies and programs that help reduce the company's environmental impact.⁸¹

75. Vogel, *supra* note 6, at 73–74 (citing examples of codes initiated by NGOs, trade associations, trade unions, and international standards bodies); see also Vandenberg, *supra* note 4, at 922 (describing "collective standards").

76. Vogel, *supra* note 6, at 72; see also *ICC Business Charter for Sustainable Development*, INT'L INST. FOR SUSTAINABLE DEV., http://www.iisd.org/business/tools/principles_icc.asp (last visited Jan. 26, 2014).

77. Neil Gunningham, *Environmental Management Systems and Community Participation: Rethinking Chemical Industry Regulation*, 16 UCLA J. ENVTL. L. & POL'Y 319, 338 (1998).

78. Errol E. Meidinger, *The New Environmental Law: Forest Certification*, 10 BUFF. ENVTL. L.J. 211, 218 (2002).

79. Short & Toffel, *supra* note 18, at 361 (stating that self-regulation is commonly undertaken either "to demonstrate a commitment to comply with legal mandates or bring corporate conduct into line with widely shared normative ideals like workplace fairness or environmental sustainability"). For an interesting discussion of the forms of self-regulation and their various problems, see Black, *supra* note 30. On corporate codes of conduct, see, e.g., Elizabeth F. Brown, *No Good Deed Goes Unpunished: Is There a Need for a Safe Harbor for Aspirational Corporate Codes of Conduct?*, 26 YALE L. & POL'Y REV. 367 (2008).

80. Lyon & Maxwell, *supra* note 7, at 93; Wood, *supra* note 72, at 238.

81. See McAllister, *supra* note 21, at 16 n.105; Stepan Wood, *Environmental Management Systems and Public Authority in Canada: Rethinking Environmental Governance*, 10 BUFF. ENVTL. L.J. 129 (2002). Firms may also adopt international environmental management systems such as ISO 14001 or European Eco-Management and Audit Scheme (EMAS). See

Private firms also engage in regulatory standard setting when they impose social and environmental requirements on their suppliers.⁸² Every Fortune 500 Company and thousands of other major transnational corporations have adopted supplier codes of conduct, which usually set forth their expectations of suppliers with regard to the environment, labor, and human rights.⁸³ These codes of conduct may then be incorporated into supplier contracts.⁸⁴ Alternatively, or in addition, the parties to the contract may create a private standard or incorporate voluntary codes developed by industry groups or non-governmental organizations.⁸⁵ By including private standards of these various sorts, supply chain contracts often require suppliers to exceed public regulatory requirements.⁸⁶ A 2007 study found that more than half of the top firms in eight different sectors imposed private environmental requirements on their suppliers.⁸⁷

2. Implementation

In regulatory implementation, mechanisms are developed and deployed to monitor for compliance. Diverse private standards are implemented in diverse ways. As noted above, those private technical standards developed by SDOs that further the goals of uniformity and interchangeability are readily implemented by interested private actors for reasons of market expansion and profitability.⁸⁸ Even voluntary consensus standards that deal with health and safety are likely to attract high levels of compliance because they are generally developed with industry participation and compliance

Magali A. Delmas, *Barriers and Incentives to the Adoption of ISO 14001 by Firms in the United States*, 11 DUKE ENVTL. L. & POL'Y F. 1, 3–4 (2000).

82. Vandenbergh, *supra* note 1, at 156 (stating that “a growing number of corporate buyers impose environmental requirements on their global suppliers”).

83. Mayer & Gereffi, *supra* note 6, at 6 (explaining that Levi Strauss was one of the first multinational companies to tout its corporate code of conduct in 1991); Michael W. Toffel, et al., *Reinforcing Regulatory Regimes: How States, Civil Society, and Codes of Conduct Promote Adherence to Global Labor Standards* 6, (Harvard Bus. Sch., Working Paper No. 13-045, 2012) (stating that codes typically call for the supplier to comply with domestic labor, environmental, and human rights law as well as forbid practices such as child labor and prison labor).

84. Toffel et al., *supra* note 83, at 2.

85. Vandenbergh, *supra* note 1, at 154–55.

86. *Id.*

87. Vandenbergh, *supra* note 4, at 927–36.

88. See Tim Büthe, *The Power of Norms; the Norms of Power: Who Governs International Electrical and Electronic Technology*, in WHO GOVERNS THE GLOBE? 292, 324 (Deborah D. Avant et al. eds., 2010); Scott, *supra* note 30, at 7.

with them may reduce legal risk.⁸⁹ In these situations, private standards are often reliably implemented at the firm level.

Implementation of voluntary codes developed by industries, NGOs, and firms tend to require more complex mechanisms. Voluntary codes developed by industry associations and NGOs are often implemented through voluntary programs. In voluntary programs, participating firms (often referred to as members) commit to adhering to a set of requirements designed to produce social benefits.⁹⁰ Voluntary programs relating to environmental and labor practices have particularly proliferated in the past several decades.⁹¹ They often award a product label or other public recognition to their members. Examples include the FSC label for sustainable forest management and Social Accountability International's SA8000 logo for decent workplaces.⁹² Firms can implement self-regulatory standards through internal behavior modifications and supply-chain standards through contracts with their suppliers.

The audit is a common mechanism to monitor for compliance in private regulation.⁹³ Audits may be conducted by firms subject to regulation (commonly referred to as self-audits), another organization interested in the firm's compliance (for example, a purchaser of its products or an industry association to which it belongs), or an external entity paid by either the firm or an interested organization (commonly referred to as an independent or third-party audit). Voluntary programs increasingly rely on independent auditors to verify compliance. As explained by one observer, "[e]xternal inspection and monitoring have also become a standard part of private

89. Bütche, *supra* note 88, at 327 (discussing how international standards are often considered "best practices" and may provide a safeguard in civil litigation, particularly product liability litigation).

90. Matthew Potoski & Aseem Prakash, *Voluntary Clubs: An Introduction*, in VOLUNTARY PROGRAMS: A CLUB THEORY PERSPECTIVE 2 (Matthew Potoski & Aseem Prakash eds., 2009).

91. Tim Bartley & Shawna N. Smith, *Communities of Practice as Cause and Consequence of Transnational Governance: The Evolution of Social and Environmental Certification*, in TRANSNATIONAL COMMUNITIES: SHAPING GLOBAL ECONOMIC GOVERNANCE 347 (Marie-Laure Djelic & Sigrid Quack eds., 2010) (stating that the "transformation of certification into a mode of social/environmental regulation has occurred mainly since the 1990s"); ASEEM PRAKASH & MATTHEW POTOSKI, THE VOLUNTARY ENVIRONMENTALISTS: GREEN CLUBS, ISO 14001, AND VOLUNTARY REGULATIONS 60 (2006).

92. Vandenbergh, *supra* note 1, at 148–49 (discussing the FSC). See generally Tim Bartley, *Standards for Sweatshops: The Power and Limits of the Club Approach to Voluntary Labor Standards*, in VOLUNTARY PROGRAMS: A CLUB THEORY PERSPECTIVE, *supra* note 90 (on programs for labor standards).

93. For a theorization of the phenomenon of audit, see MICHAEL POWER, THE AUDIT SOCIETY: RITUALS OF VERIFICATION (1997); Michael Power, *Expertise and the Construction of Relevance: Accountants and Environmental Audit*, 22 ACCT., ORGS. & SOC'Y, 123, 126 (1997).

regulation.”⁹⁴ Others comment that third-party auditing is considered a “best practice” in voluntary programs.⁹⁵ Third-party audits are also used to assess compliance with self-regulation and supply-chain regulation.⁹⁶ Dubbed the private “assurance industry” by one commentator, private auditing companies form a “rapidly growing global army of privately trained and authorized inspectors and certifiers.”⁹⁷

While third-party audits are considered more rigorous than self-audits, many issues of reliability remain.⁹⁸ The auditors are formally independent but may still lack objectivity because the companies whose products or processes are being audited often arrange and pay for the audit.⁹⁹ Scholars of financial accounting have identified many reasons for auditor bias in this situation.¹⁰⁰ Concerns about auditor competence also arise. Because of competitive pressures, third-party verifiers will seek to reduce their costs, which may result in inadequate audits. An observer of garment factory audits in Asia conducted by a major auditing firm found that auditors had not effectively gathered information because they made short visits and failed to conduct sufficient interviewing or inspection.¹⁰¹ A related concern is that

94. Meidinger, *supra* note 31, at 238; *see also* Wood, *supra* note 72, at 242–43 (noting the trend toward increased third party verification of voluntary codes). *But see* Vogel, *supra* note 74, at 269 (“Relatively few industry and corporate codes are independently monitored; some contain no monitoring provisions at all, and others are monitored by the firms themselves.”).

95. PRAKASH & POTOSKI, *supra* note 91, at 59.

96. *See, e.g.*, Dara O’Rourke, *Outsourcing Regulation: Analyzing Nongovernmental Systems of Labor Standards and Monitoring*, 31 POL’Y STUD. J. 1, 11 (2003) (describing the “small army of monitors”); Toffel et al., *supra* note 83 (analyzing data obtained from one of the largest social auditing forms).

97. Margaret M. Blair, Cynthia A. Williams & Li-Wen Lin, *The New Role for Assurance Services in Global Commerce*, 33 J. CORP. L. 325, 329 (2008); *see also* Wood, *supra* note 72, at 261 (referring to the “huge industry of auditors, certifiers, and accreditation bodies that has emerged”).

98. *See, e.g.*, Neil Gunningham & Joseph Rees, *Industry Self-Regulation: An Institutional Perspective*, 19 LAW & POL’Y 363, 368 (1997) (discussing how the Gap’s sourcing standards initially included only “seriously defective” internal monitoring, but then the company agreed to use third-party monitoring which was much more effective); McAllister, *supra* note 21, at 38–45 (discussing the problems of auditor independence and competence).

99. Blair et al., *supra* note 97, at 334.

100. *See, e.g.*, Max H. Bazerman et al., *Why Good Accountants Do Bad Audits*, HARV. BUS. REV., Nov. 2002, at 97, 98; Jonathan Macey & Hillary A. Sale, *Observations on the Role of Commodification, Independence, and Governance in the Accounting Industry*, 48 VILL. L. REV. 1167, 1167 (2003); Patricia A. McCoy, *Realigning Auditors’ Incentives*, 35 CONN. L. REV. 989, 990 (2003) (stating that the basic problem afflicting the accounting industry is that “accounting firms work for the companies they audit”).

101. Dara O’Rourke, *Monitoring the Monitors: A Critique of Corporate Third-Party Labor Monitoring*, in CORPORATE RESPONSIBILITY AND LABOUR RIGHTS: CODES OF CONDUCT IN THE GLOBAL ECONOMY 196–208 (Rhys Jenkins et al. eds., 2002) (documenting observa-

auditing might consist of mechanically applied checklists and “box-ticking” that fail to capture the true compliance situation of a regulated entity.¹⁰²

Given the importance to business actors of auditing themselves and others for compliance with private standards, ISO and IEC developed a series of applicable international standards. ISO/IEC’s 17000 series standardizes “conformity assessment,” defined as the “demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.”¹⁰³ These standards set forth the various types of conformity assessment and how organizations that conduct conformity assessment should look and act. As specified in ISO/IEC 17000, first-party conformity assessment is performed by the organization that provides the object of the assessment, second-party conformity assessment is performed by an organization that has a user interest in the object, and third-party conformity assessment is performed by a body independent of both the organization that provides the object and organizations with user interests.¹⁰⁴

The main forms of conformity assessment under ISO/IEC standards are testing, inspection, and certification.¹⁰⁵ “Testing” means the “determination of one or more characteristics of an object of conformity assessment, according to a procedure,” while inspection is an “examination of a product design, product, process or installation and determination of its conformity” with requirements.¹⁰⁶ “Certification” refers to the issuance of a statement by a third party whose products, processes, systems, or persons fulfill specified requirements.¹⁰⁷ Different ISO/IEC standards in the 17000 series apply to testing bodies (usually laboratories), inspection bodies, and

tions of factory audits in Asia by PriceWaterhouseCoopers, which was the world’s largest private monitor of labor and environmental practices).

102. Friederike Albersmeier et al., *The Reliability of Third-Party Certification in the Food Chain: From Checklists to Risk-Oriented Auditing*, 20 FOOD CONTROL 927, 933 (2009); Gunningham, *supra* note 77, at 360; McAllister, *supra* note 21, at 43.

103. INT’L ORG. FOR STANDARDIZATION & INT’L ELECTROTECHNICAL COMM. [ISO/IEC], ISO/IEC DOC. 17000:2004, CONFORMITY ASSESSMENT—VOCABULARY AND GENERAL PRINCIPLES 2.1 (2004) [hereinafter CONFORMITY ASSESSMENT] (internal cross-references omitted).

104. *Id.* at 2.2–2.4.

105. *What is conformity assessment?*, INT’L ORG. FOR STANDARDIZATION, <http://www.iso.org/iso/home/about/conformity-assessment.htm> (last visited Nov. 7, 2013).

106. CONFORMITY ASSESSMENT, *supra* note 103, at 4.2–4.3. INT’L ORG. FOR STANDARDIZATION & UNITED NATIONS INDUSTRIAL DEV. ORG. [ISO/UNIDO], BUILDING TRUST: THE CONFORMITY ASSESSMENT TOOLBOX 34–35 (2010), *available at* http://www.iso.org/iso/casco_building-trust.pdf.

107. CONFORMITY ASSESSMENT, *supra* note 103, at 5.5 (defining certification with the use of the term attestation) and 5.2 (defining attestation).

certification bodies, which are collectively referred to as conformity assessment bodies.¹⁰⁸

Certification is the most well-known form of conformity assessment, and it differs from testing and inspection in an important way.¹⁰⁹ Unlike testing or inspection, certification is by definition performed by a third party, and it requires that the third party conduct not just initial conformity assessment activities like testing and inspection but also the surveillance necessary to attest to the continuing conformity of a product, process, system, or person.¹¹⁰ “Surveillance” is defined by ISO/IEC as a “systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.”¹¹¹ Market surveillance is a particular form of surveillance used in some certification schemes where samples of certified products in the marketplace are tested to determine whether they conform to specified requirements.¹¹²

Accreditation is another key aspect of conformity assessment under ISO standards.¹¹³ “Accreditation” is a “third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.”¹¹⁴ Accreditation bodies determine whether testing, inspection, and certification bodies are operating in accordance with the ISO/IEC standards that apply to them.

108. Testing is regulated by ISO/IEC 17025. ISO/IEC, ISO/IEC Doc. 17025:2005, GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES (2005). Inspection is regulated by ISO/IEC 17020. ISO/IEC, ISO/IEC Doc. 17020:2012, CONFORMITY ASSESSMENT—REQUIREMENTS FOR THE OPERATION OF VARIOUS TYPES OF BODIES PERFORMING INSPECTION (2012). Certification is regulated by ISO/IEC Guide 65 or ISO/IEC 17065. ISO/IEC, ISO/IEC GUIDE 65:1996, GENERAL REQUIREMENTS FOR BODIES OPERATING PRODUCT CERTIFICATION SYSTEMS (1996), *revised by* ISO/IEC, ISO/IEC Doc. 17065:2012, CONFORMITY ASSESSMENT—REQUIREMENTS FOR BODIES CERTIFYING PRODUCTS, PROCESSES AND SERVICES (2012) (replacing Guide 65, with the transition to the new standard expected to be completed by September 2015).

109. INT’L ORG. FOR STANDARDIZATION, *supra* note 105 (stating that testing is most common, but certification is best known).

110. Telephone Interview with Gordon Gillerman, Chief, Standards Servs. Div., Nat’l Inst. of Standards & Tech. (Aug. 15, 2012); ISO/UNIDO, *supra* note 106, at 52–55 (setting forth various systems that include surveillance and meet the definition of product certification).

111. CONFORMITY ASSESSMENT, *supra* note 103, at 6.1; ISO/UNIDO, *supra* note 106, at 44.

112. ISO/UNIDO, *supra* note 106, at 45.

113. Accreditation is regulated by ISO/IEC 17011. ISO/IEC, ISO/IEC Doc. 17011:2004, GENERAL REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING CONFORMITY ASSESSMENT BODIES (2004).

114. CONFORMITY ASSESSMENT, *supra* note 103, at 5.6; ISO/UNIDO, *supra* note 106, at 24.

Accreditation bodies may be public or private entities, and some countries have one or more private accreditation bodies in addition to or instead of a national accreditation body.¹¹⁵ Accreditation bodies, in turn, are often members of either the International Accreditation Forum (IAF) or the International Laboratory Accreditation Cooperation (ILAC), which require adherence to international standards for accreditation bodies and use a system of peer evaluation to assess accreditation bodies for membership.¹¹⁶ Their objective is that conformity assessment bodies accredited by member accreditation bodies will be recognized as competent in multiple jurisdictions and markets.¹¹⁷ In the words of the accreditation industry, “tested or certified once—accepted everywhere.”¹¹⁸

It is useful to understand that conformity assessment encompasses a spectrum of rigor and independence.¹¹⁹ Depending on the level of confidence or assurance required, the technical activities of conformity assessment may be more or less rigorous, and the organizations that conduct conformity may be more or less independent. When the user of a conformity assessment system—for example, a purchaser—needs just a basic level of assurance, a first-party testing or inspection may be adequate. When the purchaser needs more assurance, it could require, for example, testing in an accredited third-party laboratory. When the purchaser needs much more

115. ISO/UNIDO, *supra* note 106, at 25, 86–88.

116. See e.g., INT’L LAB. ACCREDITATION COOPERATION, <https://www.ilac.org/> (last visited Nov. 29, 2013). IAF is comprised of accreditation bodies that accredit certification bodies whereas ILAC is comprised of accreditation bodies that accredit laboratories. Both IAF and ILAC have established voluntary agreements through which member accreditation bodies agree to adhere to international standards when accrediting testing and certification bodies: the IAF Multilateral Recognition Agreement (IAF MLA) and the ILAC Mutual Recognition Agreement (MRA). OFFICE OF THE U.S. TRADE REPRESENTATIVE [USTR], REPORT ON TECHNICAL BARRIERS TO TRADE 28 (2012), available at http://www.us-tr.gov/webfm_send/3323; see also INT’L ACCREDITATION FORUM & INT’L LAB. ACCREDITATION COOPERATION [IAF/ILAC], IAF/ILAC-A3:01/2013, IAF/ILAC MULTILATERAL MUTUAL RECOGNITION ARRANGEMENTS (ARRANGEMENTS): NARRATIVE FRAMEWORK FOR REPORTING ON THE PERFORMANCE OF AN ACCREDITATION BODY (AB) (2013), available at https://www.ilac.org/documents/IAF-ILAC_A3_01_2013.pdf.

117. ISO/UNIDO, *supra* note 106, at 89; see also USTR, *supra* note 116, at 28 (explaining that by demonstrating the equivalence of the accreditation bodies that accredit testing and certification bodies, they aim to “provide governments, as well as suppliers, assurances that a body—regardless of its location—is competent to test and certify products for relevant markets”).

118. IAF: *What is the International Accreditation Forum, INC.?*, U.K. ACCREDITATION SERVICE, <http://www.ukas.com/technical-information/international-role/iaf.asp> (last visited Nov. 29, 2013); see also INT’L ACCREDITATION FORUM, <http://www.iaf.nu/> (last visited Nov. 29, 2013) (showing the slogan “certified once, accepted everywhere” in the bottom right hand corner of the page).

119. Telephone Interview with Gordon Gillerman, *supra* note 110.

assurance, it could require certification by an accredited third party based on testing conducted in an accredited third-party laboratory.

ISO conformity assessment standards are increasingly being adopted by private regulators. For example, since 2006, FSC has required that its certification bodies be accredited by ASI International, which operates in accordance with the ISO/IEC standard for accreditation bodies.¹²⁰ Also, in 2009, FSC promulgated a standard specifying the requirements for FSC certification bodies that explicitly incorporates many of the requirements of the ISO/IEC standard for certification bodies.¹²¹

3. Enforcement

Enforcement, the process by which deviance from regulatory standards is corrected, is often a weakness of private regulatory regimes that impose requirements relating to health, safety, and the environment.¹²² According to one scholar of private regulation, few voluntary codes contain explicit sanctions for nonconformity or formal mechanisms for enforcement or dispute resolution.¹²³ In the words of another, “business compliance with most codes has been uneven” and few are effectively enforced.¹²⁴

Notably, the subjects of private regulation—whether they are members of a voluntary program, firms that self-regulate, or suppliers subject to contract conditions—have incentives to cheat. Companies may establish codes of conduct or join voluntary programs for public relations reasons and lack a serious commitment to changing their behavior.¹²⁵ Companies may find monitoring their compliance with codes to be costly and have limited incentives to enforce them.¹²⁶ Not all voluntary programs require third-

120. *Programs*, ACCREDITATION SERVICES INT'L, <http://www.accreditation-services.com/programs> (last visited Nov. 29, 2013).

121. FOREST STEWARDSHIP COUNCIL, FSC-STD-20-001 (VERSION 3-0) EN, FSC INTERNATIONAL STANDARD: GENERAL REQUIREMENTS FOR FSC ACCREDITED CERTIFICATION BODIES—APPLICATION OF ISO/IEC GUIDE 65:1996 (E) (2009), *available at* <http://ic.fsc.org/download.fsc-std-20-001-v3-0-en-general-requirements-for-fsc-accredited-certification-bodies.a-1130.pdf>.

122. *Cf.* Gunningham & Rees, *supra* note 98, at 370 (“According to the critics, self-regulatory standards are usually weak, enforcement is ineffective and punishment is secret and mild.”).

123. Wood, *supra* note 72, at 261–62 (stating further that “[t]his lack of sanctions and enforcement is often identified as one of the key weaknesses of voluntary codes”).

124. Vogel, *supra* note 6, at 80.

125. Cary Coglianese & David Lazer, *Management-Based Regulation: Prescribing Private Management to Achieve Public Goals*, 37 LAW & SOC'Y REV. 691, 708 n.14 (2003) (discussing the incentives of firms to cheat).

126. Mayer & Gereffi, *supra* note 6, at 19.

party monitoring, and even fewer involve the public disclosure of monitoring information and sanctions for members that do not comply.¹²⁷

Even companies that impose codes of conduct on their global suppliers may have weak incentives to enforce them. Companies have often developed codes in response to pressure from NGOs, shareholders, and governments. This pressure may subside once the code is adopted.¹²⁸ Also, rigorously enforcing compliance with codes is likely to increase the cost of doing business, which runs against the very reason for global supply chains.¹²⁹ Importantly, it is easy for buyer and supplier firms to hide code violations, given that supplier firms tend to be numerous and geographically dispersed and their identities are often confidential.¹³⁰

When private regulators are serious about enforcement, there are a variety of sanctions they may employ to correct deviations. In voluntary programs that award a label or recognition, the private regulators may revoke or threaten to revoke this benefit.¹³¹ Removal from a voluntary program might also involve expulsion from an industry association, which may limit the firm's economic opportunities.¹³² When the administrator of a voluntary program has such strong sanctions available, it may also be able to impose remedial measures such as product recalls or environmental reparations.¹³³ Buyers that include private standards in supply chain contracts can respond to violations by refusing to buy from offending suppliers.

Public disclosure of code violations also constitutes a powerful sanction. Private regulators can require the public release of third-party audit reports regarding the compliance of firms with voluntary programs or supply chain requirements. Also, a label or other recognition may be revoked in a way that involves a public process of "naming and shaming."¹³⁴ NGOs, trade unions, consumers, and investors may thereby contribute to the sanction by denying a company's "social license to operate."¹³⁵

127. Potoski & Prakash, *supra* note 90, at 27 (referring to programs that require all three components as "strong sword" programs).

128. Toffel et al., *supra* note 83, at 7.

129. *Id.* at 8.

130. *Id.* at 9.

131. Gunningham & Rees, *supra* note 98, at 396; *see also* Meidinger, *supra* note 31, at 238 (stating that "[t]he only formal sanction in most private regulatory systems is the loss of the certifying organization's approval, or the threat of that loss").

132. Gunningham & Rees, *supra* note 98, at 396.

133. *Id.*

134. Edward J. Balleisen, *The Prospects for Effective Coregulation in the United States: A Historian's View from the Early Twenty-First Century*, in GOVERNMENT AND MARKETS: TOWARD A NEW THEORY OF REGULATION 443, 447 (Edward J. Balleisen & David A. Moss eds., 2009); Vandenbergh, *supra* note 1, at 137–38.

135. Gunningham et al., SHADES OF GREEN: BUSINESS, REGULATION, AND THE ENVIRONMENT 36–37 (2003) (introducing the concept of the social license to operate, that

Responsible Care illustrates how enforcement mechanisms can be weak even in a voluntary program characterized by significant industry mobilization and other conditions favoring effective private regulation.¹³⁶ While Responsible Care has been implemented by fifty-five national chemical industry associations and thousands of their member companies participate, revocations of a company's Responsible Care status have occurred rarely, if at all, over its twenty-five-year history.¹³⁷ Moreover, third-party auditing is generally not required and national industry associations do not make membership contingent on participation in Responsible Care.¹³⁸

The FSC stands as an example of a private regulatory regime with relatively well-developed monitoring and enforcement mechanisms.¹³⁹ The FSC requires that an accredited third party certify that a forestry operation is in compliance with its standards.¹⁴⁰ The FSC has at times removed the accreditation status of certifiers,¹⁴¹ and forestry operations have at times had their certifications revoked.¹⁴² The negative impact of a certification revocation

depend on a firm meeting social expectations concerning environmental performance and other forms of social responsibility); RHYS JENKINS, UNITED NATIONS RESEARCH INST. FOR SOC. DEV., CORPORATE CODES OF CONDUCT: SELF-REGULATION IN A GLOBAL ECONOMY 8–18 (2001) (discussing the attitudes of various stakeholders toward self-regulation).

136. See Gunningham, *supra* note 77, at 339–44 (discussing the characteristics of the chemical industry and the Responsible Care program that favor its effectiveness).

137. INT'L COUNCIL OF CHEM. ASS'NS, ICCA RESPONSIBLE CARE PROGRESS REPORT: GROWING OUR FUTURE (2012), available at www.icca-chem.org/ICCADocs/RC%20annual%20report.pdf (documenting membership and practices in various countries, with no reference to revocation actions); Freeman, *supra* note 16, at 647 (stating that there have been no expulsions from Responsible Care); Gunningham, *supra* note 77, at 348 (stating that the likelihood of expulsion is very low and there have been no documented cases).

138. See INT'L COUNCIL OF CHEM. ASS'NS, *supra* note 137, at 22–50 (surveying the “verification and performance” descriptions).

139. Scott, *supra* note 14, at 73 (referring to FSC as one of the “more complete regimes, which involve not only the setting of norms but also the generation of mechanisms for monitoring and enforcement”).

140. FSC relies on another private organization, Accreditation Services International, to perform the accreditation. *Accreditation Program: Ensuring Excellence in Certification*, FOREST STEWARDSHIP COUNCIL, <https://ic.fsc.org/accreditation.28.htm> (last visited Nov. 5, 2013). As of 2013, there were thirty-three accredited certification bodies for the program. *Certification Bodies for FSC*, ACCREDITATION SERVS. INT'L, <http://www.accreditation-services.com/archives/standards/fsc> (last visited Jan. 27, 2014).

141. Errol Meidinger, *The Administrative Law of Global Private-Public Regulation: The Case of Forestry*, 17 EUR. J. INT'L L. 47, 74 (2006).

142. See, e.g., Jeremy Hance, *Paper Company Loses Green Certification After Rainforest Destruction in Indonesia*, MONGABAY.COM (Apr. 18, 2010), http://news.mongabay.com/2010/0418-hance_april.html.

is amplified by NGOs that publicize the loss of certification and buyers that are committed to buying only certified forest products.¹⁴³

B. Harnessing Private Regulation

Under certain circumstances, private regulation may “prove more effective than public regulation.”¹⁴⁴ As early as 1937, one legal commentator observed that actors who are “part of the relation to be regulated are likely to have a more urgent sense of the problem and the possibilities of effective solution: experience and experiment lie immediately at hand” and therefore suggested that “public administrations . . . should not be the exclusive method of regulation.”¹⁴⁵ Oft-cited advantages of private regulation include the proximity of the regulator to the regulated activity, the flexibility of the regulatory process, greater compliance, and additional regulatory resources.¹⁴⁶ Private regulation developed to certify Kosher food and the fire safety of building materials and electrical products have been cited as two cases in which private certification overcame political and resource constraints that hampered government regulation.¹⁴⁷

However, private regulation often suffers from limitations that reduce its effectiveness. An important limitation is the inherently voluntary nature of participation. Firms that no longer want to comply can choose not to participate. Other “[p]otential disadvantages include conflicts of interest, inadequate enforcement and accountability, and insufficient monitoring of compliance.”¹⁴⁸ In the evaluation of one observer, private regulatory schemes are often not “effectively enforced and most cover only a minority of relevant global producers.”¹⁴⁹ Scholars have noted that private regulation is more likely to be effective in some contexts than others. Factors favoring more effective private regulation include the extent to which companies care about their reputation, “the existence of sufficient bureaucratic capacity

143. Meidinger, *supra* note 141, at 75.

144. Fabrizio Cafaggi & Andrea Renda, *Public and Private Regulation: Mapping the Labyrinth* 12 (CEPS Working Document, No. 370, 2012).

145. Louis L. Jaffe, *Law Making by Private Groups*, 51 HARV. L. REV. 201, 212 (1937) (further observing that “group self-government” is likely to develop positive qualities such as efficiency and the sense of responsibility).

146. Cafaggi & Renda, *supra* note 144, at 12; *see also* Lytton, *supra* note 40 (citing technical expertise, flexibility, monitoring, responsiveness, cooperation, and efficiency as comparative institutional advantages of private certification over government regulation).

147. Lytton, *supra* note 40.

148. Cafaggi & Renda, *supra* note 144, at 12.

149. Vogel, *supra* note 6, at 80.

and autonomy on the part of nongovernmental regulators,” and “the degree of transparency in [the] regulatory process.”¹⁵⁰

Recognizing that private regulation is prevalent and that it may have advantages over public regulation in certain situations raises the question of how private and public regulation might be combined to create stronger, more effective regulatory regimes. Scholarly writing on co-regulation and “public-private partnerships” has explored this idea to some extent.¹⁵¹ Scholars tend to approach the issue from one of two directions. They may analyze how the effectiveness and legitimacy of private regulation might be improved by being more closely integrated into public regulation.¹⁵² Alternatively, they may recognize that private actors are “regulatory resources capable of contributing to the efficacy and legitimacy” of public regulation and ask how “private capacity [could be harnessed] to serve public goals.”¹⁵³

Harnessing, as used in this Article, analyzes how public legislators and regulators can intentionally construct regulatory frameworks that rely upon and incorporate private regulation. When private regulation is harnessed by public regulation, “structures of private governance” are embedded and integrated into a “broader framework of public oversight.”¹⁵⁴ Public regulators tap into private regulatory capacity, constituting a “state-sanctioned

150. Balleisen & Eisner, *supra* note 34, at 131.

151. See especially Balleisen, *supra* note 134, at 468–76; Balleisen & Eisner, *supra* note 34, at 129; Jody Freeman, *Extending Public Law Norms Through Privatization*, 116 HARV. L. REV. 1285, 1288 (2003); Freeman, *supra* note 16, 549.

152. See Coglianese & Lazer, *supra* note 125, at 726 (discussing how management-based regulation gets an enforcement edge from government presence); Freeman, *supra* note 151, at 1285 (examining how privatization might extend public norms); Mayer & Gereffi, *supra* note 6, at 19 (“In our view, unless private governance is supplemented and reinforced by public institutions of governance, it cannot provide adequate governance capacity for the global economy.”); Scott, *supra* note 20, at 1334–35 (discussing how private regulatory regimes can gain legitimacy though having relationship to governmental policy); Vogel, *supra* note 6, at 83 (“Until the world’s developed countries are willing to more closely integrate the norms of civil regulations into their domestic laws and international relations, the global regulatory failures private social regulation was intended to redress will persist.”).

153. Freeman, *supra* note 16, 549; see also Balleisen, *supra* note 134, at 445 (stating that this “essay offers an analytical framework for evaluating the growing reliance on nongovernmental rule making and oversight as a basic tool of regulatory policy”); Ian Bartle & Peter Vass, *Self-Regulation within the Regulatory State: Towards a New Regulatory Paradigm?*, 85 PUB. ADMIN. 885, 885, 903 (2007) (discussing how “the achievement of regulatory outcomes can be delegated downwards to the regulated organizations and self-regulatory bodies while being offset by increasing public regulatory oversight based on systems of accountability and transparency”); Gunningham & Rees, *supra* note 98, at 399–400 (asking “how should co-regulatory mechanisms best be designed, in order to take advantage of the strengths and virtues of industry self-regulation, while compensating for its weaknesses as a stand alone mechanism?”); Meidinger, *supra* note 31, at 243 (discussing how government agencies can act as conductors when public and private regulation interacts).

154. Balleisen & Eisner, *supra* note 34, at 129.

and state-bolstered involvement of private actors in governance processes.”¹⁵⁵ The public policy objective of harnessing private regulation is to exploit the strength and resources of private regulatory institutions and actors in support of public goals.¹⁵⁶ Concerns likely to be raised about harnessing include the legality of delegating power to private actors and the ability of government to ensure that private power does not impede the attainment of those goals.¹⁵⁷

This Article is concerned primarily with strong forms of harnessing in which public regulation incorporates elements of private regulation such that they become an essential part of the regulatory regime. In weaker forms of harnessing, public regulation may provide incentives to private actors to fulfill one or more complementary regulatory function, but the private regulatory function does not become essential. An example is EPA’s Audit Policy, which provides an incentive to regulated entities for self-auditing by reducing the penalties for violations that entities discover through environmental audits.¹⁵⁸ Weak harnessing is also effectuated by provisions in federal environmental laws that grant a right of action to private citizens to sue violators.¹⁵⁹ Citizen enforcement is thought to motivate and improve governmental enforcement by serving as a “competitive spur” and helping to “keep compliance issues high on the agendas of top agency officials.”¹⁶⁰

In strong forms of harnessing, the private regulatory function can take the place of or substitute for a public regulatory function in a regulatory regime constructed by public actors. In strong harnessing, legal regulation

155. See ANDREAS KRUCK, PRIVATE RATINGS, PUBLIC REGULATIONS: CREDIT RATING AGENCIES AND GLOBAL FINANCIAL GOVERNANCE 5 (2011).

156. Cf. Perritt, *supra* note 42, at 215 (“Hybrid regulation—the combination of broad public law frameworks within which private regulatory regimes work out the details—is a promising way to realize the advantages of private regulation while mitigating the disadvantages.”).

157. See especially Coglianese, *supra* note 125, at 721–23; Hamilton, *supra* note 19, at 1437–38; McAllister, *supra* note 21, at 29–30; Miriam Seifter, *Rent-a-Regulator: Design and Innovation in Privatized Governmental Decisionmaking*, 33 *ECOLOGY L.Q.* 1091, 1125–27 (2006); Shapiro, *supra* note 17, at 410–11.

158. Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations, 65 *Fed. Reg.* 19,618, 19,625 (Apr. 11, 2000) (defining environmental audit as a “systematic, documented, periodic and objective review by regulated entities of facility operations and practices related to meeting environmental requirements”); see also Short & Toffel, *supra* note 18, at 366–67.

159. On environmental citizen suits, see especially Barry Boyer & Errol Meidinger, *Privatizing Regulatory Enforcement: A Preliminary Assessment of Citizen Suits Under Federal Environmental Laws*, 34 *BUFF. L. REV.* 833 (1985); Barton H. Thompson, Jr., *The Continuing Innovation of Citizen Enforcement*, 2000 *U. ILL. L. REV.* 185.

160. Boyer & Meidinger, *supra* note 159, at 957.

and private governance are “yoked together” and “integrated into a single system in which the functioning of each element is necessary for the successful operation of the other.”¹⁶¹ When strong harnessing is present, public regulators often assume new roles relating to the evaluation and oversight of the private regulators.¹⁶²

1. Incorporation of Private Standards

A longstanding example of strong harnessing is the incorporation of private standards into public law.¹⁶³ A 1978 study reported “that most regulatory standards applicable today were developed initially by the nongovernmental sector and made mandatory by incorporation by reference” and that “government-developed standards were a relatively insignificant fraction of all mandatory standards.”¹⁶⁴ By 2013, over 9,500 private standards had been incorporated by reference into federal regulation.¹⁶⁵ A variety of public benefits may be attained through public reliance on existing private standards. As explained by one commentator, relying on private standards is more cost-effective for the federal government, allows agencies to tap into expertise in the private sector, and facilitates industry compliance.¹⁶⁶

Federal regulatory laws such as the Occupational Safety and Health Act of 1970 and the Consumer Products Safety Act of 1972 directed agencies to rely on existing voluntary standards in various ways.¹⁶⁷ In its first two years,

161. Trubek & Trubek, *supra* note 17, at 541, 543.

162. Cf. Gunningham et al., *Harnessing Third Parties as Surrogate Regulators: Achieving Environmental Outcomes by Alternative Means*, 8 BUS. STRATEGY & ENV'T 211, 219 (1999) (explaining that “there is an essential policy role for government to shape market orderings and to facilitate the constructive activities of non-governmental institutions”); Perritt, *supra* note 42, at 250 (“Hybrid regulation can be understood as providing public law frameworks to assure accountability.”).

163. See, e.g., Bremer, *supra* note 19; Mendelson, *supra* note 19; Strauss, *supra* note 19, at 502 (explaining that private standards are sometimes converted into regulatory requirements).

164. Hamilton, *supra* note 54, at 459 (considering, for example, building codes, plumbing codes, electrical codes, fire protection).

165. Bremer, *supra* note 19, at 135; *Standards Incorporated by Reference (SIBR) Database*, NAT'L INST. OF STANDARDS & TECH., <https://standards.gov/sibr/query/index.cfm> (last visited Nov. 26, 2013) (showing 10,562 records in the “All Regulatory” link).

166. Bremer, *supra* note 19, at 140. *But see* Shapiro, *supra* note 17, at 406–11 (analyzing the possibilities for opportunistic behavior, incomplete contracting, and hold-up problems).

167. Cf. Hamilton, *supra* note 19; Elliot Klayman, *Standard Setting Under the Consumer Product Safety Amendments of 1981—A Shift in Regulatory Philosophy*, 51 GEO. WASH. L. REV. 96, 100–01 (1982); see also OFFICE OF COMMERCIAL SPACE TRANSP., *supra* note 63 (citing additional examples in the work of the U.S. Coast Guard, the Federal Aviation Administration, the Nuclear Regulatory Commission and other agencies).

the Occupational Health and Safety Administration (OSHA) was directed to adopt voluntary consensus standards as governmental standards unless such adoption would not result in improved worker health or safety.¹⁶⁸ After this initial period, a preference for consensus standards was maintained by the law's requirement that OSHA state its reasons for adopting any rule that differs substantially from an existing consensus standard.¹⁶⁹ Similar statutory support for the use of consensus standards led the Consumer Products Safety Administration to adopt a policy not to develop governmental standards if "acceptable" consensus standards were developed and adhered to by consumer product manufacturers.¹⁷⁰

The federal government has also endorsed the public use of private standards in general laws and policies. In 1982, the Office of Management and Budget (OMB) issued a Circular stating that it was the "policy of the Federal Government in its procurement and regulatory activities to [r]ely on voluntary standards, both domestic and international, whenever feasible and consistent with law and regulation pursuant to law."¹⁷¹ Congress gave statutory force to this endorsement in 1995 with the National Technology Transfer Advancement Act (NTTAA), mandating that federal agencies use technical standards developed by voluntary consensus standards bodies rather than government-unique standards as a means of carrying out policy objectives unless "inconsistent with applicable law or otherwise impractical."¹⁷² While the Act's legislative history acknowledges a distinction between technical standards and regulatory standards, this Congressional endorsement strengthened the authority of federal agencies to rely on voluntary consensus standards in carrying out their regulatory objectives.¹⁷³

168. Freeman, *supra* note 16, at 640 n.401; Hamilton, *supra* note 19, at 1388.

169. HARM SCHEPEL, THE CONSTITUTION OF PRIVATE GOVERNANCE: PRODUCT STANDARDS IN THE REGULATION OF INTEGRATING MARKETS 95 (2005) (discussing OSHA Section 6(b)(8)).

170. Hamilton, *supra* note 54, at 467.

171. OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, CIRCULAR NO. A-119, DEPARTMENT OF COMMERCE PARTICIPATION IN THE DEVELOPMENT AND USE OF VOLUNTARY STANDARDS (1983), available at http://www.osec.doc.gov/opog/dmp/daos/dao216_14.html (revised by the passage of the National Technology Transfer Advancement Act, 63 Fed. Reg. 8546 (Feb. 19, 1998)).

172. National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, 110 Stat. 775, § 12(d)(3) (1996) (codified in scattered sections of 15 U.S.C.).

173. The NTTAA formally covers only technical standards, as distinguished from regulatory standards. See Strauss, *supra* note 19, at 526, 526 n.201 (discussing legislative history of NTTAA suggesting that the Act's and the Circular's endorsement of incorporation by reference applies to technical standards and not regulatory standards, wherein the former pertain to matters such as the "size, strength, or technical performance of a product, process, or material" and the latter "establish[] overall regulatory goals and outcomes"). However, as Strauss recognizes, the Act and Circular are used to support the incorporation

Although a longstanding practice, incorporation of private standards continues to raise important policy concerns. One is that public regulation will incorporate standards that were created without the due process protections of public standardization. To some extent, this concern has been addressed by the norms that govern the creation of voluntary consensus standards.¹⁷⁴ According to one commentator, “private standardization has assimilated the canons of administrative law to such an extent that it is hard to find a difference” between its procedures and those of public law.¹⁷⁵

Yet while procedures may seem similar, private interests may overwhelm public interests more than in public rulemaking. A 1990 study that compared public and private safety standards in several industries found that private standard setting may be “controlled by those who want the least done,” resulting in standards that are “watered down.”¹⁷⁶ The study also found that the consensus process allows industry interests to outweigh consumer and other public interests.¹⁷⁷ A consumer advocate, for example, may cast a negative vote, but be overridden by a larger number of industry advocates.¹⁷⁸ While consumer advocates are not excluded from the process, they are less likely to have the resources for effective participation.¹⁷⁹

Another significant concern is raised by the copyrighted status of many private standards that are incorporated by reference.¹⁸⁰ When private standards are incorporated by reference in regulation, the text of the regulation simply refers to the standard by name or other identifying information rather than reproducing it in the Federal Register.¹⁸¹ Often, to be accessed, these incorporated private standards must be purchased from SDOs at

of regulatory standards as well. *Id.* at 558–59 (recommending that regulatory standards not be able to be incorporated by reference); *see also* Mendelson, *supra* note 19, at 792 (discussing how “[s]o-called ‘technical’ standards often function to define substantive policy”).

174. *See supra* notes 49–52 and associated text; *see also* Hamilton, *supra* note 54, at 462–64 (describing the development process for consensus standards).

175. SCHEPEL, *supra* note 169, at 409; *cf.* CHEIT, *supra* note 7, at 15 (stating “there is a surprising degree of similarity in procedural requirements in the public and private sectors”); Meidinger, *supra* note 31, at 237 (stating that “certain institutional patterns have become common in private regulation for each of these functions [standard setting, etc.], and they bear many similarities to government regulation”).

176. CHEIT, *supra* note 7, at 176.

177. *Id.* at 176–77.

178. *Id.* at 176.

179. *Id.* at 177. *But see* Hamilton, *supra* note 54, at 467 (observing that SDOs have been sensitive to the charge that consumer and other public interests are not well represented and citing ASTM and other organizations’ policies to encourage participation).

180. Lawrence A. Cunningham, *Private Standards in Public Law: Copyright, Lawmaking and the Case of Accounting*, 104 MICH. L. REV. 291, 292 (2005) (“Government increasingly leverages its regulatory function by embodying in law standards that are promulgated and copyrighted by non-governmental organizations.”).

181. Bremer, *supra* note 19, at 133.

commercial prices.¹⁸² This practice undermines the principle that the content of public law should be publicly available.¹⁸³

Various reforms have been proposed to make incorporated standards publicly accessible. A 2011 recommendation of the Administrative Conference of the United States recommended that agencies “work with the copyright owner to ensure that material will be reasonably available to regulated and other interested parties both during rulemaking and following promulgation.”¹⁸⁴ One observer has argued that, at a minimum, incorporated standards should be available to all interested parties without charge through digital, read-only access.¹⁸⁵ Another recommends that the federal government derecognize the copyright of incorporated standards in certain situations.¹⁸⁶

2. Public Endorsement of Self-Regulation

Strong harnessing is also present in regulatory approaches like enforced self-regulation and audited self-regulation where the government endorses the role of private regulators in making and implementing their own rules. In enforced self-regulation, firms are required to propose particularized regulatory standards that will fulfill the public regulator’s policy objectives, and then these standards can be enforced by the public regulator.¹⁸⁷ In audited self-regulation, a private self-regulatory organization (SRO) is

182. Mendelson, *supra* note 19, at 743–44 (discussing the prices charged by SDOs).

183. *Id.* at 767–76.

184. ADMIN. CONFERENCE OF THE U.S., ADMINISTRATIVE CONFERENCE RECOMMENDATION 2011-5: INCORPORATION BY REFERENCE, at 5 (adopted Dec. 8, 2011), available at http://www.acus.gov/sites/default/files/Recommendation-2011-5-Incorporation-by-Reference_0.pdf; see also Mendelson, *supra* note 19, at 744 (referring to it as a “tepid recommendation”).

185. Mendelson, *supra* note 19, at 799–800; see also Strauss, *supra* note 19, at 558 (calling for the “[c]reation of a digital archive of incorporated standards to replace (or supplement) the current physical archive”).

186. Cunningham, *supra* note 180, at 338–41 (calling on the Director of the Federal Register to, in certain circumstances, derecognize copyright).

187. Cf. IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE 101 (1992) (referring to this approach as “enforced self-regulation”); Robyn Fairman & Charlotte Yapp, *Enforced Self-Regulation, Prescription, and Conceptions of Compliance within Small Businesses: The Impact of Enforcement*, 27 LAW & POL’Y 491, 493 (2005) (explaining that enforced self-regulation “refers to the regulator imposing a requirement for business to determine and implement their own internal rules and procedures to fulfill the regulator’s policy objectives”). This approach has also been called management-based regulation. See Coglianese & Lazer, *supra* note 125, at 691 (stating that the public regulator directs regulated companies to “engage in a planning process that aims toward the achievement of public goals, offering firms flexibility in how they achieve public goals”).

empowered “to implement and enforce laws or agency regulations with respect to the regulated entities, with powers of independent action and review retained by the agency.”¹⁸⁸ The former involves public endorsement of firm-level self-regulation, while the latter involves public endorsement of industry-level self-regulation. In both, firms generally devise their own rules and standards, subject to review and oversight by a public regulatory agency.

The USDA’s Hazards Analysis and Critical Control Points (HACCP) regulation serves as an example of enforced self-regulation.¹⁸⁹ The HACCP regulation requires firms to assess the risks of potential hazards associated with all stages of food processing and then identify all points in the production process at which hazards can likely be eliminated, minimized, or reduced.¹⁹⁰ Similarly, OSHA’s Process Safety Management (PSM) regulation requires that certain firms “implement a multistep management practice to assess risks for chemical accidents, develop procedures designed to reduce those risks, and take actions to ensure that procedures are carried out in practice.”¹⁹¹ The agencies assess compliance by reviewing the management plans and other documentation generated by the firms and by undertaking inspections and other activities to determine whether firms are implementing their plans.

In audited self-regulation, the SRO is generally an industry-level organization, which sets rules and standards that regulate the firms in its industry.¹⁹² A long-standing use of audited self-regulation is provided by the 1965 law that created Medicare.¹⁹³ The law determined that hospitals accredited by a hospital industry association, the Joint Commission (JC), would have “deemed status,” meaning that it was deemed to have met the federal standards referred to as the Medicare Conditions of Participation and was thus eligible to provide Medicare-funded services.¹⁹⁴ In this way,

188. Douglas C. Michael, *Federal Agency Use of Audited Self-Regulation as a Regulatory Technique*, 47 ADMIN. L. REV. 171, 251 (1995).

189. See Coglianese & Lazer, *supra* note 125, at 697–98.

190. *Id.* at 697.

191. *Id.* at 698.

192. Cf. Gunningham & Rees, *supra* note 98, at 365–66; see also AYRES & BRAITHWAITE, *supra* note 187, at 102 (calling this “industry co-regulation”).

193. 42 U.S.C. § 1395bb(a) (2012). See generally Freeman, *supra* note 16, at 649; Eleanor D. Kinney, *Private Accreditation as a Substitute for Direct Government Regulation in Public Health Insurance Programs: When Is It Appropriate?* 57 LAW & CONTEMP. PROBS. 47 (1994); Timothy Stoltzfus Jost, *Medicare and the Joint Commission on Accreditation of Healthcare Organizations: A Healthy Relationship?* 57 LAW & CONTEMP. PROBS. 15 (1994).

194. Jost, *supra* note 193, at 18 (“Since its inception, the Medicare program has accepted, or ‘deemed,’ Joint Commission accreditation as equivalent to compliance with Medicare certification standards.”).

the JC's accreditation process served as a substitute for direct public regulation of the quality of hospital care by the Department of Health and Human Services (HHS).¹⁹⁵ Amid concerns that HHS lacked necessary oversight power, a 2008 amendment to the Medicare law removed the automatic deeming authority of the Joint Commission and made it necessary for the JC to apply to HHS for approval to maintain its accrediting status.¹⁹⁶

3. Third-Party Verification

A final example of strong harnessing is third-party verification, which is the focus of the remaining parts of this Article. In third-party verification, governmental agencies rely on private third parties to verify regulatory compliance.¹⁹⁷ Regulated entities are either required or have the option to contract with a verifier or verification body that has been approved, or accredited, by an agency or an agency-designated accreditation body. Third-party verification harnesses the private testing, inspection, and certification capacity that has been developed to implement and monitor compliance with private regulation. In this way, third-party verification can substitute for direct compliance monitoring by a governmental agency.¹⁹⁸

A variety of state and federal regulatory programs in the United States employ third-party verification. At the state level, Massachusetts and California require third-party verification in their greenhouse gas reporting regulations.¹⁹⁹ In Massachusetts, third-party verifiers assess compliance with underground storage tank laws²⁰⁰ and hazardous waste site remediation standards, a practice that has been dubbed "rent-a-regulator" by one observ-

195. *Id.* at 15; see also Michael J. Astrue, *Health Care Reform and the Constitutional Limits on Private Accreditation as an Alternative to Direct Government Regulation*, 57 LAW & CONTEMP. PROBS. 75, 77 (1994) (noting that the subagency within the Department of Health and Human Services responsible for the accreditation process resisted becoming an independent regulator and instead chose to contract its work out to private accrediting agencies).

196. Juliet Battard Menendez, *The Impetus for Legislation Revoking the Joint Commission's Deemed Status as a Medicare Accrediting Agency*, 12 JONA'S HEALTHCARE L. ETHICS & REG. 69, 69 (2010) (noting that the legislative change was preceded by a 2004 GAO report: U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-04-850, MEDICARE: CMS NEEDS ADDITIONAL AUTHORITY TO ADEQUATELY OVERSEE PATIENT SAFETY IN HOSPITALS (2004)). In November 2009, CMS approved the continuation of the Joint Commission's deeming authority for hospitals through July 15, 2014. *The Joint Commission's Hospital Accreditation Recognized by CMS*, 30 JOINT COMMISSION PERSP., no. 1, Jan. 2010, at 1.

197. McAllister, *supra* note 21, at 2 (providing an overview of third-party verification, its strengths, and potential weaknesses).

198. *Id.* at 3.

199. *Id.* at 7.

200. *Id.* at 10.

er.²⁰¹ Private smog-check stations and building inspectors are relied on by regulatory agencies in many states and localities.²⁰²

At the federal level, agencies in diverse areas of regulation are using private third parties to carry out inspections and verify that regulated entities are in compliance with federal standards and other requirements. Third parties are charged with assessing the safety of imported food, children's products, medical devices, cell phones, and other telecommunication and electrical equipment used in workplaces.²⁰³ Third parties also ensure that products labeled as organic, energy-efficient, and water-efficient meet applicable federal standards.²⁰⁴ In these regulatory third-party programs, third parties carry out product testing, facility inspections, and other regulatory compliance activities in the place of regulatory agencies. Regulatory agencies take on new roles in coordinating and overseeing these private actors.

A variety of reasons motivate the use of third-party verification. It is a form of public-private partnership, which many view as a promising way to capitalize on the different strengths of public and private regulation while compensating for their different weaknesses.²⁰⁵ In particular, third-party verification taps into the monitoring and compliance expertise held by the large private verification industry that has developed through private regulation.²⁰⁶ Moreover, third-party verification seems suited for an era of growing regulatory demands and diminishing governmental resources.²⁰⁷ New regulatory programs such as cap-and-trade need very accurate compliance data, old regulatory programs suffer from serious deficiencies in compliance monitoring, and the budgetary resources of regulatory agencies seem to grow ever scarcer.²⁰⁸ Also, some regulatory goals are particularly difficult to meet using traditional monitoring approaches such as ensuring the safety of imported food and other products manufactured in complex international chains of production.

Yet concerns about third-party verification also abound. Compliance monitoring could be considered a core governmental function that should

201. Seifter, *supra* note 157, at 1091, 1096–97; *Third-Party UST Inspector Frequently Asked Questions*, MASS. OFFICE OF ENERGY & ENVTL. AFFAIRS, <http://www.mass.gov/eea/agencies/massdep/toxics/ust/third-party-ust-inspector-frequently-asked-questions.html> (last visited Nov. 7, 2013).

202. McAllister, *supra* note 21, at 10.

203. *See infra* Part II.A.

204. *See infra* Part II.B.2–4.

205. *Cf.* Balleisen, *supra* note 134, at 454–59 (discussing how the strengths of self-regulation can help overcome the weaknesses of governmental regulation).

206. McAllister, *supra* note 21, at 15–20.

207. *Id.* at 2.

208. *Id.* at 20–28.

not be performed by private actors.²⁰⁹ Third-party verifiers may not be adequately independent from the regulated entities they assess or adequately competent to reliably detect noncompliance. Potential problems of accountability arise in third-party verification, as they do in other forms of public-private partnerships.²¹⁰ And while third-party verification offers the possibility of shifting some of the cost of assessing compliance from government agencies to regulated industry, it also creates new types of costs for both, which may not be cost-effective.²¹¹

4. Harnessing in the European Union

These various forms of strongly harnessing private regulation are more prevalent in the European Union than the United States. The “New Approach,” established by EU directive in 1985 to harmonize the health, safety, and environmental requirements of EU Member States and thereby facilitate trade, gave European standards bodies a great deal of regulatory authority.²¹² Under the New Approach, EU directives lay down the “essential requirements” for product safety, and technical specifications are drawn up by one of three European standards bodies.²¹³ These “harmonized standards” are automatically transposed into member state standards, and conflicting standards must be withdrawn.²¹⁴ Companies that comply with

209. *Id.* at 28–31.

210. Balleisen, *supra* note 134, at 465–68; Freeman, *supra* note 151, at 1326–27; Minow, *supra* note 3, at 1259.

211. McAllister, *supra* note 21, at 44–46.

212. Council Resolution on a New Approach to Technical Harmonization and Standards, 1985 O.J. (C 136) 1, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:1985:136:0001:0009:EN:PDF>; SCHEPEL, *supra* note 169, at 63–65; EUROPEAN COMM. FOR ELECTROTECHNICAL STANDARDIZATION, PRIMER ON STANDARDS: UNCOVERING THE MYSTERIES OF STANDARDIZATION IN EUROPE 30–31 (2002), available at <http://oek.ove.at/CenelecInfo.pdf>.

213. NAT’L INST. OF STANDARDS & TECH., A GUIDE TO EU STANDARDS AND CONFORMITY ASSESSMENT 14 (Helen Delaney & Rene van de Zande eds., 2000), available at http://gsi.nist.gov/global/docs/EU_Stds&CA_2000.pdf. New Approach directives exist for example on topics such as energy efficiency requirements, low-voltage equipment, medical devices, and toy safety. *Id.* at 5–6. The three European standards bodies are CEN, the European Committee for Standardization, responsible for standards in all fields except electrotechnology and telecommunications; CENELEC, the European Committee for Electrotechnical Standardization, responsible for electrotechnology standards; and ETSI, the European Telecommunications Standards Institute, responsible for telecommunications standards. EUROPEAN COMM. FOR ELECTROTECHNICAL STANDARDIZATION, *supra* note 212, at 31.

214. EUROPEAN COMM. FOR ELECTROTECHNICAL STANDARDIZATION, *supra* note 212, at 17; *The “New Approach”*, EUROPEAN COMM., http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/new-approach_en.htm (last updated Feb. 2, 2013).

the harmonized standards are presumed to be in compliance with the EU directive and their products can circulate freely in the EU.²¹⁵ Manufacturers can also choose not to comply with the harmonized standards, but member states can impose costly testing and certification requirements to ensure that their products still comply with the directive's essential requirements.²¹⁶

Also, European countries have employed various forms of co-regulation to a greater extent than the United States.²¹⁷ Enforced self-regulation is widespread in European health, safety, and environmental regulation.²¹⁸ In the Netherlands, audited self-regulation pertaining to the environment has taken the form of “negotiated agreements,” wherein industry legally binds itself to achieve the environmental objectives embodied in legislation.²¹⁹ Such agreements have been common in agriculture, oil refining, and waste disposal.²²⁰ In France, the Ministries of Industry and Environment negotiated with car manufacturers, importers, and trade associations to reduce the amount of landfill waste resulting from automobile disposal.²²¹

Forms of third-party verification are also much more common in European regulation. Complementing its New Approach to set product safety standards, the EU developed a Global Approach to Testing and Certification to implement standards.²²² The global approach relies on third-party verifiers, referred to as “notified bodies,” to certify that products

215. SCHEPEL, *supra* note 169, at 64–65.

216. *Id.* at 65.

217. See, e.g., Eric W. Orts & Kurt Deketelaere, *Introduction: Environmental Contracts and Regulatory Innovation*, in ENVIRONMENTAL CONTRACTS: COMPARATIVE APPROACHES TO REGULATORY INNOVATION IN THE UNITED STATES AND EUROPE 5 (Eric W. Orts & Kurt Deketelaere eds., 2001) (stating that “environmental ‘agreements’ or ‘covenants’ have been used for several decades in many European countries” including Belgium, France, Germany, and the Netherlands).

218. Fairman & Yapp, *supra* note 187, at 493.

219. Anastasia Telesetsky, *Experimenting with International Collaborative Governance for Climate Change Mitigation by Private Actors: Scaling Up Dutch Co-Regulation*, 4 EUR. J. OF LEGAL STUD. 58, 64–65 (2011); see also Dennis D. Hirsch, *Understanding Project XL: A Comparative Legal and Policy Analysis*, in ENVIRONMENTAL CONTRACTS: COMPARATIVE APPROACHES TO REGULATORY INNOVATION IN THE UNITED STATES AND EUROPE, *supra* note 217, at 115, 122–26; Orts & Deketelaere, *supra* note 217, at 6–7.

220. Telesetsky, *supra* note 219, at 65.

221. Lyon & Maxwell, *supra* note 7, at 80.

222. *Commission Proposal for a Global Approach to Certification and Testing*, COM (1989) 209 final (July 24, 1989) (completed by Council Decision 90/683/EEC, 1990 O.J. (L380) (EEC), replaced and updated by Council Decision 93/465, 1993 O.J. (L 220) (EEC)); EUROPEAN COMM. FOR ELECTROTECHNICAL STANDARDIZATION, *supra* note 212, at 43; see also MICHELLE EGAN, *CONSTRUCTING A EUROPEAN MARKET: STANDARDS, REGULATION, AND GOVERNANCE* 125–28 (2001) (describing negotiations to develop the Global Approach in the 1980s).

conform to relevant EU directives.²²³ Notified bodies are accredited by national accreditation bodies and “notified” to the European Commission, which is the reason for their name.²²⁴ As explained by one commentator, the “EU has created an administrative structure . . . supported, above all, by private entities, which ultimately and bindingly decide on market access for products in their function as ‘Notified Bodies.’”²²⁵ Member states have the authority to withdraw the accreditation of notified bodies and are required to conduct surveillance activities to ensure that marketed products comply with legal requirements.²²⁶

Third-party verification is also used in a variety of other EU regulatory programs. Entities regulated by the EU Emissions Trading Scheme, for example, must generally contract with an accredited third party to verify the accuracy of their annual emissions reports.²²⁷ Also, a company or other organizations can earn the right to display the European Eco-Management and Audit Scheme (EMAS) logo by having an accredited third party verify that it has established an environmental management system, carried out an internal audit, and provided a public statement of its environmental performance.²²⁸

II. FEDERAL THIRD-PARTY VERIFICATION PROGRAMS

Third-party verification programs operated by federal agencies in the United States vary in important ways. In many cases, Congress provided

223. Hans Christian Röhl, *Conformity Assessment in European Product Safety Law*, in THE EUROPEAN COMPOSITE ADMINISTRATION 201, 206 (Oswald Jansen and Bettina Schöndorf-Haubold eds., 2001) (explaining that certified products receive the CE mark and noting that manufacturers can often certify themselves, but for more dangerous products, they must consult a Notified Body).

224. *Id.* at 206, 222–23 (explaining that notified bodies are generally accredited to ISO standards 17000 and 17011).

225. *Id.* at 201.

226. *Id.* at 223–25.

227. McAllister, *supra* note 21, at 7; *see also* Commission Decision 2004/156, Establishing Guidelines for the Monitoring and Reporting of Greenhouse Gas Emissions Pursuant to Directive 2003/87/EC of the European Parliament and of the Council, arts. 1–2, 2004 O.J. (L 59) 1, 1. The Commission adopted a revised version of these guidelines on July 18, 2007. Commission Decision 2007/589, Establishing Guidelines for the Monitoring and Reporting of Greenhouse Gas Emissions Pursuant to Directive 2003/87/EC of the European Parliament and of the Council, arts. 2–3, 2007 O.J. (L 229) 1, 3.

228. European Eco-Management & Audit Scheme, *EMAS Reporting*, Question 7 of *Frequently Asked Questions*, EUROPEAN COMMISSION, http://ec.europa.eu/environment/emas/tools/faq_en.htm#Section7Question1 (last updated Jan. 16, 2014); *see also* David W. Case, *Corporate Environmental Reporting as Informational Regulation: A Law and Economics Perspective*, 76 U. COLO. L. REV. 379, 402 (2005); Eric W. Orts, *Reflexive Environmental Law*, 89 NW. U. L. REV. 1227, 1290 (1995).

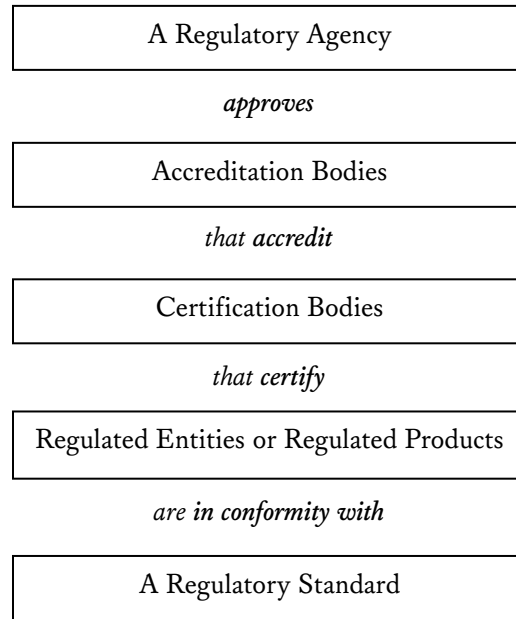
legislative authority for the third-party program and set forth certain design elements in statutes. In other cases, agencies have implemented third-party programs under existing statutory authority. Several programs are a decade or two old, but most have been established more recently. Depending on the program, third parties assess compliance with mandatory or voluntary regulatory standards, and regulated entities may either be required or may have the option to contract with third parties for such assessment. Table 1 summarizes several relevant program attributes such as the assessment activities that third parties perform, whether the applicable standard is set by the government or privately (i.e. a voluntary consensus standard), and whether the agency directly accredits the third parties or relies on private accreditation bodies.

Notably, federal agencies have increasingly incorporated ISO standards and terminology relating to conformity assessment into their third-party programs. Agencies have most often relied on international standards that concern how testing bodies should conduct testing (ISO/IEC 17025); how certification bodies should conduct certifications (ISO/IEC Guide 65 or ISO/IEC 17065, issued in 2012 to replace Guide 65); and how accreditation bodies should conduct accreditations (ISO/IEC 17011). By doing so, agencies tap into the international networks of accreditation bodies, certification bodies, and testing bodies that operate in accordance with these standards and perform the work of conformity assessment.

In most of the programs discussed below, regulatory agencies rely on third parties that serve the function of certification bodies. Regulatory agencies have used a variety of names for these third parties, such as Third-Party Auditors, Telecommunications Certification Bodies, and Accredited Persons. The programs tend to share the same basic structure (see Figure 1). Regulated entities contract with a third-party certification body to assess and certify whether they are in conformity with an applicable regulatory standard. The certification bodies are generally private entities that have been accredited to perform this task by an accreditation body that has been approved or recognized by the regulatory agency.

TABLE 1: FEDERAL REGULATORY THIRD-PARTY PROGRAMS WITH
SELECTED PROGRAM ATTRIBUTES

Figure 1: General Structure of Third-Party Programs to Assess Regulatory Compliance



However, this general structure varies. In some programs, for example, the regulatory agency itself accredits the certification bodies directly, without reliance on an accreditation body. In other programs the regulatory agency may require the certification body to be accredited by an accreditation body, but the agency may not explicitly approve or recognize accreditation bodies. Also, several of the programs rely on a combination of certification bodies and testing bodies.

The first section below discusses four programs designed to assess compliance with mandatory standards, with which regulated companies must comply. The second section discusses four programs designed to assess compliance with voluntary standards with which companies can choose to comply.

A. Programs for Mandatory Standards

Several federal laws enable regulatory agencies to rely on third parties to assess compliance with mandatory standards. Mandatory standards are those that regulated entities must comply with in order to legally operate or sell a regulated product. In two of the programs—imported food programs administered by the Food and Drug Administration (FDA) and children's product safety rules administered by the Consumer Product Safety Commission (CPSC)—the third-party certifier is an obligatory part of the

compliance process: the regulated company is required to contract with the third party for compliance assessment.²²⁹ In FDA's programs for medical devices, in contrast, the use of a third party is optional: companies have the choice of hiring a third party or having the agency conduct the review or inspection instead.²³⁰ In the FCC's program for telecommunications equipment, the use of a third party was optional for most types of equipment in the past, but a proposed regulation would make it obligatory for all types.²³¹

1. Imported Food

As amended by the Food Safety Modernization Act of 2011 (FSMA), the Federal Food, Drug, and Cosmetic Act (FDCA) enables the FDA to rely on third-party audits in its regulation of imported foods.²³² Overall, the FDA is responsible for ensuring the safety of about 80% of the U.S. food supply, all but the meat, poultry, and processed egg products that are regulated by U.S. Department of Agriculture.²³³ Increasingly, much of this food supply is imported, including 80% of seafood and 60% of fruits and vegetables.²³⁴

FSMA significantly strengthened FDA's authority to regulate imported food, and it relies on accredited third-party auditors in two different ways. First, the law provides that the FDA may require that an importer present a certification from a third-party auditor in order to import food into the United States.²³⁵ With this authority, the FDA may require that imported food be accompanied by a certification that it satisfies the applicable requirements of the FDCA.²³⁶ To decide whether a food import requires certification, the law instructs FDA to consider factors such as the safety risks of the food and its place of origin.²³⁷ The law also instructs the FDA to make a scientifically supported finding that the "food safety programs, systems, and standards in the country, territory, or region of origin of the

229. See *infra* Part II.A.1–2.

230. See *infra* Part II.A.3.

231. See *infra* Part II.A.4.

232. See FDA Food Safety Modernization Act (FSMA) of 2011 § 307, Pub. L. No. 111-353, 124 Stat. 3885, 3959 (codified at 21 U.S.C. 384d (2012)).

233. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-933, FOOD SAFETY: FDA CAN BETTER OVERSEE FOOD IMPORTS BY ASSESSING AND LEVERAGING OTHER COUNTRIES' OVERSIGHT RESOURCES 1 (2012).

234. *Id.*

235. See Federal Food, Drug, and Cosmetic Act (FDCA) § 801(q), 21 U.S.C. § 381(q) (2012) (amended by the FDA Food Safety Modernization Act § 303); see also 21 U.S.C. § 384d(c)(2)(B)(i) (2012).

236. 21 U.S.C. § 381(q) (2012).

237. *Id.* § 381(q)(2).

food are inadequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this chapter.”²³⁸

Second, the law requires FDA to create a Voluntary Qualified Importer Program (VQIP) through which participating importers may receive expedited importation if the facility from which the imported food comes has been certified by a third-party auditor.²³⁹ In contrast to mandatory food certifications, these facility certifications are voluntary. Importers that import foods from facilities that have received certification from a third-party auditor may request to have that food become part of the VQIP.²⁴⁰ The law directs the FDA to consider a range of factors to make a determination on whether the food should receive expedited review and importation through the VQIP, including the safety risks of the food, the compliance history of the suppliers used by the importer, and the capability of the exporting country’s regulatory system.²⁴¹

In both programs, the third-party auditors would be responsible for performing the audits to assess and certify compliance with the mandatory requirements of the law.²⁴² Under the statute, a third-party auditor refers to a “foreign government, agency of a foreign government, foreign cooperative, or any other third party” as deemed appropriate by the FDA in its regulations.²⁴³ Private third-party auditors can be single individuals, but are more likely to be companies that employ “audit agents.”²⁴⁴ Under the statute, the audits for food and facility certifications are termed “regulatory audit[s].”²⁴⁵ Importers and other regulated entities may also contract with

238. *Id.* § 381(q)(2)(C)(i).

239. FDCA § 806, 21 U.S.C. § 381(b) (2012) (amended by FSMA § 302); *see also* 21 U.S.C. § 384d(c)(2)(B)(ii) (2012).

240. An importer “means the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States.” 21 U.S.C. § 384b(g) (2012). Elsewhere the law defines an importer as “the United States owner or consignee of the article of food at the time of entry,” or if none, “the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry.” 21 U.S.C. § 384a (2012).

241. 21 U.S.C. § 384b(d) (2012).

242. The law provides that the FDA may provide certifications, 21 U.S.C. § 384d(c)(2)(C)(ii) (2012), but it seems likely that FDA will generally require the use of an accredited third-party auditor.

243. *Id.* § 384d(a)(3).

244. *Id.* § 384d(a)(3) (stating that a third-party auditor may be a single individual and third-party auditors may employ “audit agents,” defined at 21 U.S.C. § 384d(a)(1) (2012) as “an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party auditor”).

245. *Id.* § 384d(a)(7).

an accredited third-party auditor to conduct a “consultative audit,” defined in the law to be for internal purposes only.²⁴⁶

The structure of the third-party program contemplated by FSMA is shown in Figure 2. The law provides that the FDA will recognize accreditation bodies that will, in turn, accredit the third-party auditors that can audit and certify foreign food imports and facilities.²⁴⁷ An accreditation body is “an authority that performs accreditation of third-party auditors.”²⁴⁸ The law requires FDA to establish a system for the recognition of accreditation bodies²⁴⁹ and to develop model accreditation standards, including requirements for regulatory audit reports.²⁵⁰ If the FDA has not recognized any accreditation bodies within two years after establishing a system, the FDA may directly accredit third-party auditors.²⁵¹ The law further provides that FDA will establish a user-fee program through which accredited third-party auditors and audit agents will reimburse the FDA for “the work performed to establish and administer the accreditation system.”²⁵²

246. *Id.* § 384d(a)(5).

247. *See generally* FDCA § 808, 21 U.S.C. § 384d (2012) (amended by FSMA § 307).

248. *Id.* § 384d(a)(2).

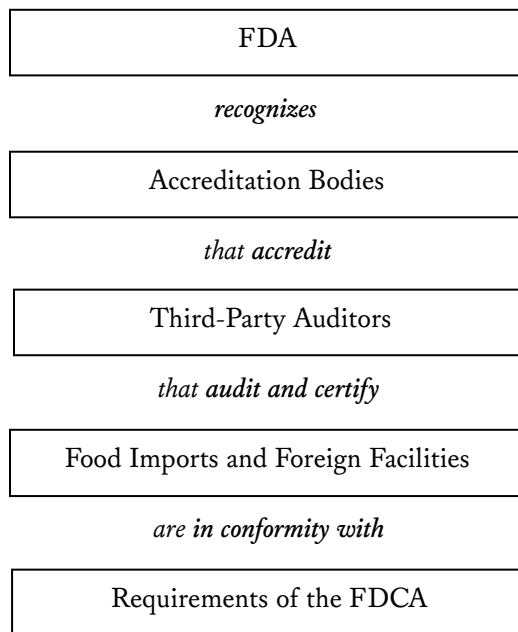
249. *Id.* § 384d(b)(1)(A)(i).

250. *Id.* § 384d(b)(2).

251. *Id.* § 384d(b)(1)(A)(ii).

252. *Id.* § 384d(c)(8).

FIGURE 2: STRUCTURE OF THIRD-PARTY PROGRAM FOR FOOD AND FACILITY CERTIFICATIONS



The statute sets forth certain requirements for the accreditation of different types of third-party auditors. It states that foreign governments and their agencies may be accredited based on a review of their food safety programs to ensure that the foreign government is capable of determining that U.S. requirements are met.²⁵³ Foreign cooperatives and other third parties may be accredited based on a review of internal systems and the training and qualifications of their audit agents to ensure conformity with the model standards to be issued by the FDA.²⁵⁴

The statute addresses the potential of conflicts of interest between accredited third-party auditors and the companies that contract with them to perform audits.²⁵⁵ It provides that third-party auditors may not perform a regulatory audit of an entity for which it has performed a consultative audit or a regulatory audit in the previous thirteen months.²⁵⁶ It also states that third-party auditors cannot be owned or operated by the same person as the entities they certify, must have procedures to protect against financial conflicts of interest, and must annually disclose to the FDA how they have

253. *Id.* § 384d(c)(1)(A).

254. *Id.* § 384d(c)(1)(B).

255. *Id.* § 384d(c)(5)(C).

256. *Id.* § 384d(c)(4)(C)(i).

complied with conflicts-of-interest rules and procedures.²⁵⁷ Similarly, audit agents cannot own or operate the entity they certify, must have procedures to protect against financial conflicts of interest, and must make an annual disclosure.²⁵⁸ The law also requires FDA to promulgate regulations to further protect against conflicts of interest.²⁵⁹

The law contains several specific provisions regarding how the FDA should oversee accreditation bodies and accredited third-party auditors and what audit information must be made available to the agency and to the public. Accreditation bodies are required to provide a list of all third-party auditors they have accredited and their audit agents,²⁶⁰ and the FDA is required to establish a public registry of all accreditation bodies and accredited third-party auditors.²⁶¹ FDA must re-evaluate accreditation bodies at least once every four years²⁶² and must revoke the recognition of an accreditation body that is out of compliance with its rules.²⁶³

Accredited third-party auditors are directly answerable to the FDA in a variety of ways. The FDA may at any time require an accredited auditor to submit an onsite audit report from a regulatory audit and any related reports or documents.²⁶⁴ In contrast, the FDA may not directly require an auditor to submit the reports from a consultative audit, but can still access the results of such audits based on its general authority to inspect records when FDA has a reasonable belief that an article of food “presents a threat of serious adverse health consequences or death to humans or animals.”²⁶⁵ Also, an accredited auditor must immediately notify the FDA if it “discovers a condition that could cause or contribute to a serious risk to the public health” during either a regulatory or a consultative audit.²⁶⁶

257. *Id.* § 384d(c)(5)(A).

258. *Id.* § 384d(c)(5)(B).

259. *Id.* § 384d(c)(5)(C) (further stating that FDA’s conflict-of-interest regulations shall require that audits performed by accredited third-party auditors be unannounced; shall establish timing, disclosure, fee payment and other rules that decrease the potential for conflicts of interest; and shall place limits on the extent to which there may be financial affiliations between auditors and audit agents and the entities they certify).

260. *Id.* § 384d(b)(1)(B).

261. *Id.* § 384d(g).

262. *Id.* § 384d(f)(1).

263. *Id.* § 384d(b)(1)(C).

264. *Id.* § 384d(c)(3)(B).

265. *Id.* § 384d(c)(3)(C) (referring to FDA’s authority to inspect records at 21 U.S.C. § 350c (2012)).

266. 21 U.S.C. § 384d(c)(4)(A) (2012); *see also Imports*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/food/guidanceregulation/fsma/ucm257980.htm> (last visited Nov. 1, 2013) (answering in the affirmative the question, “I.4.2 Is the accredited auditor required to notify the FDA if a condition of concern is found during a consultative audit?”).

In addition, FDA is required to evaluate the performance of each accredited third-party auditor at least once every four years, which should include the review of its regulatory audit reports and the compliance history of its certified entities.²⁶⁷ The FDA may also conduct its own onsite audit of any certified entity whether or not the certifying third-party auditor is present.²⁶⁸ The FDA may withdraw accreditation from an auditor if food from a facility it has certified is linked to a serious outbreak of food-borne illness, if FDA evaluates it and finds it to be out of compliance with accreditation requirements, if it refuses to allow the government to conduct necessary audits and investigations, or if the FDA revokes the recognition of the accreditation bodies which accredited it.²⁶⁹ Also, false statements or representations made to an accredited third-party auditor by a regulated entity or to the FDA by an accredited third-party auditor are subject to criminal penalties.²⁷⁰

In July 2013, FDA proposed a rule to implement many of these statutory provisions.²⁷¹ The regulations set forth FDA's system for recognizing accreditation bodies, including the requirements and procedures for recognition. To be recognized, accreditation bodies must be able to, inter alia, show certain levels of competency and capacity, protect against conflicts of interest, assess and monitor third-party auditors, and meet recordkeeping and reporting requirements.²⁷² The regulations also address the requirements and procedures for the accreditation of third-party auditors. Accredited third-party auditors, like recognized accreditation bodies, must show certain levels of competency and capacity, protect against conflicts of interests, and meet recordkeeping and reporting requirements.²⁷³ The rule further specifies how third-party auditors must ensure the competence of its audit agents, conduct audits, write audit reports, and monitor foods and facilities that it has certified.²⁷⁴ While the proposed rule contains a framework for accreditation standards, FDA has committed to issuing Model

267. 21 U.S.C. § 384d(f)(2) (2012).

268. *Id.* § 384d(f)(3).

269. *Id.* § 384d(c)(6)(A)-(B).

270. *Id.* § 384d(e); *see also* CHARLES F. WOODHOUSE, IMPORTED FOOD PROVISIONS OF THE FOOD SAFETY MODERNIZATION ACT (2011), available at <http://www.food-label-compliance.com/Sites/5/Downloads/White-Paper-FSMA-IMPORT-PROVISIONS-Woodhouse-Nov-8-2011.pdf> (a white paper emphasizing the significance of specific inclusion of provisions relating to False Statements).

271. Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. 45,782 (Jul. 29, 2013) (to be codified at 21 C.F.R. pts. 1, 16).

272. *Id.* at 45,827–31.

273. *Id.* at 45,831–38.

274. *Id.* at 45,832–34.

Accreditation Standards that will elaborate on the framework and detail the qualifications that third-party auditors must demonstrate for accreditation.²⁷⁵

It is worth noting that the FSMA also requires FDA to establish a system for the accreditation of laboratories to conduct food safety tests.²⁷⁶ Accredited labs must be used to test food in certain situations, such as when FDA identifies or suspects a food safety problem.²⁷⁷ Similar to its accredited auditor program, FDA is to establish an accredited laboratory program and publish a registry of accreditation bodies and accredited laboratories.²⁷⁸ The statute also states that FDA shall develop model accreditation standards that include, for example, appropriate sampling methods and employee training requirements.²⁷⁹

2. Children's Products

Pursuant to the Consumer Product Safety Improvement Act of 2008 (CPSIA), the CPSC requires manufacturers and importers of nearly all children's products to demonstrate that they meet mandatory product safety standards through third-party testing.²⁸⁰ Testing must be conducted by a Third Party Conformity Assessment Body (TPCAB), defined by regulation as "a testing laboratory whose accreditation has been accepted by the CPSC to conduct certification testing on children's products."²⁸¹ Based on the

275. *Id.* at 45785.

276. 21 U.S.C. § 350k.

277. *Id.* § 350k(b)(1).

278. *Id.* § 350k(a)(1).

279. *Id.* § 350k(a)(6).

280. Consumer Product Safety Improvement Act of 2008 § 102(a)(2), 15 U.S.C. § 2063(a)(2) (2012). The law defines a "children's product" as a consumer product designed or intended primarily for children twelve years of age or younger. 15 U.S.C. § 2052(a)(2) (2012). In 2011, Congress enacted amendments to the CPSIA that, among other things, provided an exemption from third-party testing for some products produced by "small batch manufacturers," defined as those that produce fewer than 7,500 units and collect less than \$1 million in consumer products revenues. Authority and Discretion—Consumer Product Safety Commission § 2(a)(4), Pub. L. No. 112-28, 125 Stat. 273 (codified at 15 U.S.C. 2063(d) (2012)); *see also Small Batch Manufacturers and Third Party Testing*, U.S. CONSUMER PROD. SAFETY COMM'N, <http://www.cpsc.gov/en/business--manufacturing/small-business-resources/small-batch-manufacturers-and-third-party-/> (last visited Feb. 1, 2014). An exemption was also provided for ordinary books for children aged four to twelve. 15 U.S.C. § 2063(d)(5)(A)(i) (2012).

281. 16 C.F.R. § 1107.2 (2014); *see also* 15 U.S.C. § 2063(f)(2)(A) (2012) (defining a "third party conformity assessment body" to mean a conformity assessment body that is not owned, managed, or controlled by the manufacturer or private labeler of a product assessed by the laboratory, unless such a laboratory has satisfied certain statutory criteria). It is worth noting that while the statute uses the term certification, the third-party program that it

results of the third-party testing, the manufacturer or importer submits a Children's Product Certificate indicating compliance.²⁸² Under the law, third-party testing is mandatory: manufacturers cannot opt out of the third-party testing system and rely instead on CPSC to assess compliance. The structure of this third-party program is shown in Figure 3.

Different rules and standards apply depending on the product. For example, the CPSC has promulgated safety rules with standards for products such as bicycle helmets,²⁸³ bunk beds,²⁸⁴ infant bath seats,²⁸⁵ and electrically operated toys or articles.²⁸⁶ CPSC product safety rules containing standards for flammability,²⁸⁷ small parts,²⁸⁸ and lead content²⁸⁹ may also apply. In addition, CPSC has mandated compliance with a variety of toy safety standards established by ASTM regarding, for example, toy chests, stuffing materials, and sound producing toys.²⁹⁰

requires is a third-party testing program rather than a certification program under the definitions of international standards.

282. 15 U.S.C. § 2063(a)(2) (2012); *see also* Consumer Product Safety Act Regulations, 16 C.F.R. § 1110 (2014).

283. Safety Standard for Bicycle Helmets, 16 C.F.R. § 1203 (2014).

284. *Id.* § 1513 (Requirements for Bunk Beds).

285. *Id.* § 1216 (Safety Standards for Infant Walkers).

286. *Id.* § 1505 (Requirements for Electrically Operated Toys or Other Electronically Operated Articles Intended for Use by Children).

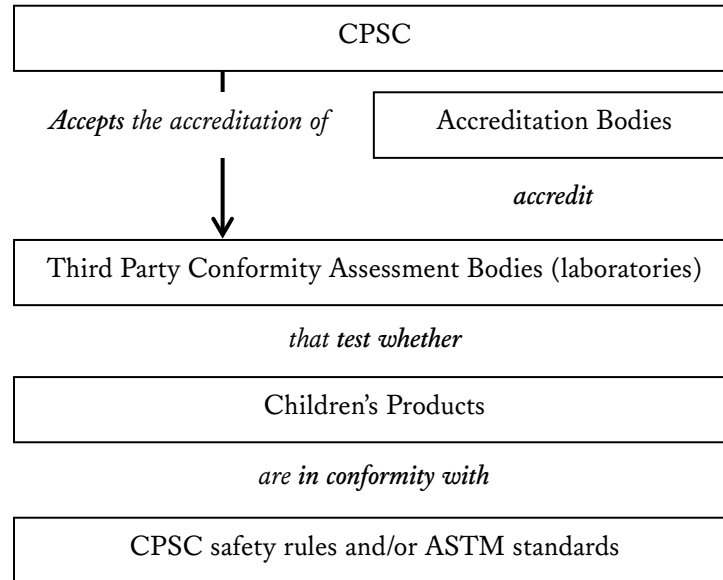
287. *Id.* §§ 1610–11, 1615–16, 1630–33.

288. *Id.* § 1501 (Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts).

289. *See* DIV. OF CHEMISTRY, U.S. CONSUMER PROD. SAFETY COMM'N, TEST METHOD CPSC-CH-E1001-08 (2008); DIV. OF CHEMISTRY, U.S. CONSUMER PROD. SAFETY COMM'N, TEST METHOD CPSC-CH-E1001-08.1 (2010).

290. *ASTM F963 Standard Consumer Safety Specifications for Toy Safety*, provided as a reference for *List of CPSC-Accepted Testing Laboratories*, U.S. CONSUMER PROD. SAFETY COMM'N, <http://www.cpsc.gov/cgi-bin/labsearch/> (last visited Feb. 1, 2014) (list of rules that require third-party testing and certification).

FIGURE 3: STRUCTURE OF THIRD-PARTY PROGRAM FOR CHILDREN'S PRODUCT TESTING



The CPSIA established a schedule for implementing third-party testing and included a timeline for the accreditation of third-party conformity assessment bodies.²⁹¹ The law specifies that “third party testing requirements apply to any children’s product manufactured more than 90 days after the [CPSC] has published requirements for accreditation of third party testing laboratories to assess conformity with a children’s product safety rule.”²⁹² For example, the CPSC published such a notice of requirements for the lead paint rule on September 22, 2008 and the third-party testing requirement for lead paint became effective December 22, 2008 for products manufactured on or after that date.²⁹³ In total, CPSC published

291. 15 U.S.C. § 2063(a)(3) (2012).

292. Memorandum from Scott Heh, Special Assistant, and Robert J. Howell, Acting Assistant Exec. Dir., Consumer Prod. Safety Comm’n, to the Consumer Prod. Safety Comm’n (Sept. 2, 2008), *available at* <http://www.cpsc.gov/PageFiles/88264/thirdp.pdf>; *see also* 15 U.S.C. § 2063(a)(3)(A) (2012); Requirements Pertaining to Third Party Conformity Assessment Bodies, 77 Fed. Reg. 31,086 (May 24, 2012) (stating that the third-party testing requirement does not commence until “more than 90 days” after the Commission publishes a notice of requirements pertaining to the regulation or standard to which the children’s product is subject).

293. U.S. CONSUMER PROD. SAFETY COMM’N, GUIDANCE DOCUMENT: TESTING AND CERTIFICATION REQUIREMENTS UNDER THE CONSUMER PRODUCT SAFETY

nineteen notices of requirements between 2008 and 2011.²⁹⁴ However, there have been delays and stays of enforcement that have led to departures from the statutory schedule. For example, the CPSC stayed the enforcement of testing and certification requirements that would have gone into effect in February 2009 for new total lead content limits, phthalates limits for certain products, and mandatory toy standards, among other things.²⁹⁵ As of January 2012, almost all stays had been lifted, and third-party certification and testing was required under nearly all the children's product safety rules.²⁹⁶

Rulemaking for the CPSC third-party program has also progressed. In 2011, the CPSC issued a final rule that establishes the "protocols and standards" for certification and testing of children's products and details the requirements for the labeling of certified products.²⁹⁷ In 2012, the CPSC issued a final rule that sets forth requirements for the periodic audit of third party conformity assessment bodies as a condition of their continuing accreditation.²⁹⁸ And in 2013, the CPSC issued a final rule to establish the requirements related to CPSC acceptance of the accreditation of laboratories for purposes of testing children's products.²⁹⁹ The requirements in this

IMPROVEMENT ACT OF 2008 (2009), available at <http://www.cpsc.gov/library/foia/foia10/brief/102testing.pdf> (proposed guidance document).

294. U.S. CONSUMER PROD. SAFETY COMM'N, PROPOSED RULE: REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES 6 (2012), available at <http://www.cpsc.gov/library/foia/foia12/brief/tprequirements.pdf>.

295. Press Release, U.S. Consumer Prod. Safety Comm'n, CPSC Grants One Year Stay of Testing and Certification Requirements for Certain Products (Jan. 30, 2009), available at <http://www.cpsc.gov/en/Newsroom/News-Releases/2009/CPSC-Grants-One-Year-Stay-of-Testing-and-Certification-Requirements-for-Certain-Products/>; see Notice of Stay of Enforcement of Testing and Certification Requirements, 74 Fed. Reg. 6396 (Feb. 9, 2009) (staying the enforcement of certain provisions of section 14(a) of the CPSA); Consumer Product Safety Act: Notice of Commission Action on the Stay of Enforcement of Testing and Certification Requirements, 74 Fed. Reg. 68,588 (Dec. 28, 2009) (revising the terms of stay of enforcement); Consumer Product Safety Act: Notice of Commission Action on the Stay of Enforcement of Testing and Certification Requirements, 76 Fed. Reg. 6765 (Feb. 8, 2011) (continuing the stay of enforcement for testing and certification of children's products for which a notice of requirements for accreditation of laboratories had not yet been published).

296. *FAQs—Certification and Third Party Testing*, U.S. CONSUMER PROD. SAFETY COMM'N, <http://www.cpsc.gov/en/business--manufacturing/testing-certification/third-party-testing/faqs-certification-and-third-party-testing/> [hereinafter *CPSC FAQs*] (last visited Feb. 1, 2014).

297. CPSC Testing and Labeling Pertaining to Product Certification, 76 Fed. Reg. 69,482 (Nov. 8, 2011) (codified at 16 C.F.R. pt. 1107).

298. CPSC Audit Requirements for Third Party Conformity Assessment Bodies, 77 Fed. Reg. 31,074 (May 24, 2012) (codified at 16 C.F.R. pt. 1112).

299. CPSC Requirements Pertaining to Third Party Conformity Assessment Bodies, 78 Fed. Reg. 15,836 (Mar. 12, 2013) (codified at 16 C.F.R. pts. 1112, 1118).

final rule are largely the same as the requirements that the CPSC had set forth in the various notices of requirements that it published since 2008.

There are three types of third-party testing: (1) initial certification testing, (2) material change testing, and (3) periodic testing.³⁰⁰ Initial testing is required for all children's products. They must be tested by a CPSC-accepted, third-party laboratory to ensure compliance with applicable children's product safety rules.³⁰¹ Material change testing by a third-party CPSC-accepted laboratory is required if a material change is subsequently made to any component part of that children's product.³⁰² Periodic testing refers to ongoing testing during production of the children's product. Regardless of whether a material change occurs, the production of certified children's products is subject to periodic testing to ensure compliance with children's product safety rules. These periodic and material testing requirements went into effect in February 2013.³⁰³ The requirements to test children's products when there is a material change and to undertake periodic testing became effective in February 2013.³⁰⁴

The law provides that accreditation of TPCABs may be conducted either by the CPSC or by a designated accreditation body.³⁰⁵ Three types of TPCABs are contemplated by the law: (1) those that are not owned, managed, or controlled by a manufacturer or private labeler of a children's product to be tested for certification purposes ("independent" laboratories); (2) those that are owned, managed, or controlled by a manufacturer or private labeler of the children's product ("firewalled conformity assessment bodies"); and (3) those owned or controlled, in whole or in part, by a government ("governmental laboratories").³⁰⁶

For a TPCAB to be accepted to test children's products for conformity with children's product safety rules, it must be accredited by an accreditation body that is a signatory to the ILAC MRA.³⁰⁷ To be an ILAC-MRA signatory, an accreditation body must, inter alia, operate in accordance with

300. CPSC FAQs, *supra* note 296. See generally 15 U.S.C. § 2063 (2012).

301. 15 U.S.C. § 2063(d)(2)(B)(i) (2012); CPSC FAQs, *supra* note 296.

302. 15 U.S.C. § 2063(d)(2)(B)(i) (2012); CPSC FAQs, *supra* note 296.

303. CPSC FAQs, *supra* note 296.

304. *Id.*

305. 15 U.S.C. § 2063(a)(3)(C) (2012).

306. See CPSC Requirements Pertaining to Third Party Conformity Assessment Bodies, 78 Fed. Reg. at 15859 (codified at 16 C.F.R. pt. 1112.11); see also 15 U.S.C. § 2063(f)(2) (2012).

307. See CPSC Requirements Pertaining to Third Party Conformity Assessment Bodies, 78 Fed. Reg. at 15860 (codified at 16 C.F.R. pt. 1112.13(a)(2)); see also Requirements Pertaining to Third Party Conformity Assessment Bodies, 73 Fed. Reg. 54564 (Sept. 22, 2008), available in unpublished form at <http://www.cpsc.gov/PageFiles/91441/tprequirements.pdf>.

ISO/IEC 17011.³⁰⁸ To make an accreditation determination, the accreditation body assesses the laboratory's conformity with ISO/IEC 17025.³⁰⁹ As described by the CPSC, ISO/IEC 17025 includes technical requirements relating to the competence of laboratory staff, suitability and maintenance of test equipment, and quality assurance of test data.³¹⁰ It also includes management requirements relating to organization, management systems, document controls, audits, and management reviews.³¹¹

Laboratories are accredited with a defined scope of accreditation, which indicates the "children's product safety rule and/or test methods" for which it is accredited to test.³¹² As required by the CPSIA, the commission maintains an online listing of accredited TPCABs and their scopes of accreditation.³¹³ The current list includes hundreds of laboratories in about thirty-five countries.³¹⁴ For example, the U.S.-based laboratory NSF International is accredited by International Accreditation Services Inc. (IAS), and its scope of accreditation includes about forty-five different product safety rules and ASTM standards.³¹⁵

Several measures exist to address conflicts of interest that could raise doubts about the impartiality of product certifications. As part of being accredited to ISO/IEC 17025, a laboratory must "have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity."³¹⁶ A laboratory must further demonstrate that its personnel are free from any undue "commercial, financial and other pressures and influences that may

308. See *ILAC MRA and Signatories*, INT'L LABORATORY ACCREDITATION COOPERATION, <http://www.ilac.org/ilacarrangement.html> (last visited Nov. 9, 2013).

309. CPSC Requirements Pertaining to Third Party Conformity Assessment Bodies, 78 Fed. Reg. at 15860 (codified at 16 C.F.R. pt. 1112.13(a)(2)).

310. U.S. CONSUMER PROD. SAFETY COMM'N, THIRD PARTY CONFORMITY ASSESSMENT BODY ACCREDITATION REQUIREMENTS FOR TESTING COMPLIANCE WITH 16 C.F.R. PART 1501 (SMALL PARTS REGULATIONS) 4 (2008), available at <http://www.cpsc.gov/PageFiles/127865/smallparts.pdf>.

311. *Id.*

312. See *CPSC Form 223—Lab Accreditation*, U.S. CONSUMER PROD. SAFETY COMM'N, <http://www.cpsc.gov/cgibin/labregentry/> (last visited Nov. 9, 2013).

313. See 15 U.S.C. § 2063(a)(3)(E) (2012) (requiring that the Commission maintain on its website an up-to-date list of entities that have been accredited to assess conformity with children's product safety rules).

314. *List of CPSC-Accepted Testing Laboratories*, *supra* note 290.

315. *Id.* (detailed information displayed by highlighting the laboratory name and clicking "submit").

316. ISO/IEC, ISO/IEC DOC. 17025, GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES 3 (2005), available at http://www.saba.org.ir/saba_content/media/image/2011/04/1821_orig.pdf (last visited Feb. 3, 2014).

adversely affect the quality of their work.”³¹⁷ Accredited laboratories are subject to either an on-site surveillance or a full reassessment every two years to ensure that they maintain their standards of independence and technical expertise.³¹⁸

In addition to the baseline accreditation requirements, firewalled laboratories and governmental laboratories seeking CPSC approval must meet additional requirements that relate to their impartiality and independence. The CPSIA specifies that the CPSC may approve a firewalled laboratory if the laboratory has established procedures to ensure that “its test results are protected from undue influence by the manufacturer” and other interested parties, the CPSC is “notified immediately of any attempt by the manufacturer . . . or other interested party to hide or exert undue influence over test results,” and “allegations of undue influence may be reported confidentially.”³¹⁹ Similarly, the CPSIA contains five criteria that a governmental laboratory must satisfy for its accreditation to be accepted by the CPSC, including that manufacturers located in any nation are permitted to choose a laboratory that is not owned or controlled by the government of that nation and that the governmental laboratory does not exercise undue influence on the decisions of other governmental authorities that make decisions affecting its operation or controlling distribution of products.³²⁰

TPCABs undergo a periodic audit that includes reassessment by its accreditation body and reregistration with CPSC.³²¹ CPSC does not specify the frequency of the periodic audit but rather says that it must occur at a minimum “at the frequency established by its accreditation body.”³²² CPSC observes that, according to ISO/IEC 17011, a full reassessment must occur at least every two years, unless an accreditation body undertakes less comprehensive surveillance visits every six months.³²³ In this case, the time between reassessments must be no more than five years.³²⁴

The law provides that the CPSC may withdraw its acceptance of a TPCAB if it finds that “(A) a manufacturer, private labeler, or governmental entity has exerted undue influence on such conformity assessment body or otherwise interfered with or compromised the integrity of the testing process with respect to the certification of a children’s product under this

317. *Id.*

318. U.S. CONSUMER PROD. SAFETY COMM’N, *supra* note 310, at 4.

319. 15 U.S.C. § 2063(f)(2)(D)(ii) (2012).

320. *Id.* at § 2063(f)(2)(B).

321. CPSC Audit Requirements for Third Party Conformity Assessment Bodies, 77 Fed. Reg. at 31083–85.

322. *Id.* at 31085 (codified at 16 C.F.R pt. 1112.35).

323. *Id.* at 31083.

324. *Id.*

section; or (B) such conformity assessment body failed to comply with an applicable protocol, standard, or requirement established by the Commission.”³²⁵ The law also provides that the CPSC may suspend a laboratory’s accreditation if it fails to cooperate with the CPSC in an investigation regarding its certification activities.³²⁶ Implementing these provisions, CPSC has issued regulations that establish whether, when, and how the CPSC may deny a TPCAB’s application, suspend accreditation, and withdraw accreditation.³²⁷

3. Medical Devices

In fulfillment of statutory requirements, the FDA has developed two programs through which regulated entities can opt to have third parties perform compliance assessment tasks related to medical devices that the regulatory agency would otherwise perform. Through the first program, manufacturers of certain medical devices may have third parties review their 510(k) premarket notifications (“510(k) Review Program”). Through the second program, third parties may conduct inspections of facilities that manufacture certain medical devices (“Accredited Person (AP) Inspection Program”). In both, third-party organizations recognized by FDA evaluate a manufacturer’s compliance with mandatory standards in the Federal Food, Drug, and Cosmetic Act.³²⁸

The 510(k) Review Program was established pursuant to the FDA Modernization Act of 1997 (FDAMA). Congress directed FDA to accredit private third parties (referred to as either Accredited Persons (APs) or Recognized Third Parties) to conduct premarket review for low risk (Class I) and certain moderate risk (Class II) devices.³²⁹ FDA established

325. 15 U.S.C. § 2063(e)(1) (2012); *see also* § 2063(e)(2) (setting forth procedures for accreditation withdrawals).

326. 15 U.S.C. § 2063(e)(3) (2012).

327. CPSC Requirements Pertaining to Third Party Conformity Assessment Bodies, 78 Fed. Reg. at 15860 (codified at 16 C.F.R. pt. 1112.41).

328. As used in the program, the term “Persons” refers to organizations. *See* U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-07-157, MEDICAL DEVICES: STATUS OF FDA’S PROGRAM FOR INSPECTIONS BY ACCREDITED ORGANIZATIONS 3 (2007) [hereinafter STATUS OF FDA’S PROGRAM].

329. *See* U.S. FOOD & DRUG ADMIN., *Implementation of Third Party Programs under the FDA Modernization Act of 1997: Final Guidance for Staff, Industry and Third Parties* (2001), available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094459.pdf> [hereinafter *Implementation of Third Party Programs*] (noting that “FDA’s policy permitted third party review of class II devices only if device-specific guidance or recognized consensus standards existed”); *see also* 21 U.S.C. § 360m (2012) (containing the statutory requirement). *See generally* U.S. FOOD & DRUG ADMIN., *Guidance for Third Parties and FDA Staff: Third Party Review of Premarket Notifications* (2004),

accreditation criteria (including criteria to prevent conflicts of interest) and conducted accreditations,³³⁰ published a list of APs,³³¹ and conducted a training program for APs.³³² By creating this option for device manufacturers, Congress intended “to enable FDA to use its scientific review resources for higher-risk devices, while maintaining a high degree of confidence in the review of low-to-moderate risk devices by Accredited Persons, and to provide manufacturers of eligible devices an alternative review process that may yield more rapid 510(k) decisions.”³³³

Several years later, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) authorized FDA to establish a program by which APs would be able to conduct inspections of certain medical device facilities.³³⁴ Under the AP Inspection Program, certain manufacturers of Class II (medium-risk) and Class III (high-risk) medical devices may voluntarily contract with an AP to conduct a “Third-Party Inspection” of their facility. The structure of the program is shown in Figure 4.

available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082194.pdf>.

330. See Medical Devices; Implementation of Third Party Review under the Food and Drug Administration Modernization Act of 1997; Emergency Processing Request Under OMB Review, 63 Fed. Reg. 28,388 (May 22, 1998) (publishing these criteria); *Implementation of Third Party Programs*, *supra* note 329.

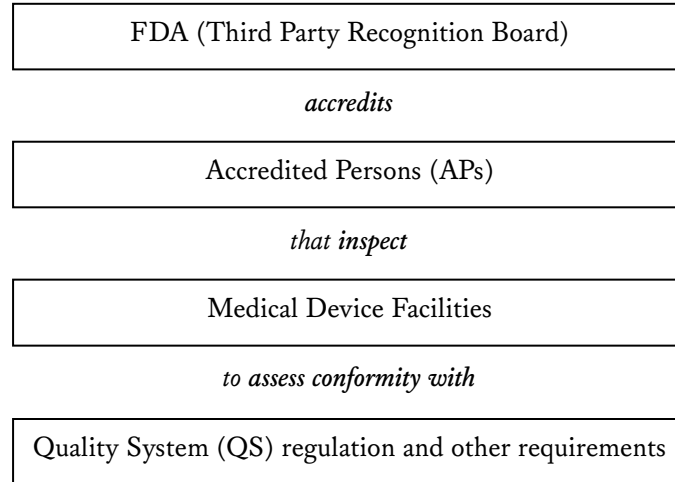
331. See *Current List of Accredited Persons for 510(k) Review under the FDA Modernization Act of 1997*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm> (last visited Feb. 28, 2014).

332. *Implementation of Third Party Programs*, *supra* note 329, at 13.

333. *Id.* at 4.

334. See Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107–250, § 201, 116 Stat. 1588 (2002) (codified at 21 U.S.C. § 374 (g) (2012)) (amended section 704 of the Federal Food, Drug, and Cosmetic Act by adding subsection (g)). The rest of this section focuses on this program rather than the premarket program because information about it was more readily available.

FIGURE 4: STRUCTURE OF THIRD-PARTY PROGRAM FOR MEDICAL DEVICE FACILITIES



FDA considers an inspection by an AP to be “an alternative to the traditional inspection by an FDA official.”³³⁵ In requiring its establishment, Congress sought to address the FDA’s inability to meet its inspection burden.³³⁶ The program also purported to offer an advantage to manufacturers that produce for both the U.S. market and foreign markets by providing the opportunity to undergo a single inspection process that satisfies multiple jurisdictions.³³⁷

The mandatory standard that applies in such inspections is the Quality System (QS) regulation and other device requirements in the FDCA and its regulations.³³⁸ The QS regulation requires that domestic and foreign manufacturers establish a quality system that implements current good manufacturing practices relevant to the “design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended

335. *Accredited Persons Inspection Program*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm125410.htm> (last visited Feb. 3, 2014) (stating that accredited third parties may conduct inspections “in lieu” of the FDA).

336. *See generally* U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-08-428T, *MEDICAL DEVICES: CHALLENGES FOR FDA IN CONDUCTING MANUFACTURER INSPECTIONS* (2008) [hereinafter *CHALLENGES FOR FDA*] (statement of Marcia Crosse, Director, Health Care, United States Government Accountability Office) (citing H.R. REP. NO. 107-728, pt. 1, at 35–36 (2002)).

337. *Id.*

338. 21 C.F.R. § 820 (2010).

for human use” in the United States.³³⁹ In a QS inspection, FDA inspectors “examine manufacturing controls, processes, and records.”³⁴⁰ When a manufacturer participates in the AP Inspection Program, the AP prepares and submits its reports to FDA, which remains responsible for making a final compliance assessment.³⁴¹

FDA has also implemented the MDUFMA’s third-party inspection provisions through its Pilot Multipurpose Audit Program (PMAP).³⁴² PMAP was established in 2006 in partnership with FDA’s Canadian counterpart Health Canada, which also had a third-party certification and inspection program for medical devices.³⁴³ PMAP aimed to include ten inspections in which manufacturers would hire a single accredited third party to conduct an audit that would serve the regulatory purposes of both FDA and Health Canada.³⁴⁴ In total, eleven such inspections were conducted, and the agencies produced a final joint report to summarize lessons learned.³⁴⁵

Importantly, the AP Inspection Program is completely voluntary. Eligible manufacturers may choose to utilize an AP to conduct an inspection or they may continue to have FDA perform inspections.³⁴⁶ If a manufacturer is inspected by an AP, FDA removes the manufacturer from its routine inspection work plan for two years.³⁴⁷ In effect, the manufacturer receives a

339. *Id.* § 820.1(a)(1).

340. STATUS OF FDA’S PROGRAM, *supra* note 328, at 1.

341. See *Accredited Persons Inspection Program*, *supra* note 335; see also 21 U.S.C. § 374(g)(7)(A) (2012) (stating that APs shall prepare an inspection report and that “[a]ny official classification of the inspection shall be determined by the Secretary”).

342. See *Pilot Multi-Purpose Audit Program (PMAP)—Questions and Answers Related to the Pilot*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm125453.htm> (last visited Feb. 3, 2014) [hereinafter *PMAP Q&A*]; see also CHALLENGES FOR FDA, *supra* note 336, at 9, 19–21.

343. *PMAP Q&A*, *supra* note 342.

344. *Final Joint Report of the Pilot Multipurpose Audit Program (PMAP)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm232806.htm> (last visited Feb. 3, 2014) [hereinafter *PMAP Report*]. On international cooperation in regulation, see generally ADMIN. CONFERENCE OF THE U.S., ADMINISTRATIVE CONFERENCE RECOMMENDATION 2011-6 (2011), available at <http://www.acus.gov/acus-recommendations/international-regulatorycooperation/>.

345. *PMAP Report*, *supra* note 344; Telephone Interview with Kim Trautman, Assoc. Dir., Int’l Affairs, Office of the Ctr. Dir., Ctr. for Devices and Radiological Health, U.S. Food & Drug Admin. (Jun. 5, 2012) (reporting that eleven PMAP inspections were conducted).

346. *Accredited Persons Inspection Program*, *supra* note 335.

347. Telephone Interview with David Kalins, Senior Policy Advisor, Office of Compliance, Ctr. for Devices and Radiological Health, U.S. Food & Drug Admin. (July 31, 2012).

two-year “inspection holiday” from regular FDA inspections unless FDA receives a complaint or has other cause to inspect.

Only certain manufacturers are eligible to participate in the program. The manufacturer must manufacture a Class II or Class III device.³⁴⁸ Further, it must market at least one of these medical devices in the United States and also market or plan to market at least one of these medical devices in a foreign country that certifies, accredits, or otherwise recognizes the chosen AP as having the authority to conduct device inspections.³⁴⁹ Also, the program was limited to establishments whose “most recent inspection . . . [was classified] as ‘no action indicated’ or ‘voluntary action indicated.’”³⁵⁰ The Food and Drug Administration Amendments Act of 2007 (FDAAA) “streamlined the Accredited Person for Inspection Program by eliminating the requirement that a device establishment must seek prior FDA approval for a Third Party Inspection” and by “eliminat[ing] the limit of two consecutive Third Party Inspections unless FDA granted a waiver.”³⁵¹ After the amendments, eligible manufacturers may simply submit notification of their intent to use the program.³⁵²

Unlike the two programs reviewed above, FDA does not utilize independent accreditation bodies in this program. Rather, accreditation

348. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, FDA STAFF, AND FDA-ACCREDITED THIRD PARTIES: MANUFACTURER’S NOTIFICATION OF THE INTENT TO USE AN ACCREDITED PERSON UNDER THE ACCREDITED PERSONS INSPECTION PROGRAM AUTHORIZED BY SECTION 228 OF THE FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT OF 2007 (FDAAA) (2009), *available at* <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm#3>.

349. *Id.* at 6 (stating that “[a]t least one foreign country where you market or intend to market your class II or class III device must certify, accredit, or otherwise recognize the AP you have chosen as a person authorized to conduct device inspections”); *see* 21 U.S.C. § 374(g)(6)(A)(ii)(IV)(bb) (2012).

350. 21 U.S.C. § 374(g)(6)(A)(i); *see also* STATUS OF FDA’S PROGRAM, *supra* note 328, at 6 (“Based upon its findings during inspection, FDA classifies completed inspections into one of three categories based on the extent to which the establishment deviates from applicable requirements of the quality system regulation: No action indicated (which indicates no deviations or only minor deviations), voluntary action indicated (which indicates minor to significant deviations), or official action indicated (which indicates significant deviations and warnings).”); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, FDA STAFF, AND THIRD PARTIES: INSPECTION BY ACCREDITED PERSONS UNDER THE MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002 AND THE FDA AMENDMENTS ACT OF 2007; ACCREDITATION CRITERIA (2009), *available at* <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089702.htm> (last visited Feb. 3, 2014) [hereinafter GUIDANCE FOR INDUSTRY].

351. GUIDANCE FOR INDUSTRY, *supra* note 350 at 4.

352. Manufacturer’s Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program, 76 Fed. Reg. 29,764 (May 23, 2011); *see also* GUIDANCE FOR INDUSTRY, *supra* note 350, at 4 (noting the specific information that the notice must include).

determinations are made by FDA's Third Party Recognition Board (TPRB), which was established in 1998 to make accreditation determinations for the 510(k) Review Program.³⁵³ MDUFMA required FDA to establish criteria for the accreditation of APs and to conduct further activities to approve their employees to conduct inspections.³⁵⁴ Under the law, an applicant for accreditation must not be a federal government employee and must be a legally constituted independent entity with no organizational, material, or financial affiliation with a manufacturer, supplier, or vendor of articles regulated under the Act.³⁵⁵

According to FDA guidance, the applicant must agree to "operate in accordance with generally accepted professional and ethical business practices and agree in writing" to, inter alia, limiting its "work to that for which competence and capacity are available," promptly responding and attempting to resolve complaints regarding accredited activities, and protecting against officer and employee financial conflicts of interest.³⁵⁶ FDA also requires that APs have sufficiently trained personnel, including at least one individual with supervisory capability and authority, and the necessary infrastructure "to interface with FDA's electronic data systems" and protect confidential information.³⁵⁷ After an organization is approved as an AP, its employees must complete classroom training and perform several inspections jointly with FDA.³⁵⁸

FDA instructs APs to prepare an inspection report to be submitted to both the manufacturer and the FDA "using the format defined in the Inves-

353. GUIDANCE FOR INDUSTRY, *supra* note 350, at 5. The Third Party Recognition Board is situated within the FDA's Center for Devices and Radiological Health and chaired by William Sutton. *Id.* at 22. On how the TPRB interacts with applicants and reviews applications, see Implementation of the Inspection by Accredited Persons Program under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties; Availability, 68 Fed. Reg. 22,400, 22,402-03 (Apr. 28, 2003). On the 510(k) program generally, see *supra* notes 322-25 and accompanying text.

354. 21 U.S.C. § 374(g)(2) (2012). These criteria were published at 68 Fed. Reg. 22,400-01 (Apr. 28, 2003), and most recently revised in 2009. See GUIDANCE FOR INDUSTRY, *supra* note 350.

355. 21 U.S.C. § 374(g)(3) (2012). See also GUIDANCE FOR INDUSTRY, *supra* note 350.

356. GUIDANCE FOR INDUSTRY, *supra* note 350, at 6-8.

357. *Id.* at 6-8, 13 (noting that an AP "must protect from public disclosure trade secret, confidential commercial or financial information, and private personal identifier information in records . . . except that such information may be made available to FDA"); see also 21 U.S.C. § 374(g)(2) (2012); § 374(g)(3)(E)(iii); GUIDANCE FOR INDUSTRY, *supra* note 350, at 5 (indicating that AP personnel should be as qualified as FDA personnel).

358. GUIDANCE FOR INDUSTRY, *supra* note 350, at 9-10 (providing that APs are not eligible to conduct independent inspections until they successfully complete classroom training and three joint inspections with FDA).

tigations Operations Manual (IOM).”³⁵⁹ The report must describe in detail each significant nonconformity found and identify any “other matters that relate or that may influence compliance with this act.”³⁶⁰ The report must also “describe any recommendations made to the establishment during the inspection or at the inspection’s closing meeting” and “describe any promised corrective actions or other discussions with the management at the conclusion of the inspection.”³⁶¹ APs are required to maintain certain records regarding their initial and continuing qualifications to be APs and regarding each inspection.³⁶² The law also requires an AP that discovers a problem that “could cause or contribute to an unreasonable risk to public health” to immediately report it to FDA.³⁶³

MDUFMA and its regulations require that APs and their employees (including contract employees) be “free from conflicts of interest and the appearance of conflicts of interest” that could “affect the inspection process” or the preparation of reports.³⁶⁴ APs may not be owned, operated, or controlled by a “manufacturer, supplier, or vendor” of any article “regulated under the [A]ct,” and no “personnel” of an “AP involved in inspections,” nor “their spouse or minor children,” may have ownership of or other financial interest in any product, manufacturer, supplier or vendor regulated under the Act.³⁶⁵ Potential conflicts of interest are also present if the AP or any of its inspection personnel “provides consultative services to any manufacturer, supplier, or vendor of products regulated under the [A]ct”; if inspection personnel participate “in an inspection of a firm they were employed by within the last 12 months”; or if the “fees charged or accepted are contingent or based upon the observations in the report made by the AP.”³⁶⁶

FDA is also required by statute to monitor manufacturers’ requests to use a particular AP, and it can “stop inspections by APs who may have developed inappropriate business relationships” with manufacturers.³⁶⁷ As described by FDA, “[b]usiness relationships that may undermine the

359. GUIDANCE FOR INDUSTRY, *supra* note 350, at 12; *see* 21 U.S.C. § 374(g)(7)(A) (2012) (stating that APs are required to prepare inspection reports in the form and manner designated by U.S. FDA); *Investigations Operation Manual*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/Inspections/IOM/default.htm> (last updated Sept. 5, 2013).

360. GUIDANCE FOR INDUSTRY, *supra* note 350, at 12.

361. *Id.*

362. *Id.* at 13–14.

363. 21 U.S.C. § 374(g)(7)(E) (2012); GUIDANCE FOR INDUSTRY, *supra* note 350, at 12.

364. GUIDANCE FOR INDUSTRY, *supra* note 350, at 17; *see* 21 U.S.C. § 374(g)(2)–(3) (2012). FDA uses a rating criteria checklist to evaluate whether APs have adequately protected against conflicts of interest. GUIDANCE FOR INDUSTRY, *supra* note 350, at 15.

365. GUIDANCE FOR INDUSTRY, *supra* note 350, at 8; *see* 21 U.S.C. § 374(g)(3) (2012).

366. GUIDANCE FOR INDUSTRY, *supra* note 350, at 9.

367. *Id.* at 11.

independence or objectivity of an AP include contracts between a manufacturer and an AP that represent a significant share of the AP's income such that continuation or termination of the contract may create undue financial influence or at least the appearance of such influence."³⁶⁸ Evidence of a "financial conflict of interest between the AP and the owner or operator of the inspected device establishment" may constitute cause for withdrawal of the AP's accreditation.³⁶⁹ Finally, the statute requires each AP to "annually make available to the public the extent to which the AP complies with conflict of interest requirements."³⁷⁰ Also, "inspection records and information collected from the manufacturer and submitted to FDA by APs" are generally available for public disclosure "after the agency issues a compliance decision, unless such information is exempt from disclosure by law."³⁷¹

The law provides that FDA will audit APs on a periodic basis, and the FDA states in guidance that it will "make onsite visits on a periodic basis to each AP to audit performance and inspect records, correspondence, and other materials relating to" the AP Inspection Program.³⁷² FDA may withdraw accreditation when an AP is substantially not in compliance with the standards of accreditation, poses a threat to the public health, or fails to act in a manner consistent with the Act.³⁷³ FDA may also "withdraw accreditation" where "FDA determines that there is a financial conflict of interest between the AP and the owner or operator of a device establishment that the AP has inspected."³⁷⁴ Before FDA withdraws an AP's accreditation, it notifies the AP and provides "an opportunity for an informal hearing."³⁷⁵

Since 2003, the FDA has accredited sixteen U.S.- and foreign-based organizations as APs.³⁷⁶ For example, the U.S.-based Underwriters Laboratories, Inc. (UL) is recognized to inspect facilities that make all regulated medical devices, as are other organizations based in the U.K. and China.³⁷⁷

368. *Id.* at 11–12.

369. 21 U.S.C. § 374(g)(5) (2012); GUIDANCE FOR INDUSTRY, *supra* note 350, at 12.

370. 21 U.S.C. § 374(g)(3)(E) (2012); GUIDANCE FOR INDUSTRY, *supra* note 350, at 17.

371. GUIDANCE FOR INDUSTRY, *supra* note 350, at 13. Applicable disclosure laws include the Freedom of Information Act (5 U.S.C. § 552), the Trade Secrets Act (18 U.S.C. § 1905), relevant provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 331(j)) and FDA regulations implementing these statutes (see, for example, 21 C.F.R. § 20 (2013) (the FDA regulations implementing the Freedom of Information Act) and *Freedom of Information*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/foi/default.htm>) (last visited Feb. 3, 2014).

372. GUIDANCE FOR INDUSTRY, *supra* note 350, at 5, 11 (further stating that it audits APs on a periodic and "for cause" basis); see 21 U.S.C. § 374 (g)(5)(A)(i) (2012).

373. 21 U.S.C. § 374(g)(5) (2012); GUIDANCE FOR INDUSTRY, *supra* note 350, at 14.

374. 21 U.S.C. § 374(g)(5) (2012); GUIDANCE FOR INDUSTRY, *supra* note 350, at 14.

375. GUIDANCE FOR INDUSTRY, *supra* note 350, at 14.

376. *Id.* at 3–4.

377. For a list of APs, see *Accredited Persons Inspection Program*, *supra* note 335.

However, by 2012, the AP Inspection Program was largely inactive and a single FDA employee administered the program as a collateral duty.³⁷⁸ Also by 2012, the 510(k) Review Program had no full-time positions committed to it; rather, administrative responsibilities were spread over three employees as part of their other workload.³⁷⁹

4. Telecommunications Equipment

In 1998, the FCC adopted rules for the establishment of Telecommunication Certification Bodies (TCBs) that have the authority to certify that equipment meets the FCC's requirements and issue a written grant of equipment authorization.³⁸⁰ FCC requirements generally apply to all devices that generate radio frequency (RF) energy to ensure that they operate effectively without causing harmful interference to radio communications. Certain devices must also be evaluated for radiofrequency radiation exposure to protect human health.³⁸¹

Only certain types of equipment require certification, and often the certification can be conducted by either a TCB or the FCC.³⁸² Examples of devices that may be submitted to either include, but are not limited to cell phones, RF lights, microwave ovens, RC transmitters, family radios, telemetry transmitters, wireless phones, and walkie-talkies.³⁸³ Some devices may only be submitted to the FCC (such as certain new technologies) or TCBs

378. E-mail from Jean Cooper, Senior Staff Fellow, U.S. Food & Drug Admin., to author (July 17, 2012) (on file with author).

379. *Id.*

380. Frequency Allocations and Radio Treaty Matters, 64 Fed. Reg. 4995 (Feb. 2, 1999); 47 C.F.R. §§ 2.960–62, 68.160–62 (2013). The applicable telecommunications equipment regulations are at 47 C.F.R. §§ 0-101. *See also* OFFICE OF ENG'G & TECH., FED. COMM'NS COMM'N, TCB POST-MARKET SURVEILLANCE 1 n.1 (2008), available at <http://ftp.tiaonline.org/tr-41/TR-41.9/Public/0-Archive/2008-Archive/2008-02-New%20Orleans/TR41.9-08-02-011-TCB%20Surveillance%20Guidelines.pdf> (“The requirements for Telecommunication Certification Bodies (TCBs) were specified in the Commission's Report and Order (R&O) in GEN Docket 98-68 (FCC 98-338), adopted on December 17, 1998. Further guidance on the requirements for TCBs was given in Public Notice DA 99-1640, *FCC Provides Further Information on the Accreditation Requirements for Telecommunication Certification Bodies GEN Docket 98-68*, released on August 17, 1999.”).

381. 47 C.F.R. §§ 2.1091, 2.1093 (2013); *see also* *Radio Frequency Safety*, FED. COMM'NS COMM'N, <http://www.fcc.gov/encyclopedia/radio-frequency-safety> (last visited Nov. 27, 2013).

382. *See* 47 C.F.R. § 2.907 (2013) (on “certification”). Equipment with a low risk of causing harmful interference may generally satisfy FCC requirements through a manufacturer's “verification,” 47 C.F.R. § 2.902 (2013), or “Declaration of Conformity,” 47 C.F.R. § 2.906 (2013).

383. *See* Office of Eng'g & Tech., *Equipment Authorization (EA)*, FED. COMM'NS COMM'N, <http://transition.fcc.gov/oet/ea/procedures.html> (last updated Mar. 22, 2013).

(all computers and computer peripherals). When a manufacturer seeks certification directly from the FCC, equipment authorization fees apply.³⁸⁴

Figure 5 shows the third-party structure of the TCB program. TCBs are required to be accredited as operating in accordance with ISO/IEC Guide 65 and FCC's technical requirements for TCBs.³⁸⁵ Under its National Voluntary Conformity Assessment Evaluation (NVCASE) program, the National Institute of Standards and Technology (NIST) is responsible for recognizing the private accreditation bodies that accredit TCBs in the United States. The two recognized accreditation bodies are American National Standards Institute (ANSI) and the American Association for Laboratory Accreditation (A2LA).³⁸⁶ "Certification bodies located outside the United States may be recognized [by the FCC] as a TCB when there is a government-to-government [Mutual Recognition Agreement] between the country they are located in and the United States."³⁸⁷ In that case, the TCB is accredited by appropriate authorities in that country.³⁸⁸ An online list of recognized TCBs is maintained by FCC.³⁸⁹ The TCB program went into effect in June 2000 with thirteen recognized TCBs, and as of 2012, there are thirty-four recognized TCBs.³⁹⁰

384. See Office of Eng'g & Tech., *What Fees Are Applicable to an Equipment Authorization?*, FED. COMM'NS COMM'N, <https://apps.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?id=41712&switch=P> (last visited Feb. 9, 2014) (showing fees ranging from \$490-\$3,870 for certification of devices).

385. OFFICE OF ENG'G & TECH., FED. COMM'NS COMM'N, TCB PROGRAM ROLES AND RESPONSIBILITIES (2006), available at <https://apps.fcc.gov/kdb/GetAttachment.html?id=LRwF49tahbJq3RjO7IgzAg%3D%3D>; see also 47 C.F.R. § 68.160(b) (2013).

386. See OFFICE OF ENG'G & TECH., *supra* note 385, at 1.

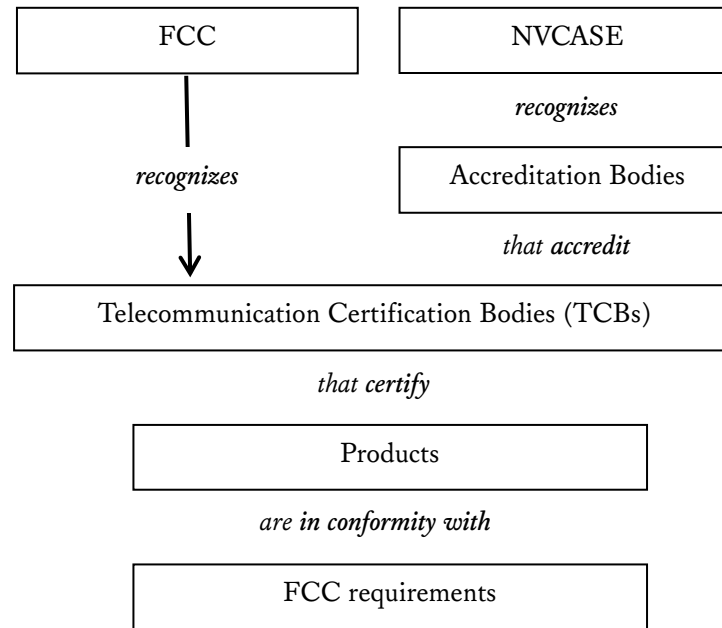
387. *Id.*; see also 47 C.F.R. § 68.160(c) (2013).

388. See OFFICE OF ENG'G & TECH., *supra* note 385, at 1; see also 47 C.F.R. § 68.160(c) (2013).

389. See Office of Eng'g & Tech., *OET Telecommunications Certification Bodies System*, FED. COMM'NS COMM'N, <https://apps.fcc.gov/tcb/index.html> (last visited Nov. 27, 2013).

390. David A. Case & William Graff, *Approval Options: A Look at the FCC and TCB Approval Processes*, COMPLIANCE ENGINEERING, Sept.-Oct. 2001, available at <http://www.cemag.com/archive/01/09/case.html> (providing 2001 number); Telephone Interview with George Tannahill, Office of Eng'g and Tech., Fed. Comm'ns Comm'n, (Aug. 27, 2012) (providing 2012 number).

FIGURE 5: STRUCTURE OF THIRD-PARTY PROGRAM FOR TELECOMMUNICATION EQUIPMENT



The task of the TCB has two steps: first, to evaluate the product (which involves laboratory testing or reliance on testing conducted by the manufacturer); and second, to make the certification decision.³⁹¹ TCBs are accredited with certain scopes, which indicate the product types they may approve (e.g., Scope A: Unlicensed Radio Frequency Devices; Scope B: Licensed Radio Service Equipment). For accreditation, TCBs must “demonstrate expert knowledge of the regulations” for the product types in each of their scopes.³⁹² Also, the TCB must have the “technical expertise and capability to test the equipment it will certify and shall also be accredited in accordance with ISO/IEC Guide 25 to demonstrate it is competent to perform such tests.”³⁹³ Testing of products may be performed by subcontractors of TCBs, but the TCB must maintain oversight and remains responsible for the test results.³⁹⁴ The FCC has not established conflict-of-

391. See OFFICE OF ENG’G & TECH., *supra* note 380, at 2–3; see also 47 C.F.R. § 68.162(b)(2) (2013).

392. 47 C.F.R. § 68.162(c)(2) (2013).

393. 47 C.F.R. § 68.162(c)(3) (2013); OFFICE OF ENG’G & TECH., *supra* note 380, at 2.

394. See 47 C.F.R. § 68.162(d) (2013).

interest rules for TCBs beyond what is required for accreditation to ISO Guide 65.³⁹⁵

Before a TCB can grant an equipment authorization, it must submit all required information to the FCC's online system.³⁹⁶ After the system automatically performs certain validity checks, it can be used to grant the authorization. FCC reserves to itself thirty days to review the completed action and set aside the authorization if necessary. Much of the information that is uploaded, such as pictures of the product, pictures of the label, and certain testing data, becomes publicly available. Other information entered into the system may be considered proprietary and kept confidential.

Also, the FCC requires TCBs to conduct certain surveillance testing of equipment they certify.³⁹⁷ TCBs must test additional equipment samples for at least 5 percent of the grants they issue and electronically submit an annual surveillance report. If a TCB finds that a certified product fails to comply, it must notify FCC and the manufacturer, which will be asked to take actions to correct the situation.³⁹⁸ Subject to certain procedural requirements, the FCC retains authority to withdraw its recognition of TCBs and revoke the certification of products by TCBs.³⁹⁹ FCC itself also conducts market surveillance activities that may include pre-grant testing, post-grant testing, and off-the-shelf product testing. Upon receiving a complaint from a TCB or the public about a problem with another TCB or certified equipment, FCC may pursue the complaint itself, request an assessment by the relevant accreditation body, or require further testing by the relevant TCB.⁴⁰⁰

In May 2013, the FCC issued a proposed rule that would significantly reform the TCB program.⁴⁰¹ Under the new rule, the FCC would rely on

395. Guide 65 states that a certification body should "ensure that activities of related bodies do not affect the confidentiality, objectivity and impartiality of its certifications, and it shall not 1) supply or design products of the type it certifies, 2) give advice or provide consultancy services to the applicant as to methods of dealing with matters which are barriers to the certification requested, 3) provide any other products or services which could compromise the confidentiality, objectivity or impartiality of its certification process and decisions." ISO/IEC, GUIDE 65: GENERAL REQUIREMENTS FOR BODIES OPERATING PRODUCT CERTIFICATION SYSTEMS, at 3 (1996).

396. Telephone Interview with George Tannahill, *supra* note 390.

397. See 47 C.F.R. § 2.962(g)(2) (2013); see also OFFICE OF ENG'G AND TECH., FED. COMM'NS COMM'N, TCB Post-Market Surveillance 1 (2011), available at <https://apps.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?id=20540&tswitch=P>.

398. See 47 C.F.R. § 68.162(g)(3) (2013).

399. Cf. 47 C.F.R. § 68.162(f)(6) (2013).

400. Telephone Interview with George Tannahill, *supra* note 390.

401. See Authorization of Radiofrequency Equipment, 78 Fed. Reg. 25,916 (May 3, 2013) (to be codified at 47 C.F.R. pts. 0, 2, 15, 68).

TCBs to perform all certifications.⁴⁰² The rule clarifies the post-market surveillance that is required of TCBs and the steps that the FCC can take when the performance of a TCB is deficient.⁴⁰³ It also incorporates updated ISO/IEC standards, replacing ISO/IEC Guide 65 with ISO/IEC 17065.⁴⁰⁴

B. Programs for Voluntary Standards

In four programs, federal agencies rely on third parties to assess and certify compliance with voluntary standards. Unlike mandatory standards, companies do not have to comply with voluntary standards in order to conduct their business. Rather, companies may choose to comply in order to receive a marketing label or other desired benefit. The four programs described below all offer companies the opportunity to display a label on their products attesting to their compliance. In all of them, the use of third parties is obligatory: to participate in the program, the company that sells the labeled product has to contract with a third party.

1. Workplace Product Safety

Since 1988, the Occupational Safety and Health Administration (OSHA) has operated a third-party program through which it ascertains that specified equipment and materials (products) used in OSHA-regulated workplaces meet safety standards.⁴⁰⁵ The program's structure is illustrated in Figure 6. Under OSHA's Nationally Recognized Testing Laboratory (NRTL) Program, private sector organizations approved by OSHA are hired by manufacturers of specified products to test and certify them. The NRTL then authorizes the manufacturer to affix a label (or mark) on the products, which is visible to the OSHA workplace inspector.

OSHA requires NRTL certification for many different types of products, such as printers and copiers, electric heaters and air conditioners, alarm systems, fire extinguishers, acetylene torches, and liquefied petroleum

402. *Id.* at 25,920.

403. *Id.* at 25,922–24.

404. *Id.* at 25,925.

405. See Safety Testing or Certification of Certain Workplace Equipment and Materials, 53 Fed. Reg. 12,102 (Apr. 12, 1988) (to be codified at 29 C.F.R. pts. 1907, 1910); 29 C.F.R. § 1910, sbpt. S (2013); see also Bernard Pasquet, *OSHA Requirements for Nationally Recognized Testing Laboratory Approval of Products*, U.S. DEP'T OF LABOR, <http://www.osha.gov/dts/otpc/nrtl/NRTLarticle.html> (last visited Feb. 9, 2014) (stating that workplaces subject to OSHA's jurisdiction include the "vast majority of private employers in the United States and its territories"; "most Federal Government places of employment"; and "State and local government places of employment in States that have received OSHA approval to administer their own occupational safety and health program").

gas ovens.⁴⁰⁶ The standards that the products must meet to be certified by an NRTL are voluntary consensus standards, rather than government-unique OSHA standards.⁴⁰⁷ These standards are set by national standards-producing organizations such as ANSI, ASTM, Factory Mutual Research Corporation (FMRC), and UL.⁴⁰⁸ In effect, manufacturers are not required by law to meet these standards to market their products, but workplaces that are regulated by OSHA are required to utilize products that are certified to these standards.

NRTLs are private organizations that are recognized by OSHA to be qualified to perform safety testing and product certification.⁴⁰⁹ OSHA regulations set forth the requirements for NRTLs.⁴¹⁰ NRTLs must be capable of performing the proper testing, meaning that they must have the proper equipment and facilities, staff, procedures, and quality control programs.⁴¹¹ They shall, as necessary, implement control procedures, inspect the production of items at factories, and conduct field inspections to monitor the proper use of their marks on products.⁴¹² They must be “completely independent” of both the manufacturers and vendors of equipment subject to testing and the employers subject to the tested equipment requirements.⁴¹³ NRTLs must maintain effective procedures for producing objective and unbiased reports and for fairly handling complaints and disputes.⁴¹⁴

406. See Pasquet, *supra* note 405; see also Occupational Safety & Health Admin. [OSHA], *Type of Products Requiring NRTL Approval*, U.S. DEP'T OF LABOR, <http://www.osha.gov/dts/otpc/nrtl/prodcatg.html> (last visited Feb. 9, 2014) (setting forth thirty-seven product categories, of which electrical equipment is the largest, and citing to General Industry Standards, 29 C.F.R. pt. 1910 (2013)).

407. See OSHA, *Frequently Asked Questions*, U.S. DEP'T OF LABOR, https://www.osha.gov/dts/otpc/nrtl/faq_nrtl.html#8 (answering the question “What product safety test standards can an NRTL use in certifying products?”).

408. See OSHA, U.S. DEP'T OF LABOR, *NATIONALLY RECOGNIZED TESTING LABORATORY PROGRAM APPLICATION GUIDELINES 1 (2000)*, available at <https://www.osha.gov/dts/otpc/nrtl/applguid.pdf> [hereinafter OSHA APPLICATION GUIDELINES]. A list of standards recognized by OSHA is available at https://www.osha.gov/pls/oshaweb/owasrch.search_form?p_doc_type=STANDARDS&p_toc_level=0&p_keyvalue=.

409. See OSHA, *Frequently Asked Questions (FAQs)*, U.S. DEP'T OF LABOR, http://www.osha.gov/dts/otpc/nrtl/faq_nrtl.html#1 (last visited Nov. 8, 2013) (“OSHA’s recognition is not a government license or position, or a delegation or grant of government authority. Instead, the recognition is an acknowledgment that an organization has necessary qualifications to perform safety testing and certification of the specific products covered within its scope of recognition.”).

410. See 29 C.F.R. § 1910.7 (2013).

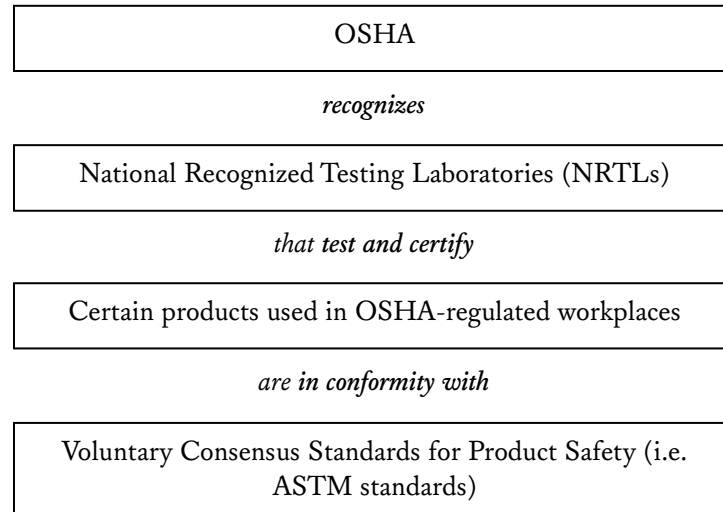
411. See *id.* § 1910.7(b)(1).

412. *Id.* § 1910.7(b)(2).

413. *Id.* § 1910.7(b)(3).

414. *Id.* §§ 1910.7(b)(4)(i)–(ii).

FIGURE 6: STRUCTURE OF THIRD-PARTY PROGRAM FOR
WORKPLACE PRODUCT SAFETY



If its application is approved by OSHA, an NRTL's initial recognition is valid for five years.⁴¹⁵ OSHA approves NRTLs with certain “scopes of recognition” by specifying the test standards with which they can certify conformity. OSHA maintains an online registry of NRTLs and their scopes of recognition.⁴¹⁶ Currently, fifteen NRTLs are recognized by OSHA.⁴¹⁷ Twelve are headquartered in the United States, and three NRTLs are headquartered in other countries.⁴¹⁸ Some NRTLs are based in one country but also have offices in others. For example, CSA International is based in Toronto, Canada and also has offices in Ohio and California, and UL is based in Illinois and also has offices in four other U.S. states and ten foreign countries.

NRTLs and applicants for NRTL recognition must pay fees.⁴¹⁹ OSHA assesses fees for processing applications for “initial recognition, expansion of recognition, or renewal of recognition, including on-site reviews; review and evaluation of the applications; and preparation of reports, evaluations

415. See OSHA APPLICATION GUIDELINES, *supra* note 408 at 1.

416. See OSHA, *Nationally Recognized Testing Laboratories (NRTLs)*, U.S. DEP'T OF LABOR, <http://www.osha.gov/dts/otpc/nrtl/> (last visited Nov. 8, 2013) (listing recognized NRTLs).

417. E-mail from Kevin Robinson, OSHA, U.S. Dep't of Labor (Oct. 11, 2012).

418. *Id.*

419. 29 C.F.R. § 1910.7(f) (2013).

and Federal Register notices; and audits of sites.”⁴²⁰ Fees first went into effect on October 1, 2000.⁴²¹ They were revised in 2002, 2007, and 2011.⁴²² A current listing of the applicable fees is maintained online.⁴²³ For example, total fees to become recognized as an NRTL currently amount to over \$40,000 (including an initial application review fee of \$17,750, an assessment fee of \$4,440 plus travel expenses, and a final report and Federal Register notice fee of \$19,520).⁴²⁴ Substantial fees also apply when an NRTL expands or renews its recognition. For the audits that OSHA requires of recognized NRTLs, OSHA charges at least \$4,400 plus travel expenses for an on-site audit and \$1,120 for an office audit.⁴²⁵ Audit fees are significantly higher if nonconformances are found or if more than one day is required.

2. Organic Food

The National Organic Program (NOP), administered by the United States Department of Agriculture’s Agricultural Marketing Service (AMS), relies on a system of third-party certification. The Organic Foods Production Act of 1990, the authorizing legislation for the NOP, states that the “Secretary shall implement the program . . . through certifying agents.”⁴²⁶ In regulations promulgated in 2000, AMS set the organic standards that cover the production, postharvest handling, and processing of organic foods and specified the third-party certification system that would determine whether a certain product met those standards.⁴²⁷

These regulatory standards are voluntary in that food producers or handlers are only required to conform to them if they label their products

420. *Id.* § 1910.7(f)(1)(i)–(ii) (describing how fees are determined and stating that the fees reflect the full cost of performing the listed activities).

421. OSHA, *Fee Payment Instructions and Information*, U.S. DEP’T OF LABOR, <http://www.osha.gov/dts/otpc/nrtl/nrtlfees.html> (last visited Nov. 29, 2013); *see also* OSHA, *Nationally Recognized Testing Laboratories—Fees*; Public Comment Period on Recognition Notices, 65 Fed. Reg. 46,798 (July 31, 2000) (to be codified at 29 C.F.R. pt. 1910), *available at* http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=FEDERAL_REGIS TER&p_id=15480.

422. *Nationally Recognized Testing Laboratories Fees*, 76 Fed. Reg. 10,500 (Feb. 25, 2011), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2011-02-25/html/2011-3937.htm> (last visited Nov. 29, 2013) (revising the fee regulations).

423. OSHA, *Fee Schedule (effective March 28, 2011)*, U.S. DEP’T OF LABOR, <http://www.osha.gov/dts/otpc/nrtl/nrtlschedule.html> (last visited Sept. 11, 2012).

424. *Id.*

425. *Id.*

426. 7 U.S.C. § 6503(d) (2012).

427. The final organic rule was published on December 21, 2000, and the regulations implementing the NOP became effective October 21, 2002. *See* 7 C.F.R. § 205 (2013).

as organic. However, if food producers or handlers label their products as organic, it is mandatory that they use an accredited third party to provide the required certification.⁴²⁸ The certifying agents are responsible for all aspects of the certification process: conducting inspection as necessary to verify compliance with regulatory requirements, issuing certification decisions, issuing notices of noncompliance, and suspending or revoking the certification of clients that are out of compliance.⁴²⁹

As shown in Figure 7, third-party certifying agents are directly accredited by the AMS. They may be private or governmental entities, and under certain circumstances, the agency may accept a foreign government's accreditation of foreign certifying agents.⁴³⁰ To be accredited, the entity must have sufficient expertise and adequately trained personnel to comply with the terms of the organic certification program.⁴³¹ Certifying agents must also conduct an annual program review of their certification activities and correct any noncompliance,⁴³² and they must maintain records of certification processes and make them available for inspection upon request.⁴³³ As of 2012, about ninety entities—about fifty domestic and forty foreign—were accredited by the NOP to act as certifying agents.⁴³⁴ Examples of domestic certifying agents include private organizations like Global Organic Alliance, Inc., based in Ohio, and the Idaho State Department of Agriculture's Division of Plant Industries.⁴³⁵ Overall, state agencies constituted seventeen of the fifty-one domestic organic certifiers.⁴³⁶ Examples of foreign domestic certifying agents include Argencert S.A., based in Argentina, and CAAE Certification Service, based in Spain.⁴³⁷

The NOP regulations include several provisions to avoid potential conflicts of interest.⁴³⁸ Certifying agents are required to prevent conflicts of interest by not certifying operations that they have any commercial interest

428. *National Organic Program: Organic Certification & Accreditation*, U.S. DEP'T OF AGRIC., <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&navID=NationalOrganicProgram&leftNav=NationalOrganicProgram&page=NOPAccreditationandCertification&description=Accreditation%20and%20Certification&acct=nopgeninfo> (last visited Nov. 29, 2013).

429. 7 C.F.R. §§ 205.403–205.406 (2013).

430. *Id.* § 205.500(c) (2013).

431. *Id.* § 205.501(a)(1)–(6) (2013).

432. *Id.* § 205.501(a)(7) (2013).

433. *Id.* § 205.501(a)(9) (2013).

434. *National Organic Program: Organic Certification & Accreditation*, *supra* note 428.

435. See *Complete Domestic ACA List*, U.S. DEP'T AGRIC., <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5074486> (last visited Nov. 29, 2013).

436. *Id.*

437. See *Complete Foreign ACA List*, U.S. DEP'T AGRIC., <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5074487> (last visited Nov. 29, 2013).

438. 7 C.F.R. § 205.501(a)(11) (2013).

in, excluding the participation of employees or contractors that have any such commercial interests, not permitting employees or contractors to accept any payment or gifts other than prescribed fees for certification, not providing consultation services to certified operations, requiring employees and contractors to complete annual conflict-of-interest disclosure reports, and requiring that the decision to certify be made by someone different from those conducting prior certification activities.⁴³⁹

FIGURE 7: STRUCTURE OF THIRD-PARTY PROGRAM FOR ORGANIC FOOD LABEL



The regulations provide that AMS will conduct on-site reviews of accredited certifying agents. Such reviews encompass “the certifying agent’s certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent.”⁴⁴⁰ Such reviews should occur before or soon after initial accreditation, before renewal of accreditation, and one or more times during the five-year period of accreditation.⁴⁴¹ NOP reports that fifty-six such onsite reviews or inspections occurred in 2012.⁴⁴²

439. *Id.*

440. *Id.* § 205.508(a).

441. *See* 7 C.F.R. §§ 205.508(b), 205.500 (2013) (specifying that the duration of accreditation is five years).

442. Telephone Interview with Cheri Courtney, Acting Dir., Accreditation & Int’l Activities Div., Nat’l Organic Prog. (Aug. 16, 2012). Some audit reports and corrective action reports can be found on the NOP website. *See Appeals and Settlement Reports*, U.S. DEPT AGRIC., <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateJ&page=NOPReadingRoomHome> (last visited Sept. 9, 2012).

The authorizing legislation stated that the NOP should provide for the “collection of reasonable fees from producers, certifying agents and handlers who participate in such program.”⁴⁴³ The NOP regulations specify that the cost of the program’s accreditation services will be collected from applicants for initial accreditation and accredited certifying agents for review of annual reports and accreditation renewal.⁴⁴⁴ In 2010, the average cost to a domestic certifying agent applicant was \$4,428, and the average cost to a foreign certifying agent was \$24,082.⁴⁴⁵

3. Energy Efficiency

The Environmental Protection Agency (EPA) established the Energy Star Program in 1992 as a labeling system for products that met specified voluntary efficiency standards.⁴⁴⁶ The Department of Energy (DOE) has jointly administered the program since 1995, when labeled products expanded from computers and monitors to “additional office equipment and residential heating, ventilation, and cooling (HVAC) equipment.”⁴⁴⁷ Over sixty product categories may now carry the Energy Star label including major appliances, office equipment, lighting, home electronics, new homes, and commercial and industrial buildings.⁴⁴⁸ As of 2010, more than 40,000 individual product models made by over 1,600 manufacturers had earned the Energy Star label.⁴⁴⁹

Effective in 2011, after a critical report by the Government Accountability Office, Energy Star was significantly restructured by EPA to require

443. 7 U.S.C. § 6506(a)(10) (2012).

444. 7 C.F.R. § 205.640 (2013).

445. *National Organic Program FAQ: Becoming a Certifying Agent*, U.S. DEP’T AGRIC., <http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=NOPFAQsHowAccredited&topNav=&leftNav=NationalOrganicProgram&page=NOPFAQsHowAccredited&description=FAQ:%20%20Becoming%20a%20Certifying%20Agent&acct=nopgeninfo> (last visited Nov. 29, 2013).

446. See *infra* note 528.

447. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-10-470, ENERGY STAR PROGRAM: COVERT TESTING SHOWS THE ENERGY STAR PROGRAM CERTIFICATION PROCESS IS VULNERABLE TO FRAUD AND ABUSE 3 (2010).

448. For general information, see *History*, subsection of *About ENERGY STAR*, ENERGY STAR, U.S. ENVTL. PROT. AGENCY, http://www.energystar.gov/index.cfm?c=about.ab_history (last visited Nov. 29, 2013) (discussing the history of the Energy Star labeling system and the types of products labeled).

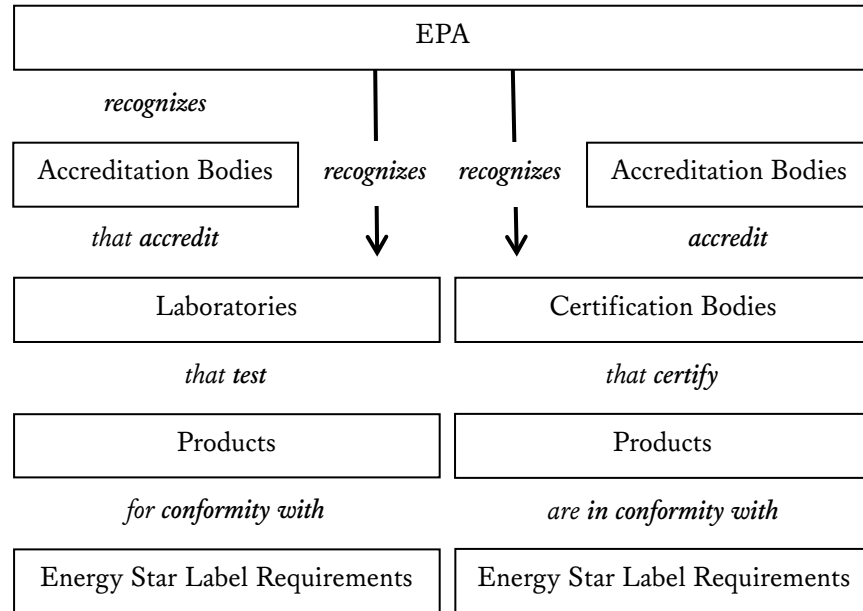
449. U.S. ENVTL. PROT. AGENCY, ENERGY STAR OVERVIEW OF 2010 ACHIEVEMENTS (2011), available at <http://www.energystar.gov/ia/partners/publications/pubdocs/2010%20CPD%204pgr.pdf>.

that products carrying the label be certified by third parties.⁴⁵⁰ The new third-party structure for the program is shown in Figure 8. “Previously, manufacturers self-declared . . . that their products met the Energy Star requirements. With the new third-party certification requirement, product testing must be conducted in an [EPA-recognized] laboratory and the results must be certified and submitted to EPA by an [EPA-recognized] certification body.”⁴⁵¹ EPA recognition, in turn, generally depends on accreditation to an appropriate ISO standard by an EPA-recognized accreditation body.

450. See U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 447. See generally *Third-Party Certification*, ENERGY STAR, U.S. ENVTL. PROT. AGENCY, http://www.energystar.gov/index.cfm?c=third_party_certification.tpc_index (last visited Nov. 29, 2013).

451. McAllister, *supra* note 21 at 19.

FIGURE 8: STRUCTURE OF THIRD-PARTY PROGRAM FOR ENERGY STAR PRODUCT LABEL



Accreditation bodies play the role of providing the accreditation that certification and laboratories require to become EPA-recognized. To accredit certification bodies, an accreditation body must be a signatory to the IAF MLA.⁴⁵² In 2013, there were about seventy signatories to the IAF MLA based in about fifty different countries.⁴⁵³ In the United States, there are four IAF MLA signatories, including A2LA, IAS, and ANSI.

To accredit laboratories, an accreditation body must be itself recognized by the EPA. For recognition, the accreditation body must operate its accreditation program in accordance with ISO/IEC 17011 and maintain an affiliation with ILAC.⁴⁵⁴ By 2013, EPA had recognized twenty-seven

452. *Accreditation Body Resources*, ENERGY STAR, U.S. ENVTL. PROT. AGENCY, http://www.energystar.gov/index.cfm?c=third_party_certification.tpc_accred_bodies (last visited Nov. 29, 2013).

453. *See IAF Members and Signatories*, INT'L ACCREDITATION FORUM, http://www.iaf.nu/articles/Accreditation_Body_Members_by_Name/52, accessible from *IAF MLA*, INT'L ACCREDITATION FORUM, http://www.iaf.nu/articles/IAF_MLA/14 (last visited Feb. 10, 2014).

454. *Conditions and Criteria for Recognition of Accreditation Bodies for Energy Star Laboratory Recognition*, ENERGY STAR, http://www.energystar.gov/ia/partners/downloads/mou/Criteria_Accreditation_Bodies_Labs.pdf?e75e-ee91 (last visited Nov. 29, 2013).

accreditation bodies around the world, including A2LA, IAS, and three others in the United States.⁴⁵⁵

EPA-recognized certification bodies (CBs) certify that eligible products meet the requirements of the Energy Star label. A key requirement for recognition is accreditation to ISO/IEC Guide 65 or ISO/IEC 17065 by an accreditation body that is an IAF MLA signatory.⁴⁵⁶ These standards require, for example, that the CB operate in a non-discriminatory manner and make certification decisions based on information gathered during the evaluation process.⁴⁵⁷ EPA also imposes a variety of other requirements regarding how CBs determine whether a product qualifies for the Energy Star label and how CBs must conduct a verification testing program to verify that their certified products continue to meet Energy Star requirements.⁴⁵⁸ More specifically, CBs are required to annually select and test at least 10 percent of all models they have certified, with half the models being randomly selected and half selected based on EPA referrals. As of 2013, Energy Star had recognized about twenty-five certification bodies around the world.⁴⁵⁹

In general, qualifying Energy Star products should be tested in an EPA-recognized laboratory. For recognition, laboratories must be accredited to ISO/IEC 17025 by an EPA-recognized accreditation body. ISO/IEC 17025 requires, for example, that a laboratory employ experienced personnel with adequate training, have adequate physical plant facilities and test equipment, and ensure that measuring equipment is accurate.⁴⁶⁰ Recognized labs must also agree to a variety of other requirements, such as reporting to EPA and otherwise enabling EPA oversight.⁴⁶¹ Recognized labs need not be independent; they may be owned by the manufacturers of the products they test.

455. See *EPA-Recognized Accreditation Bodies*, ENERGY STAR, U.S. ENVTL. PROT. AGENCY, http://www.energystar.gov/index.cfm?c=partners.epa_recognized_accreditation_bodies (last visited Nov. 29, 2013).

456. See *Conditions and Criteria for Recognition of Certification Bodies for the ENERGY STAR Program*, ENERGY STAR, U.S. ENVTL. PROT. AGENCY, http://www.energystar.gov/ia/partners/downloads/mou/Conditions_and_Criteria_for_Recognition_of_Certification_Bodies.pdf (last visited Feb. 10, 2014).

457. *Id.*

458. *Id.*

459. *EPA-Recognized Certification Bodies (CBs) and Laboratories*, ENERGY STAR, U.S. ENVTL. PROT. AGENCY, http://www.energystar.gov/index.cfm?fuseaction=recognized_bodies_list.show_RCB_search_form (last visited Nov. 8, 2013) (generating a list of certification bodies with the search menu).

460. *Conditions and Criteria for Recognition of Laboratories for the ENERGY STAR Program*, ENERGY STAR, U.S. ENVTL. PROT. AGENCY, at 1, http://www.energystar.gov/ia/partners/downloads/mou/Criteria_Laboratories.pdf (last visited Nov. 29, 2013).

461. *Id.*

Manufacturers' laboratories that are not accredited may also be used for testing under the Energy Star's Witnessed Manufacturers' Testing Laboratory or Supervised Manufacturers' Testing Laboratory programs.⁴⁶² Under these programs, a CB may operate a testing program to accept test data from such a lab if the CB commits to exercising and documenting a high degree of oversight, including on-site assessment and monitoring to ensure the laboratory's compliance with ISO 17025 and applicable test methods. As of August 2012, Energy Star testing was being conducted in 463 laboratories: 224 accredited labs, 180 supervised labs, and 59 witnessed labs.⁴⁶³ About 200 of these labs were located in the Asia-Pacific region, most of which were fully accredited.⁴⁶⁴

4. Water Efficiency

EPA's WaterSense product certification program, which provides a label for high-performing, water-efficient products, also relies on third-party certification as shown in Figure 9. Modeled after Energy Star, WaterSense was launched in 2006 and has required third-party certification since 2009.⁴⁶⁵ All products bearing the WaterSense label must be assessed for conformity with the WaterSense product specification by an accredited third-party certifying body. The certifying bodies, in turn, are accredited by an accreditation body approved by EPA.

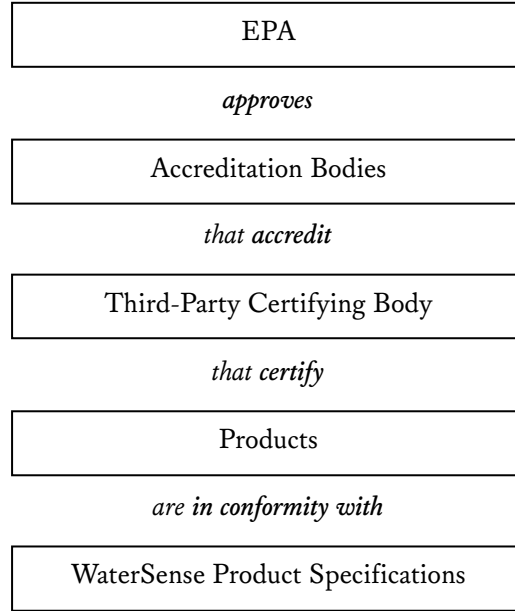
462. *Id.* at 1 n.1.

463. Telephone Interview with Eamon Monahan, Energy Star Program, U.S. Env'tl. Prot. Agency (Aug. 6, 2012).

464. *Id.*

465. *Comprehensive List of All Frequent Questions*, WATERSENSE, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/watersense/full_list.html (last visited Nov. 29, 2013). EPA issued the first WaterSense product certification system in 2009. WATERSENSE, U.S. ENVTL. PROT. AGENCY, WATERSENSE PRODUCT CERTIFICATION SYSTEM (2009) *available at*, http://www.epa.gov/watersense/docs/cert_system_revised508.pdf. EPA issued a revised version in 2011. WATERSENSE, U.S. ENVTL. PROT. AGENCY, WATERSENSE PRODUCT CERTIFICATION SYSTEM VOLUME 2.0 (2011), *available at* http://www.epa.gov/watersense/docs/cert_system_508.pdf [hereinafter WATERSENSE 2.0].

FIGURE 9: STRUCTURE OF THIRD-PARTY PROGRAM FOR
WATERSENSE PRODUCT LABEL



The applicable standards in WaterSense are EPA's "product specifications," which are currently finalized for seven product categories: Tank-Type Toilets, Lavatory Faucets, Flushing Urinals, Showerheads, Weather-Based Irrigation Controllers, Commercial Pre-Rinse Spray Valves, and Product and Labeling Clarifications.⁴⁶⁶ Manufacturers seeking to use the WaterSense label on products in these categories first enter into a WaterSense partnership agreement with EPA and then have their product(s) "certified for conformance to the WaterSense specification by an EPA licensed certifying body."⁴⁶⁷ "Manufacturers apply directly to the licensed certifying body for certification and to obtain the WaterSense label."⁴⁶⁸

To be approved by EPA, an accreditation body must be domiciled in the United States and show that it operates in accordance with the require-

466. *Compendium of Product & Program Specifications*, WATERSENSE, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/watersense/partners/product_program_specs.html (last visited Nov. 29, 2013).

467. *Product Certification & Labeling*, WATERSENSE, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/watersense/about_us/product_certification_labeling.html (last visited Nov. 8, 2013).

468. *Id.*

ments of ISO/IEC 17011.⁴⁶⁹ Also, it must offer accreditation services to ISO/IEC Guide 65 and the IAF Guidance on the Application of ISO/IEC Guide 65 and be an IAF MLA signatory for products.⁴⁷⁰ As of 2013, EPA had approved three accreditation bodies: A2LA, ANSI, and IAS.⁴⁷¹

Product-certifying bodies must be accredited by an approved accreditation body in accordance with ISO/IEC Guide 65 and the IAF Guidance on the Application of ISO/IEC Guide 65 to operate the WaterSense product certification system and certify products to the relevant WaterSense product specifications. The accreditation body determines the certifying body's scope of accreditation by accrediting it for any or all of the WaterSense product specifications established by EPA. Accredited certifying bodies also sign a licensing agreement with EPA to certify and label products for WaterSense.⁴⁷² As of May 2012, EPA had licensed six certification bodies to provide product certifications for one or more of the seven product categories.⁴⁷³ Examples of licensed certification bodies include Intertek and NSF International, based in the United States, and CSA International, based in Canada.

In addition, certifying bodies must have procedures in place to ensure that the testing data that they rely on is reliable. Independent testing labs that are used by certifying bodies must demonstrate compliance with ISO/IEC 17025 and the relevant WaterSense product specification.⁴⁷⁴ If a certifying body relies on testing data from a manufacturer's laboratory, additional requirements are imposed.⁴⁷⁵ To the extent that a certification body outsources its evaluation process to contractors, it must have "documented policies and procedures for . . . qualifying, assessing, and monitoring" them, and it must make a list of them available to the EPA or accreditation body to review.⁴⁷⁶

469. WATERSENSE 2.0, *supra* note 465, at 4. The requirement that the accreditation body be domiciled in the United States is not present in EPA's Energy Star program or other programs included in this review.

470. *Id.* (noting that references to ISO/IEC Guide 65 will be superseded by ISO/IEC 17065 once ISO/IEC 17065 is published).

471. *Accreditation & Licensed Certifying Bodies*, WATERSENSE, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/watersense/about_us/cert_bodies.html#accreditation (last visited Nov. 8, 2013).

472. WATERSENSE 2.0, *supra* note 465, at 6.

473. *Accreditation & Licensed Certifying Bodies*, *supra* note 471.

474. WATERSENSE 2.0, *supra* note 465, at 8; *see also* U.S. ENVTL. PROT. AGENCY, RESPONSE TO PUBLIC COMMENTS RECEIVED ON JUNE 2011 WATERSENSE DRAFT REVISED PRODUCT CERTIFICATION SYSTEM 11 (Sept. 29, 2011) (clarifying that WaterSense does not require ISO/IEC 17025 accreditation for testing laboratories; it only requires that labs "demonstrate compliance with ISO/IEC 17025").

475. WATERSENSE 2.0, *supra* note 465, at 8.

476. *Id.* at 9.

III. MEASURING SUCCESS

Given the growing prevalence of third-party verification programs, it is important to evaluate which work well and why. This section first sets forth five metrics to assess success. They include the reliability of third-party determinations, compliance rates, agency capacity to administer the third-party system, public acceptance, and industry acceptance. The second part discusses the incentives that are necessary to attract participation in programs where regulated entities may choose whether to contract with a third party or rely on regulatory agency for verification of regulatory compliance.

A. Reliability

A key metric of success of third-party programs is whether the third-party assessment produces determinations that are sufficiently reliable and accurate for the regulatory purpose at hand. This metric allows for some variation. It may be acceptable to the agency, for example, for the reliability of third-party determinations regarding conformity with voluntary standards to be lower than the reliability of those regarding conformity with mandatory standards. Similar to private conformity assessment systems that may vary depending on the needs of the purchaser, regulatory third-party systems may also be allowed to vary depending on regulatory needs.⁴⁷⁷

To a large degree, the reliability of determinations made by third parties will depend on their competence and independence. Generally, third parties must be competent to perform the required assessment tasks and independent (or unbiased) in their assessment. In addition, programs should be designed to enhance the consistency of third-party determinations and avoid problems that have undermined the reliability of similar assessments in non-regulatory contexts.

In some areas of regulation in which regulatory third-party programs are being constructed, third parties have been used by private parties to assess conformity for many years. However, these private systems have sometimes suffered from a lack of reliability. For example, in the food safety area, corporate purchasers have required suppliers to conduct independent third-party audits of their facilities. Newsworthy failures in these systems have suggested problems with the reliability of these audit determinations. In the case of the Peanut Corporation of America and the salmonella outbreak with which it is associated, third-party auditors had given the manufacturer a “superior rating,” but later investigation by FDA showed that product testing had revealed instances of salmonella contami-

477. Cf. *infra* note 612 and accompanying text (recommending that agencies calibrate the design of third-party programs to the level of risks associated with noncompliance).

nation.⁴⁷⁸ In cases like this, questions have been raised about both the competence and the independence of third-party auditors.

To ensure competence, an agency may have to give serious attention to the training of third parties. Two recent pilot programs undertaken by FDA have underscored the importance of such training. In a pilot program conducted by FDA in which certification bodies were selected to inspect establishments in the aquacultured shrimp industry for compliance with U.S. food safety standards, the agency's audits of the CBs found that some were not using the correct standards in their inspections even though they had been instructed to do so.⁴⁷⁹ Rather, they were using standards of other countries, which they had presumably used in other audits.⁴⁸⁰ FDA concluded that it would have to conduct additional training to implement a full-scale third-party program.⁴⁸¹ Similarly, in PMAP, FDA's pilot program with Canada for medical device facility inspections, FDA found that training was needed to ensure that "additional regulatory requirements outside of the ISO 13485:2003 standard and the QS regulation are adequately covered during audits/inspections."⁴⁸²

Despite the training issues, however, the FDA concluded in PMAP that the use of third-party auditors held promise. FDA gave an overall vote of confidence in its workability, stating that "[Health Canada] and FDA have confidence in the ability of a qualified and competent auditing organization to plan, carry out, and report on the audit/inspection according to basic [Health Canada] and FDA requirements."⁴⁸³ In a similar vein, an FDA staffer who has worked with the AP Inspection Program indicated that he perceived APs to be very competent, particularly in performing ISO 13485 facility inspections.⁴⁸⁴ He noted, however, that because they rarely do inspections for the AP Inspection Program, the information they provide to

478. Andrew Martin, *Peanut Plant Says Audits Declared It in Top Shape*, N.Y. TIMES (Feb. 4, 2009), available at http://www.nytimes.com/2009/02/05/business/05peanuts.html?_r=1&ref=peanutcorporationofamerica.

479. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., ASSESSMENT OF THE THIRD-PARTY CERTIFICATION PILOT FOR AQUACULTURED SHRIMP 12 (2011); see also Draft Guidance for Industry on Voluntary Third-Party Certification Programs for Foods and Feed Availability, 73 Fed. Reg. 39,704-05 (Jul. 10, 2008) (announcing the pilot program and calling for applications from certification bodies).

480. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, *supra* note 479, at 7.

481. *Id.* at 26.

482. PMAP Report, *supra* note 344 (stating that Canada and many other countries rely directly on ISO 13485: Medical devices—Quality management systems—Requirements for regulatory purposes in their regulation of medical devices). The QS regulation of the United States is similar, but not the same.

483. *Id.*

484. Telephone Interview with David Kalins, *supra* note 347.

FDA is generally not adequate to support an FDA enforcement action.⁴⁸⁵ He opined that if the program were mandatory or otherwise attracted high participation by regulated entities, an entire industry of competent inspectors could emerge.

In the shrimp aquaculture pilot, in contrast, the FDA's conclusions were more pessimistic. It found that the agency needed "to more fully explore communication, logistic, administration, and training options for conducting future third-party programs."⁴⁸⁶ Indeed, FDA noted significant deficiencies when it observed and assessed third parties to see if they met eleven "critical performance elements."⁴⁸⁷ These critical audit performance elements were defined as "key knowledge, skills, and abilities that, if not demonstrated by the auditor, could result in the failure of the auditor to detect the processing of potentially unsafe food."⁴⁸⁸ FDA conducted twenty-eight audits and found that only three out of eleven of its critical elements were met in the majority of the audits and only one was met in all of the audits. For example, only four out of the twenty-eight audits met elements as critical as the following: "Did the auditor demonstrate an understanding of how to identify, evaluate and control the food safety hazards associated with the product and process being audited?" and "Did the auditor recognize, through in-plant observations, deficiencies in the identification and control of hazards?"⁴⁸⁹

Another prevalent concern about third-party auditors relates to their independence. When an auditor is paid by a regulated entity to assess that entity's compliance, concerns about the objectivity of the third party arise. As discussed in the literature on financial auditing, in addition to potentially conscious motivations, a variety of unconscious biases can affect an auditor's judgment.⁴⁹⁰ For example, the standards with which the auditor must assess conformity may have ambiguities, and "[b]ias thrives wherever there is the possibility of interpreting information in different ways."⁴⁹¹ Also, an "attachment bias" results from the fact that the auditor has strong business reasons to please the client and equates his own interests with those of the client.⁴⁹² In addition, the certain and immediate beneficial consequences of

485. *Id.*

486. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, *supra* note 479, at 26.

487. *Id.* at 17.

488. *Id.*

489. *Id.* at 31 (Appendix B).

490. Bazerman et al., *supra* note 100, at 97–98.

491. *Id.* at 98.

492. *Id.* at 99; see also Amy Shapiro, *Who Pays the Auditor Calls the Tune?: Auditing Regulation and Clients' Incentives*, 35 SETON HALL L. REV. 1029, 1040 (2005) (discussing the attachment bias and explaining that working for a client creates a tendency for an auditor to make judgment calls that favor a client).

giving a positive audit opinion may outweigh the uncertain and distant negative consequences of not doing so.⁴⁹³ Another threat to independence occurs when auditors provide their clients with additional “non-audit” consulting and tax services.⁴⁹⁴ In this case, an auditor that renders a negative audit opinion risks losing not just the audit engagement but the additional business as well.

Similar issues of auditor independence can be expected to appear in third-party verification programs. An example of an issue involving third-party independence is provided by the NRTL program. Curtis Straus LLC (CSL) was recognized as an NRTL in 2000 and applied to have its recognition renewed in 2004.⁴⁹⁵ In 2007, OSHA informed CSL by letter that it did not appear to meet the NRTL program policy on independence because of a change in its ownership in 2005.⁴⁹⁶ After the change in ownership, the investment firm (Wendel) owned 58 percent of CSL as well as 32 percent of Legrand, a manufacturer of electrical products that require NRTL testing and certification.

Over the next several years, CSL sought OSHA approval by providing more information and making some changes to its business structure. For example, it sought to convince OSHA that a firewall existed to assure the independence of its certification process and that it would use external and internal audits to ensure its independence.⁴⁹⁷ In 2010, however, OSHA made a negative finding of renewal based in part on concerns that OSHA would not be able to effectively monitor CSL’s efforts, given the extent and complexity of Wendel’s and Legrand’s business operations.⁴⁹⁸ In its continued efforts to persuade OSHA to renew, Wendel decreased its ownership stake in Legrand to 11 percent in 2011.

In 2011, OSHA published notice of its preliminary finding to deny renewal.⁴⁹⁹ In the preliminary finding, OSHA explained that the NRTL program requires “complete independence,” meaning that NRTLs “must be free from commercial, financial and other pressures that could compromise . . . its testing and certification.”⁵⁰⁰ CSL’s substantial relationship with

493. Bazerman et al., *supra* note 100, at 100.

494. Keith A. Houghton & Christine A. Jubb, *The Market for Financial Report Audits: Regulation of and Competition for Auditor Independence*, 25 *LAW & POL’Y* 299, 308–09 (2003).

495. Curtis-Straus LLC, Application for Renewal of Recognition, 76 *Fed. Reg.* 62,850–51 (Oct. 11, 2011).

496. *Id.* at 62,850–56.

497. *Id.* at 62,852.

498. *Id.*

499. *Id.* at 62,856; Telephone Interview with Robert Biersner, Office of the Solicitor, Dep’t of Labor (Aug. 10, 2012).

500. *Id.* at 62,852 (quoting OSHA, U.S. DEP’T OF LABOR, CPL 01-00-003, NRTL PROGRAM POLICIES, PROCEDURES, AND GUIDELINES (1999), available at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=2004).

Legrand deriving from Wendel's partial ownership of both violates this independence requirement. By 2013, however, OSHA's final determination on CSL's renewal had still not been published, suggesting that a lengthy process is required when an agency seeks to terminate the accreditation of a certification body.⁵⁰¹

In addition to questions of competence and independence, agencies should be concerned about the consistency of third-party determinations. If third-party firms and individuals are able to conduct the required assessment tasks in different ways, their determinations may be less consistent than governmental determinations, particularly if the latter would be centralized. For example, when EPA decided to verify greenhouse gas emissions data itself rather than require emitters to contract with a third-party verifier, it suggested that this would allow it to comprehensively review the data and provide the necessary consistency and quality.⁵⁰² If EPA had opted to incorporate third-party verification, it "would still need to review and perform consistency checks after the third party verification was complete."⁵⁰³

Aside from competence and independence, there are other characteristics common in auditing that may also be preventing reliable and accurate results. One scholar of private third-party systems in the food sector found that auditors focus their review on the records kept by companies rather than actual company practices. In a study of audits performed to check the compliance of agricultural suppliers with buyers' standards, the scholar observed that "what are mostly audited are not the practices of suppliers, but their records. Put differently, auditors largely rely on proxy measures to verify compliance."⁵⁰⁴ As such, the audit may verify that there is documentation showing that a certain standard was met but not actually verify that the standard was met.

Other scholars have pointed out that audits may verify compliance with many detailed performance specifications while failing to assess true

501. E-mail from Kevin Robinson, OSHA, U.S. Dep't of Labor (Mar. 5, 2013) (explaining that OSHA was reexamining its independence policy and had decided to delay a final determination on CSL). It is worth noting that throughout the history of the program, two NRTLs have had their recognition revoked due to deficiencies in their testing and certification operations, and one NRTL's renewal application was denied due to independence issues. *Id.*

502. See Mandatory Reporting of Greenhouse Gases, 74 Fed. Reg. 56,260, 56,282 (Oct. 30, 2009) (codified at 40 C.F.R. pts. 86-87, 89, 90, 94, 98, 1033, 1039, 1042, 1045, 1048, 1051, 1054, 1065).

503. *Id.* at 56,283.

504. Maki Hatanaka, *Certification, Partnership, and Morality in an Organic Shrimp Network: Rethinking Transnational Alternative Agrifood Networks*, 38 WORLD DEV. 706, 710 (2010).

risks.⁵⁰⁵ To standardize their task, auditing organizations may develop detailed checklists, so there may be lots of “ticking the boxes” even though “crucial quality risks can go unnoticed at the same time because they are not specifically provided for on the checklist of technical requirements.”⁵⁰⁶ Moreover, there are reasons that the checklists may be favored in third-party programs run by federal agencies. Namely, it removes discretion from the auditor and may be perceived as more standardized and fair.⁵⁰⁷

When constructing third-party programs to serve regulatory purposes, agencies have many ways to respond to these various concerns and increase the reliability of third-party determinations.⁵⁰⁸ With rules regarding how third parties are accredited and how regulated entities select third parties, the agency can create a high bar for third-party competence and independence. With rules regarding how assessment tasks are performed, an agency can further enhance the reliability and consistency of third-party determinations. Importantly, agencies can also employ a variety of oversight mechanisms to make sure that third parties comply with program rules.

B. Rates of Compliance

Another metric to assess third-party verification programs can be found in the extent to which a program ensures and enhances regulatory compliance. When third-party programs are used for regulatory purposes, they should increase—not reduce—rates of compliance. A third-party program that enables a greater degree of noncompliance, and thereby eviscerates or dilutes valuable regulatory protections, cannot be considered a success.

In many existing regulatory programs, compliance inspections occur infrequently and compliance rates are hard to determine. For example, in 2011, about 254,000 foreign food facilities and 167,000 domestic food facilities were registered with the FDA.⁵⁰⁹ With limited inspectorial resources (about 1,000 inspectors), FDA inspected only 6 percent of the 421,000 registered facilities in 2010.⁵¹⁰ Also, according to the FDCA, domestic manufacturers of a class II or III medical device shall be inspected by the

505. Albersmeier et al., *supra* note 102, at 930–33.

506. *Id.* at 933.

507. *See id.*

508. *Cf.* McAllister, *supra* note 21, at 47–62 (recommending “clear and enforceable rules” for: the accreditation verifiers, “the selection of verifiers by regulated entities, the performance of verifications, and the disclosure and reporting of verification information”).

509. Kathy Gombas & Howard Seltzer, *The Reportable Food Registry: A Valuable New Tool for Preventing Foodborne Illness*, FOOD SAFETY MAG., June–July 2011, available at <http://www.foodsafetymagazine.com/article.asp?id=4117&sub=sub1>.

510. Dina ElBoghdady, *Taking New Look at Food Inspection*, WASH. POST, Mar. 5, 2012, at A1.

FDA at least once in every two-year period.⁵¹¹ However, with limited resources, FDA had not satisfied this biennial inspection mandate. As reported by the U.S. General Accountability Office (GAO) in 2008, domestic high-risk facilities receive inspections only once every three years and medium-risk facilities only once every five years.⁵¹² While the law does not impose an inspection frequency for foreign manufacturers, those that are high-risk are reportedly inspected only once every six years and medium-risk only once every twenty-seven years.⁵¹³

Third-party verification programs can enable more frequent inspections and more complete data about compliance. A program may be designed, for example, to require an assessment of the compliance status of all regulated entities or products each year or every few years. Such regular third-party inspections can help improve compliance by regulated entities. As this author has noted elsewhere, “[e]vidence suggests that when managers expect outside observers, they tend to change how they perform their jobs and how they relate to other managers in ways that favor adherence. As such, the performance of an individual or group improves when it is singled out for observation and study by an outsider. Also, in third-party assessment processes, there may be opportunities for third party assessors to educate and persuade the regulated entity to comply.”⁵¹⁴

Indeed, many third-party programs have been implemented by federal agencies in response to a perceived deficit in the agencies’ ability to inspect regulated entities. The low inspection rates of foreign food facilities by FDA led to the new third-party programs for imported food in FSMA. A decade earlier, Congress mandated the AP Inspection Program due to concern about FDA’s inability to conduct inspections every three or five years as legally required. Also, EPA introduced its third-party program for Energy Star in 2011 after a GAO inspection revealed the possibility of fraud and abuse in the previous system of self-declaration. In these programs and others, legislators and regulators appear to hope that third-party programs will lead to higher compliance rates, and ultimately better regulatory outcomes.

511. GUIDANCE FOR INDUSTRY, *supra* note 350, at 2; *see also* 21 U.S.C § 360(h) (2012) (containing the statutory requirement).

512. CHALLENGES FOR FDA, *supra* note 336, at 2nd page (unnumbered), under heading *What GAO Found*.

513. *Id.*

514. MCALLISTER, *supra* note 22, at 45 (footnotes omitted).

C. Regulatory Agency Capacity

Another metric for evaluating third-party verification programs is the sufficiency of agency resources for establishing and maintaining a program. Judging from existing programs, a great deal of agency resources may be required to set up a program. Also, without effective governmental oversight, third-party programs may lack transparency and accountability and ultimately erode public confidence in regulation and compromise public welfare. Although private actors may carry out many tasks in a third-party program, the agency must have the strength and resources to ensure that the program is effectively serving regulatory purposes.

Depending to some extent on how a third-party program is designed, a large investment of time and resources may be necessary to get it up and running. In particular, if an agency approves certification bodies itself instead of delegating this to an accreditation organization, it will need to do all the work of establishing the relevant rules and implementing them to verify the qualifications of the third parties. Even if an accreditation organization is used, the agency will have to establish the relevant rules and oversee the accreditation organization's implementation of them.

Several existing programs illustrate the challenges involved in accrediting certification bodies. In FDA's AP Inspection Program, selection and training of APs took many years to complete.⁵¹⁵ FDA's aquacultured shrimp pilot further demonstrates the resource requirements of verifying the qualifications of third parties, particularly when they are outside the United States. As part of the application process, FDA asked candidate certification bodies to assess their own conformity with certain attributes that FDA determined were necessary for CB certification programs.⁵¹⁶ These included, for example, that "auditors should understand the food safety issues related to the processes and products that they audit"; the CB should have a "quality assurance program that monitors its auditors" and audits; and the CB "should have sufficient resources, such as equipment and infrastructure."⁵¹⁷ The FDA developed self-assessment checklists, and participants reported with few exceptions that they met most of the attributes. However, when FDA performed its onsite certification program assessments, it

515. See *infra* note 555 and associated text; *cf.* GUIDANCE FOR INDUSTRY, *supra* note 350, at 9–10 (describing the requirements that APs complete a collaborative inspection (in which the trainee acts primarily as an observer of the FDA inspector); a modified performance inspection (in which the trainee conducts the inspection with the assistance of an FDA inspector); and a full performance inspection (in which the trainee independently performs an inspection that is observed and evaluated by an FDA inspector)).

516. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, *supra* note 479, at 9.

517. *Id.*

found the information in the checklist responses was often unsupported by source documents and that the self-assessment checklists themselves were not sufficient to assure attainment of the attributes. Ultimately, FDA found that most CBs did not fully meet the majority of attributes.⁵¹⁸ The FDA concluded that the “onsite program assessments and associated discussions with CB personnel” were “critical to FDA’s evaluation of the CB programs.”⁵¹⁹

Moreover, through this pilot FDA realized the difficulty of performing such onsite assessments. FDA reports that onsite assessments required at least four people to spend three to five days at the headquarters of each of the six CBs, four of which were outside the United States.⁵²⁰ It also found that not all supporting documentation and relevant personnel were available at the headquarters and, in this situation, “FDA’s ability to make a full assessment of one or more program attributes was limited.”⁵²¹ For the CBs located outside the United States, the overseas travel and need for translation services further complicated FDA’s assessment efforts.⁵²²

In the final phase of the pilot, FDA observed CBs conducting audits of shrimp processors and farms and conducted its own audits of the laboratories CBs used. Spread across seven foreign countries, FDA confronted problems in coordinating the schedules of multiple stakeholders (e.g., FDA, the CB, the competent authorities in foreign countries, and the processors, farms, and labs being audited) and in receiving permission to observe some processors, farms, and labs.⁵²³ In addition, some changes in FDA’s plans were necessitated by international crises and civil unrest in countries where audits had been planned.⁵²⁴ Given the difficulties, some CBs conducted “mock audits” to accommodate the FDA.⁵²⁵ FDA concluded that the “coordination among multiple stakeholders demanded significant time and resources.”⁵²⁶

Finally, the pilot made clear that agencies that implement third-party programs are likely to need to provide training to their own personnel and

518. *Id.* at 13 tbl.3.

519. *Id.* at 11.

520. *Id.* at 6–7 tbl.1, 11.

521. *Id.* at 12.

522. *See id.* at 25 (“Language barriers and different operating models and paradigms (i.e., industry vs. regulatory) made understanding between FDA and the CBs challenging and clear communication even more critical” and “[i]t should be noted that the number of interpreters needed for a full-scale third-party certification program are likely to be substantial.”).

523. *Id.* at 16.

524. *Id.*

525. *Id.*

526. *Id.* at 24.

develop new information technology (IT) systems. FDA concluded that operationalizing a third-party certification program in the future would require “establishing robust formal training for Agency personnel involved in on-site program assessments and performance audits of CB auditors and supporting laboratories.”⁵²⁷ The pilot, which involved only six CBs, taxed existing FDA infrastructure and indicated “that an operating program in the future would need additional resources to be successful, as well as a central coordinating point within the Agency.”⁵²⁸ Moreover, FDA reported that “current IT systems and databases were not designed to accommodate third-party certification audits” and “more in-depth evaluation, updating, and the potential development of new systems and databases” would be required for FDA to operationalize a third-party certification program.⁵²⁹

Energy Star provides an example of a program in which the agency delegates accreditation to private accreditation bodies. The accreditation bodies that accredit laboratories must themselves be approved by EPA. EPA relies extensively on that accreditation and does little oversight of accredited labs. The accreditation bodies that accredit CBs do not need specific EPA approval; any accreditation body that is a signatory to the IAF MLA may accredit Energy Star CBs. The accreditation bodies are responsible for conducting periodic assessments of the CBs they accredit, and the Energy Star program itself conducts additional oversight including audits of product certifications.⁵³⁰

Existing programs show that agencies may have difficulty maintaining the resources needed to provide adequate oversight. In 2010, the USDA Office of Inspector General (OIG) found deficiencies in AMS’s oversight of NOP certifying agents and organic operations.⁵³¹ OIG also found that NOP officials “did not make required onsite assessments and did not identify inconsistencies in implementation of NOP regulations.”⁵³² Lacking sufficiently specific rules and adequate oversight, certification agents developed different criteria for determining whether noncompliances were

527. *Id.* at 25.

528. *Id.* at 23.

529. *Id.* at 24–25.

530. See *Conditions and Criteria for Recognition of Certification Bodies for the ENERGY STAR Program*, *supra* note 456, at 2 (authorizing EPA to conduct audits at its discretion); Telephone Interview with Eamon Monahan, *supra* note 463 (mentioning that Energy Star picked at random some product categories and had CBs send all related certification files).

531. See OFFICE OF THE INSPECTOR GEN. [USDA OIG], U.S. DEPT. OF AGRIC., AUDIT REPORT 01601-03-HY, OVERSIGHT OF THE NATIONAL ORGANIC PROGRAM 29–30 (2010).

532. *Id.* at 3.

present and whether they were major or minor.⁵³³ OIG concluded that “AMS did not ensure consistent oversight of organic operations by its certifying agents.”⁵³⁴ This lack of oversight, in turn, undermined the overarching goal of NOP “to assure consumers that such products meet consistent, uniform standards.”⁵³⁵

The OIG found even more serious deficiencies in AMS’s oversight of foreign certifying agents.⁵³⁶ AMS is required to make onsite reviews of foreign certifying agents, but five of forty-four never received such a review and twenty-four of forty-four received reviews more than two years after receiving their conditional accreditation.⁵³⁷ The NOP had underestimated the number of applications they would receive when the program began in 2002 and had failed to develop a policy to handle the review of certifying agents located in countries with travel warnings issued by the Department of State.⁵³⁸ When NOP reviews were performed, NOP officials often found that certifying agents committed major noncompliances, such as failing to identify mislabeled products, maintain complete certification files, and complete annual conflict-of-interest disclosures.⁵³⁹

The response of AMS to the OIG report indicates that the root of the problem was that the NOP program lacked sufficient resources. AMS stated that the NOP budget had increased in 2009 to \$3.87 million and its staff to sixteen, and that a \$3.1 million budget increase in 2010 would enable the program to grow to thirty-one staff members.⁵⁴⁰ In 2007, the NOP had “just nine staff members and an annual budget of \$1.5 million.”⁵⁴¹

It is worth noting that the international scope of many third-party programs interacts with the issue of governmental oversight. The international dimensions of certain regulatory objectives like food safety may make third-party programs particularly attractive, but these same international dimensions complicate oversight. Not only may effective oversight be more costly, but the agency may not have the authority in foreign jurisdictions to do the kinds of oversight it would do in a domestic context.

533. *Id.* at 21–27 (describing how NOP lacked clear and sufficiently focused rules and did not oversee their implementation).

534. *Id.* at 21.

535. *Id.*

536. *Id.* at 28–29.

537. *Id.* at 29–30.

538. *Id.* at 28–29.

539. *Id.*

540. *Id.* at 37–39 (Exhibit B: AMS response).

541. Andrew Martin, *How to Add Oomph to ‘Organic’*, UNCLE MATT’S ORGANIC BLOG (Aug. 20, 2007), <http://unclematts.com/dev/how-to-add-oomph-to-organic/>.

D. Public Acceptance

Another metric of success is the support and acceptance that the third-party program receives from stakeholders. The most relevant stakeholders are the concerned public (the beneficiaries of regulation) and the regulated industry (the target of regulation). Issues relevant to the industry's acceptance of a program are discussed in the following section.

One gauge of public support for regulatory change consists of the comments received by agencies in response to rulemaking processes and other requests for comments. The public is often represented by non-governmental organizations. While most third-party programs described in this Article have garnered little public attention, there are a couple exceptions.

First, NGOs concerned with food safety have been very wary of the introduction of third-party auditors into the FDA's regulatory framework. In comments to the agency, one NGO acknowledged that FSMA authorizes third-party certification for imported food, but emphasizes that "the law does not permit it for domestic facilities."⁵⁴² The commenter then stresses the need for the agency to rigorously apply conflict-of-interest requirements and otherwise conduct oversight of third-party auditors.⁵⁴³ Another NGO criticizes the legislative decision to allow FDA to rely on third-party auditors for regulatory audits, regretting that FDA will "expend precious resources" developing conflict-of-interest standards and overseeing third parties.⁵⁴⁴ It cites failures in the National Organic Program⁵⁴⁵ and private food safety audits⁵⁴⁶ to support its conclusion that FDA "should invest its

542. Comments of Make Our Food Safe & Safe Food Coal. on Proposed Rule, RE: Docket Nos. FDA-2011-N-0145, § 303 Authority to Require Import Certifications for Food, and FDA-2011-N-0146, § 307, Accreditation of Third-Party Auditors, (May 6, 2011) at 2, <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0145-0016> [hereinafter Make Our Food Safe & Safe Food Coal.].

543. *Id.* at 3.

544. Comment of Food & Water Watch on Proposed Rule, FDA Food Safety Modernization Act: Title III-A New Paradigm for Importers; Public Meeting (Section 307. Accreditation of Third-Party Auditors) (May 6, 2011) at 2, <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0146-0007> [hereinafter Food & Water Watch].

545. *Cf.* USDA OIG, *supra* note 531 (finding that AMS fails to adequately oversee NOP third parties).

546. A prominent such failure involved the salmonella outbreak caused by peanuts processed by Peanut Corporation of America in a facility that had received a superior rating in a private food safety audit required by a buyer, Kellogg Corp. See *Lessons From The Peanut Salmonella Outbreak: Audit System Broken*, JIM PREVOR'S PERISHABLE PUNDIT (Feb. 19, 2009), <http://www.perishablepundit.com/index.php?date=02/19/09&pundit=1>.

resources into doing as many of the imported food inspections itself and should avoid at all costs a reliance on a privatized inspection system.”⁵⁴⁷

In the product safety arena, NGOs have been more supportive of third-party testing. Major consumer NGOs such as the Consumer Federation of America and US PIRG expressed strong support for “a CPSC-administered, third party safety certification program for monitoring the safety of all products” before the passage of the CPSIA in 2008.⁵⁴⁸ In the aftermath of its passage, they have participated in the regulatory process to voice support for a strong third-party testing system.⁵⁴⁹

A common concern of NGOs regarding the use of third-party inspection and certification systems is that they will weaken governmental accountability and transparency. A food-safety NGO, for example, expresses a preference for inspections performed by FDA, other U.S. agencies, or foreign governments (in that order) over inspections by third-party auditors, as the latter “may not have the same public health objective or may not be supported by the same level of expertise, training, resources, and accountability as are FDA inspectors.”⁵⁵⁰ When the Energy Star program announced its intention to establish a third-party verification and testing program, an environmental NGO expressed strong support but stressed the need for “complete transparency of the program’s procedures and testing results.”⁵⁵¹

E. Industry Acceptance

The other major group of stakeholders consists of the regulated entities. A very common reaction to an agency’s announcement that it is implementing a third-party verification program is industry concern about costs. Indeed, a third-party program will often shift some of the costs of

547. Food & Water Watch, *supra* note 544.

548. Letter from Rachel Weintraub, Senior Counsel, Consumer Fed’n of America, et al., to Sen. Daniel K. Inouye, Comm. on Commerce, Sci. & Transp. (Oct. 26, 2007), *available at* <http://consumersunion.org/news/groups-ask-senate-commerce-comm-not-to-weaken-product-safety-bill/>.

549. Comments of Consumers Union, Consumer Fed’n of Am., Kids in Danger, and U.S. PIRG on Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1215 of Title 16, Code of Federal Regulations” (July 6, 2010), *available at* [http://www.consumerfed.org/elements/www.consumerfed.org/file/Comments%20on%203PT%20Bath%20Seats%20\(Final\)%20\(2\).pdf](http://www.consumerfed.org/elements/www.consumerfed.org/file/Comments%20on%203PT%20Bath%20Seats%20(Final)%20(2).pdf).

550. Make Our Food Safe & Safe Food Coal., *supra* note 542.

551. Comments of Natural Res. Def. Council on ENERGY STAR’s Proposed Enhanced Testing and Verification Program, (Apr. 30, 2010), at 4 (emphasis omitted), *available at* http://www.energystar.gov/ia/partners/downloads/mou/Natural_Resources_Defense_Council_Comments.pdf.

inspection and compliance assessment from the government to industry.⁵⁵² To augment industry support, third-party programs should reduce the burden on industry as much as possible while still achieving regulatory objectives. Third-party programs may also be able to provide benefits to industry, for example, by reducing the processing times of product approvals applications and by creating a single approval process that satisfies various national jurisdictions. Notably, third-party programs raise special concerns about costs for small businesses.

One important way to contain costs in a third-party program is to ensure that there are a sufficient number of third parties to create competition among them.⁵⁵³ A representative of the Energy Star program stated that the primary way that the program responded to industry concerns about third-party certification was by encouraging the rapid development of a strong market of certification bodies and laboratories.⁵⁵⁴ In contrast, in the FDA's AP Inspection Program, it took the agency many years to get APs through all required training and cleared to conduct independent inspections: by May 2008, four years after the program was established, only eight APs out of sixteen had completed all training.⁵⁵⁵ Because of the delays, few APs were available to conduct independent inspections in the early years of the program.

As an agency seeks to encourage a competitive market, however, certain precautions need to be taken. First, an agency should not unduly lower its requirements for competence and independence in order to accredit more third parties. In the AP Inspection Program, for example, the training that was given may have been essential for APs to adequately carry out their tasks. Second, an agency should establish program rules to ensure that third parties cannot compete in ways that compromise the quality of the assessment. The agency can require in its program rules, for example, that third parties inspect a certain number of product samples or make a certain number of site visits to a manufacturing facility.

The CPSC's third-party program for the testing of children's products has provoked substantial industry resistance. As the CPSC has developed regulations, product manufacturers have repeatedly expressed concerns

552. See McAllister, *supra* note 21, at 27.

553. Cf. Telephone Interview with Eamon Monahan, *supra* note 463 (discussing how Energy Star sought to keep costs low for regulated entities by encouraging the participation of a sufficient number of CBs and labs to create the possibility for competition among them).

554. *Id.*

555. GOV'T ACCOUNTABILITY OFFICE, GAO-08-780T, MEDICAL DEVICES: FDA FACES CHALLENGES IN CONDUCTING INSPECTIONS OF FOREIGN MANUFACTURING ESTABLISHMENTS 19 (2008).

about the cost of the required third-party testing. It was clear that these concerns had reached Congress when it amended the CPSIA in August 2011.⁵⁵⁶ The amendments gave the CPSC new authority to exempt qualifying small batch manufacturers (mostly small businesses) from third-party testing. They also required the CPSC to issue a request for public comments on opportunities to reduce the cost of third-party testing requirements.

Manufacturers expressed many concerns about the costs of third-party testing in their comments.⁵⁵⁷ For example, they recommended that CPSC exempt more individual products and categories of products by regulation; that CPSC make additional attempts to reduce testing requirements based on the actual likelihood of exposure; and that CPSC increase efforts to harmonize federal, international and state laws applicable to consumer products. Other suggestions included decreasing the frequency of retesting and allowing more retesting to be done by the manufacturers themselves rather than a third-party lab.⁵⁵⁸

Small manufacturers have been most concerned about the new third-party testing requirements. A trade association of small jewelry makers complains of the unreasonable cost burdens imposed by the CPSIA.⁵⁵⁹ It reports that almost one quarter of its members “have reduced their children’s products offerings, and 16% have exited the children’s jewelry market entirely.”⁵⁶⁰ A European maker of heirloom quality toys calls third-party testing of its small batches “prohibitive and impossible” and warns that “specialized toys with high playing value will disappear from the US market” if the CPSIA is not amended.⁵⁶¹ This manufacturer and other small manufacturers from Europe request that the CPSA exempt products tested to the European safety standards from CPSIA’s third-party testing requirements.⁵⁶² Also, a manufacturer that describes itself as “medium-sized”

556. 15 U.S.C. § 2063(i) (2012); Application of Third Party Testing Requirements, H.R. 2715, 112th Cong. §§ 2, 10 (2011) (creating a new section 14(i) of the CPSA); Reducing Third Party Testing Burdens, 76 Fed. Reg. 69,596 (Nov. 8, 2011). Public Comments in response are available at regulations.gov (search for Docket No. “CPSC-2011-0081-0001”) (listing 23 comments).

557. See generally PUBLIC SUBMISSIONS, APPLICATION OF THIRD PARTY TESTING REQUIREMENTS; REDUCING THIRD PARTY TESTING BURDENS, COSC DOCKET NO. CPSC-2011-0081, available at <http://www.cpsc.gov/PageFiles/85937/testingburdencomm.pdf> (last visited Nov. 17, 2013).

558. See generally *id.* (especially comments submitted by the Society of the Plastics Industry, Inc., at 119–28; the Toy Industry Association, at 159–64; and Libbey, at 141–42).

559. See *id.* at 103–17 (comment submitted by the Fashion Jewelry and Accessories Trade Association).

560. *Id.* at 113 (emphasis omitted).

561. *Id.* at 11 (comment submitted by Glückskäfer).

562. *Id.* at 11–13 (comments submitted by Glückskäfer, Fagus and Grimm’s).

expressed that the exemption for small-batch manufacturers does not cover all low-volume manufacturers, even though they too are considerably different from large volume manufacturers.⁵⁶³

In Energy Star, manufacturers also voiced concerns about the cost of third-party certification. As reported in a 2011 study of Energy Star by the GAO, “[a]lmost all the manufacturing partners we spoke with stated the cost to participate in the program had increased. Some manufacturing partners—particularly small manufacturers or manufacturers with few Energy Star products—also told us the increasing costs could discourage their participation.”⁵⁶⁴ Energy Star program staff, however, perceive widespread acceptance of the new rules and have not noticed a drop in applications for the Energy Star label.⁵⁶⁵

As in the case of the CPSC rule, small businesses have been particularly concerned about the new costs of certification. If they are not able to afford certification for their products, their consumer base may be reduced. Also, delays in getting products to market may be more prejudicial to small companies. As stated by one commenter on the WaterSense program, “[h]igh cost will discourage manufacturers, especially small ones, from participating in the program at all.”⁵⁶⁶ In effect, the costs of third-party certification may benefit larger companies at the expense of smaller ones.

The Small Business Administration’s Office of Advocacy has been concerned about third-party programs.⁵⁶⁷ One concern is that once agencies shift the costs of inspection to industry, the government will not be as limited in imposing regulatory requirements. Also, whereas many governmental programs establish a lower fee for small businesses, third parties are not as likely to be as concerned with the affordability to small businesses. The Office of Advocacy suggests that when agencies establish third-party programs, they should consider mechanisms to help reduce the burden on small businesses.

While a third-party program is likely to impose costs, it may also impart benefits that were not available without the program. The TCB program, for example, cut the approval time of telecommunications equipment from

563. *Id.* at 179–82 (comment submitted by Orbit Baby, Inc.).

564. GOV’T ACCOUNTABILITY OFFICE, GAO-11-888, ENERGY STAR: PROVIDING OPPORTUNITIES FOR ADDITIONAL REVIEW OF EPA’S DECISIONS COULD STRENGTHEN THE PROGRAM (2011) at 26.

565. Telephone Interview with Eamon Monahan, *supra* note 463.

566. WATERSENSE, U.S. ENVTL. PROT. AGENCY, COMMENTS ON THE MAY 2007 DRAFT WATERSENSE CERTIFICATION SCHEME 19 (2007).

567. Telephone Interview with David Rostker, Assistant Chief Counsel, Office of Advocacy, U.S. Small Bus. Admin. (Aug. 17, 2012).

thirty to ninety days in the late 1990s to often just a few days.⁵⁶⁸ In addition, a program may be designed such that a third-party assessment satisfies the regulatory requirements of both the United States and other countries. FDA reports that it is currently developing a “single audit program” for medical devices that would result in a “saving of audit/inspection time in person days (and associated costs) and less disruption of the manufacturer’s day-to-day operations; and, greater control over the scheduling of regulatory audits/inspections.”⁵⁶⁹

Factors aside from costs and benefits may also play a role in how industry reacts to a third-party program. A third-party program may be well explained and well implemented by an agency, or it may not be. In the latter case, industry is more likely to find the program to be overly complex and objectionable.

F. Use of Optional Third Parties

Programs in which regulated entities have a choice as to whether to contract with a third party have an additional metric of success: the rate of regulated entity participation. If regulated entities do not use a program, then the resources an agency used to create it may seem wasted. Differences in participation in three programs described in this Article illustrate the situation: FDA’s AP Inspection Program for medical device production facilities, FDA’s 510(k) Review Program for medical devices, and FCC’s TCB program.

The FDA’s AP Inspection Program has had a very low rate of participation. Despite an estimated 8,000 manufacturers that could use the program,⁵⁷⁰ only eighty independent inspections (i.e., unaccompanied by FDA inspectors) have been conducted by APs in eight years of program operation.⁵⁷¹ The FDA had hoped that manufacturers would be attracted by the possibility that a single AP inspection might satisfy regulatory requirements in multiple jurisdictions.⁵⁷² However, the effect of this incentive has been limited because manufacturers have had doubts that APs could cover

568. Telephone Interview with George Tannahill, *supra* note 390.

569. PMAP Report, *supra* note 344.

570. Agency Information Collection Activities, 76 Fed. Reg. 29,764 (May 23, 2011) (reporting FDA’s estimate that there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion in the AP Inspection Program).

571. Telephone Interview with David Kalins, *supra* note 347.

572. STATUS OF FDA’S PROGRAM, *supra* note 328, at 13. This could occur if the same inspection could serve to both verify the manufacturer’s compliance with the FDA’s QS regulation and the manufacturer’s conformity with “ISO 13485: Medical devices—Quality management systems—Requirements for regulatory purposes,” which many other countries use as their standard. *See also infra* note 625 at 4.

the multiple requirements of various standards in a single inspection.⁵⁷³ Also, the program allows manufacturers to control the scheduling of inspections⁵⁷⁴ and offers a two-year inspection holiday from regular FDA inspections.⁵⁷⁵

Many disincentives to participation also exist. Under the AP Inspection Program, manufacturers have to bear the cost of the inspection, whereas FDA inspections are free. Moreover, the manufacturer may not think an FDA inspection will occur in the near future, and an AP inspection may result in further regulatory action.⁵⁷⁶ As reported by the GAO, “one industry representative questioned why manufacturers would ask for—and pay for—inspections when the result could be that FDA closes them down.”⁵⁷⁷ Manufacturers expressed concern that, because FDA makes the final determination of compliance with its requirements, FDA might want to conduct an additional inspection after reading the report prepared by the third-party inspector.⁵⁷⁸ Observing the very small number of AP inspections in 2008, the GAO stated it raised “questions about the practicality and effectiveness of establishing similar programs that rely on third parties to quickly help FDA fulfill other responsibilities.”⁵⁷⁹

The FDA’s 510(k) Review Program has attracted more participation than the AP Inspection Program. As described above, this program enables manufacturers to contract with third parties to conduct the primary pre-market review for certain medical devices. The FDA reported in July 2012 that about 8 percent of all 510(k) reviews are conducted by third parties, which is close to 300 annually.⁵⁸⁰ One difference between the AP Inspection Program and the 510(k) Review Program is that in the latter, device manufacturers pay FDA a user fee if they do not use an AP. In FY 2014, the fee is \$5,170 (\$2,585 for qualified small businesses).⁵⁸¹ However, it is likely

573. *Infra* note 625 at 4. By being able to schedule inspections, they are able to minimize facility disruptions and ensure that the necessary personnel and documentation is on hand at the right time. Also, FDA may only give a week of notice of an inspection, but AP inspections can be scheduled months in advance. *See* Telephone Interview with David Kalins, *supra* note 347.

574. STATUS OF FDA’S PROGRAM, *supra* note 328, at 13.

575. *Id.* at 8 n.18.

576. *Id.* at 15.

577. *Id.* at 16.

578. *Id.*

579. CHALLENGES FOR FDA, *supra* note 336, at 22 (reporting seven inspections between March 2004 and January 2008).

580. E-mail from Jean Cooper, *supra* note 378.

581. *FDA User Fees for 510(k) Applications*, EMERGO GROUP, <http://www.emergo-group.com/fda-user-fees-510k-applications> (last visited Feb. 3, 2014). The Medical Device User Fee and Modernization Act, enacted in 2002, gave the FDA authorization to charge manufacturers fees for premarket review. *See* E-mail from Jean Cooper, *supra* note 378.

that the user fee is lower than the amount that the manufacturer pays to a private third party.⁵⁸²

Another incentive present in the premarket program but not in the AP Inspection Program is that manufacturers want this review to happen expeditiously in order to get their products to market more quickly. According to the FDA, 510(k)s reviewed by APs in 2002 received FDA marketing clearance 29 percent faster compared to 510(k)s reviewed entirely by FDA.⁵⁸³ FDA also highlights that the APs generally “have specialized expertise in areas that may be helpful to 510(k) submitters, such as device testing, standards, or foreign regulatory requirements” and that they have locations throughout the world “so they often can provide local service.”⁵⁸⁴

In the FCC’s TCB program, there is a very high participation rate for eligible products and third-party review has become the norm. In 2011, 98.5 percent of equipment authorization certifications (13,427 out of 13,645) were issued by TCBs rather than the FCC.⁵⁸⁵ FCC staff explains that companies prefer going to TCBs because their products are approved more quickly and they can get to market faster.⁵⁸⁶ In the late 1990s, product certifications were all conducted by the FCC and processing times tended to range from thirty to ninety days. Presently, certifications conducted by TCBs may take just a few days. The 1.5 percent of certifications that continue to be conducted by FCC tend to involve new technology that the FCC excludes from TCB approval until it publishes a measurement procedure.⁵⁸⁷ Also, given that the FCC charges fees for certifications, the costs of using a TCB may be lower. In 2011, the FCC’s device certification fees ranged from \$490 to \$1,265.⁵⁸⁸

In sum, voluntary programs have varied greatly in terms of the costs and benefits of participation, and participation rates have reflected this variation. As illustrated by the AP Program, if the costs to participate are

582. Telephone Interview with David Kalins, *supra* note 347.

583. *Third-Party Review of 501(k)s*, subsection of *FY 2002 ODE Annual Report – Part 3 – Key Performance Indices*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm130097.htm> (last visited Feb. 10, 2014).

584. *FY 2003 OHIP Annual Report—Medical Device User Fees Modernization Act (MDUFMA)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm130363.htm> (last visited Feb. 10, 2014).

585. Telephone Interview George Tannahill, *supra* note 390.

586. *Id.*

587. *Id.*; see also OFFICE OF ENG’G & TECH., *supra* note 385, at 4.

588. Telephone Interview with George Tannahill, *supra* note 390; see also Office of Eng’g & Tech., *Equipment Authorization (EA)*, FED. COMM’NS COMM’N, <http://transition.fcc.gov/oet/ea/feeguide.html> (last visited Feb. 10, 2014).

high and the offsetting benefits are not clear, firms will not participate. On the other hand, the TCB program shows that in different circumstances, optional third-party certification may become the industry's preference.

IV. RECOMMENDATIONS TO FEDERAL AGENCIES

This section sets forth recommendations to federal agencies regarding the use of private third parties to assess regulatory compliance. Third-party verification programs pose risks. If third-party programs are not well conceived and well operated, they may both undermine the achievement of regulatory goals and impose high costs on regulated entities. Yet, third-party programs also offer benefits. By harnessing conformity assessment expertise in the private sector, they may extend the reach of regulatory agencies in ways that increase regulatory compliance and otherwise improve the performance of regulated entities and products. The recommendations discussed below seek to help agencies minimize the risks and maximize the benefits of third-party programs.

The first important question that agencies face may be whether or not to establish a third-party program. Alternatively, Congress may have directed the agency to develop a third-party program. Of the eight programs surveyed in this Article, four were explicitly required by Congress.⁵⁸⁹ The first set of recommendations below is targeted to situations in which agencies are themselves deciding whether to establish a third-party program. However, aspects of the recommendations will also be useful when agencies are required to do so.

Agencies that are charged with or make the choice to establish a third-party program will need to write the rules by which the program will operate. The key rules of a third-party program can be categorized into several types: accreditation rules, which determine who may be approved as a third party; selection rules, which govern how regulated entities select third parties; performance rules, which specify how third-party testing and certification should be performed; and reporting rules, which set forth what information is provided to the regulatory agency by various program actors.⁵⁹⁰ Moreover, the agency must make decisions about how it will conduct oversight and enforce these rules.⁵⁹¹

When a third-party program is required by statute, certain characteristics of the third-party program may already be determined. Yet, within the

589. See *supra* Table 1. The four that were required explicitly by Congress are the FDA programs for food imports, the CPSC program for children's products, the FDA programs for medical devices, and the USDA National Organic Program.

590. Cf. McAllister, *supra* note 21, at 47–59.

591. *Id.* at 59–61.

constraints of the statute, agencies are still likely to have many options regarding program design. The second set of recommendations regards how to establish a third-party program, with most relevance to program aspects that have not been statutorily determined.

A. Deciding Whether to Use a Third-Party Program

1. Consult Public and Private Resources Related to Conformity Assessment

There are several important governmental and nongovernmental resources available to agencies considering third-party programs. The federal government has developed expertise in conformity assessment since the passage of the National Technology Transfer and Advancement Act of 1995 (NTTAA). Most importantly, the NTTAA directed NIST to coordinate the conformity assessment activities of governmental and private sector entities “with the goal of eliminating unnecessary duplication and complexity.”⁵⁹² Also, in 1998, the Office of Management and Budget’s Circular A-119 instructed NIST to write guidance for agencies to ensure effective coordination of governmental and private conformity assessment activities.⁵⁹³ NIST published this guidance in 2000.⁵⁹⁴

The Standards Services Division of NIST is available to consult with agencies interested in incorporating third-party conformity assessment processes into their regulatory processes. Upon the request of an agency, NIST staff can become involved in helping an agency design a third-party program. For example, in the WaterSense program, the chief of the Standards Services Division essentially functioned as part of WaterSense staff for a few months to explain the relevant ISO standards and help establish the third-party program.⁵⁹⁵ NIST coordinates the Interagency Committee on Standards Policy (ICSP), which consists of one principal representative from each federal executive agency, who is referred to as the “agency standards executive.”⁵⁹⁶ According to NIST’s guidance, agency standards executives are responsible for, inter alia, promoting the development of “agency positions on conformity assessment related issues that are in the

592. National Technology Transfer and Advancement Act of 1995 § 12(b)(3), 15 U.S.C. § 272 (2012); Guidance on Federal Conformity Assessment Activities, 65 Fed. Reg. 48,894 (Aug. 10, 2000) [hereinafter NIST Guidance].

593. OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, CIRCULAR A-119 REVISED §§ 8, 13(e) (1998), available at http://www.whitehouse.gov/omb/circulars_a119/.

594. NIST Guidance, *supra* note 592.

595. Telephone Interview with Stephanie Tanner, WaterSense Program, U.S. Env’tl. Prot. Agency (Aug. 10, 2012).

596. NIST Guidance, *supra* note 592, § 287.5.

public interest”; ensuring “that agency participation in conformity assessment related activities is consistent with agency missions, authorities, priorities, and budget[s]”; and establishing an “ongoing process” for identifying “efficiencies” that “can be achieved through coordination with other agency and private sector conformity assessment activities.”⁵⁹⁷

NIST also runs the NVCASE program, which has responsibility for recognizing the private accreditation bodies that accredit TCBs for the FCC. To confer recognition, NVCASE performs an initial assessment of the accreditation body and then performs a reassessment every two years to ensure that it continues to operate in accordance with ISO/IEC 17011.⁵⁹⁸ Under its regulations, NIST accepts requests to perform these functions only in certain situations.⁵⁹⁹ Otherwise, private accreditation bodies can be recognized directly by federal agencies, and the assessment role played by NVCASE may be performed instead by an international organization like the IAF (for certification bodies) or ILAC (for laboratories).⁶⁰⁰

OMB and NIST are both currently considering revising their guidance to agencies regarding conformity assessment. In March 2012, OMB issued a request for information and notice of public workshop regarding, inter alia, whether A-119 should be revised to set out relevant principles on conformity assessment.⁶⁰¹ NIST has also expressed an interest in revising its 2000 guidance.⁶⁰²

Agencies can also tap into expertise about conformity assessment that exists in private standards organizations. Most significantly, agencies should become familiar with ISO’s conformity assessment standards and guides,

597. *Id.*; see also OFFICE OF MGMT. & BUDGET, *supra* note 587, § 15 (setting forth the roles of the ICSP and standards executives).

598. Telephone Interview with Ramona Saar, Standards Servs. Div., Nat’l Inst. of Standards & Tech. (Aug. 24, 2012) (explaining that NVCASE ensures that the accreditation bodies operate in accordance with ISO/IEC17011 in accrediting TCBs to ISO/IEC Guide 65 and the FCC’s technical requirements for TCBs).

599. 15 C.F.R. § 286.2 (2013) (stating that NIST accepts requests for recognition of accreditation bodies “when (i) directed by U.S. law; (ii) requested by another U.S. government agency; or (iii) requested to respond to a specific U.S. industrial or technical need, relative to a mandatory foreign technical requirement, if it has been determined after public consultation that (A) there is no satisfactory accreditation alternative available and the private sector has declined to make acceptable accreditation available, and (B) there is evidence that significant public disadvantage would result from the absence of any alternative”).

600. Telephone Interview with Ramona Saar, *supra* note 598; see also *supra* notes 116–18 and accompanying text.

601. Request for Information and Notice of Public Workshop, 77 Fed. Reg. 19,357 (Mar. 30, 2012).

602. *Id.*

referred to collectively as the conformity assessment (or CASCO) toolbox.⁶⁰³

It is important to note, however, that ISO standards and guides are ordinarily subject to copyright restrictions. Some have suggested that this could present a barrier to wider use of standardized conformity assessment in regulatory programs if the cost of purchasing copyrighted standards is high and other reasonable means of accessing the materials are not available to regulated entities and other stakeholders.⁶⁰⁴ Several documents that provide context for and explain these standards are publicly available.⁶⁰⁵

603. ISO/UNIDO, *supra* note 106, at 170–74 (providing a chart of all standards and guides related to conformity assessment).

604. See Adoption of Recommendations, 77 Fed. Reg. 2257 (Jan. 17, 2012), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2012-01-17/pdf/2012-621.pdf>; ADMIN. CONFERENCE OF THE U.S., ADMINISTRATIVE CONFERENCE RECOMMENDATION 2011-5: INCORPORATION BY REFERENCE (2011), *available at* <http://www.acus.gov/research/the-conference-current-projects/incorporation-by-reference/> (recommending best practices for federal agencies that incorporate by reference extrinsic materials, including voluntary consensus standards, into regulations); see also EMILY S. BREMER, ADMIN. CONFERENCE OF THE U.S., INCORPORATION BY REFERENCE IN FEDERAL REGULATIONS 26-32 (Oct. 19, 2011), *available at* <http://www.acus.gov/report/incorporation-reference-report> (discussing ways agencies have increased public access to copyrighted standards); SCOTT RAFFERTY, ENHANCING THE COMPETITIVENESS OF THE AMERICAN STANDARDS SYSTEM BY RENEWING CIRCULAR A-119, at 10–11 (2012), *available at* <https://law.resource.org/pub/us/cfr/regulations.gov.docket.01/090000648101c22e.pdf> (response to Request for Information OMB-2012-0003) (noting high cost of ISO standards and suggesting that “[l]ack of meaningful access is a particularly serious barrier to wider use of standardized conformity assessments in federal regulatory program[s] . . . Agencies can be reluctant to delegate inspection or audit functions if the procedural and operational principles are not openly posted on the internet.”).

605. See AMERICAN NAT’L STANDARDS INST., NATIONAL CONFORMITY ASSESSMENT PRINCIPLES FOR THE UNITED STATES (2007), *available at* <http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/NCAP%20second%20edition.pdf>; ISO/UNIDO, *supra* note 106; USTR, *supra* note 116; see also MAUREEN A. BREITENBERG, NAT’L INST. OF STANDARDS & TECH., THE ABC’S OF THE U.S. CONFORMITY ASSESSMENT SYSTEM (1997), *available at* http://gsi.nist.gov/global/docs/pubs/NISTIR_6014.pdf; Gordon Gillerman, *Making the Confidence Connection: Conformity Assessment System Design*, 56 STANDARDS ENGINEERING, no. 6, 2004, *available at* http://www.astm.org/SNEWS/DECEMBER_2004/gillerman_dec04.html; NAT’L RESEARCH COUNCIL, STANDARDS, CONFORMITY ASSESSMENT, AND TRADE: INTO THE 21ST CENTURY (1995), *available at* http://www.nap.edu/openbook.php?record_id=4921; Christopher Johnson, *Technical Barriers to Trade: Reducing the Impact of Conformity Assessment Measures 4–7* (U.S. Int’l Trade Comm’n, Working Paper No. ID-19, 2008), *available at* http://www.usitc.gov/publications/332/working_papers/ca-dft-rev-final082008.pdf.

2. Consider the Characteristics of the Regulatory Standards and the Regulatory Target

Different types of regulatory standards and environments entail different considerations about the suitability of a third-party program. Particular characteristics may weigh in favor or against suitability, though they may not be determinative.

The regulatory standards used in a third-party program should facilitate the objective assessment of conformity. When possible, standards should be quantitative and the qualities of interest should be measurable.⁶⁰⁶ In the absence of objective standards, the risk of unreliability and inconsistency in the determinations of third parties becomes higher. Notably, the majority of programs surveyed above involve product standards that lend themselves to objective measurement (e.g. the CPSC program, FDA's premarket program, the FCC program, the OSHA program, and the EPA Energy Star and WaterSense programs).

When noncompliance with the regulatory standard implies significant risks to health, safety, or other highly valued regulatory interests, a third-party program may also be less suitable. Inherently, reliance on third parties reduces the agency's control over regulatory implementation. If it is of paramount importance that a certain negative regulatory outcome be prevented, then the agency should retain full regulatory control. Moreover, if the risks associated with noncompliance are high, a more complete and costly conformity assessment system is warranted. At some point, the costs of operating and overseeing the third-party program may be so high as to exceed the costs of direct regulatory implementation and enforcement. As explained by an NIST official, the more control that is needed, the greater the resources that are required.⁶⁰⁷

Along these lines, voluntary regulatory standards established to confer a marketing label may be more suited to a third-party program than mandatory standards that directly protect public health and safety. Among the programs surveyed, the NOP, Energy Star, and WaterSense are the best examples of the former.⁶⁰⁸ When a program confers a marketing label, a failure in the compliance assessment system has a more limited impact than when a program is established directly to protect health and safety. Of

606. Hatanaka, *supra* note 504, at 708 (emphasizing the importance of measurability and stating that "that which is being audited must be clearly identifiable, that is, it must be objective in the sense that it is (at least in principle) independently verifiable").

607. Telephone Interview with Gordon Gillerman, *supra* note 110.

608. The NRTL program similarly confers a label, but it is different in that OSHA-regulated workplaces are required to use labeled products and that the label is more related to health and safety than the other three programs.

course, the impact may still be significant and there is an important governmental interest in the integrity of the marketing labels that agencies establish.

The CPSC program and the various FDA programs, in contrast, involve mandatory standards designed to protect public health and safety. In some ways, this represents the most difficult case for third-party compliance assessment. Notably, these programs were all created directly by Congress in response to perceived deficiencies in the ability of the responsible agencies to conduct an adequate level of testing or inspections directly.

Relatedly, a third-party program may be more suitable when the standard is a voluntary consensus standard rather than a governmental-unique standard. In the NRTL program, the standards are all voluntary consensus standards. However, in the CPSC program, only some of the consensus standards are voluntary. When the standard is a voluntary consensus standard, private sector bodies may already be familiar with it and have relevant experience testing or certifying to it. Also, if the standard to be applied in the program is an international standard, it becomes more likely that regulated entities will be able to utilize a single third-party conformity assessment process to satisfy multiple regulatory jurisdictions.⁶⁰⁹

Finally, when the regulated product or activity (the regulatory target) is international in scope because of international trade, it may be better suited to a third-party program. Many of the existing programs have regulatory targets with significant international dimensions. FDA's program for food safety is specifically focused on imported food. Children's products, medical devices, telecommunications equipment, electrical equipment, organic food, and energy- and water-efficient products are all often manufactured in an international production chain. Third-party programs enable regulatory agencies to extend their reach outside national borders by incorporating private actors around the globe. On the other hand, a new challenge arises: agencies may have difficulty overseeing the private actors operating in other countries.

609. An example is provided by ISO 13485, which by its name explicitly sets forth standards for quality management systems for regulatory purposes. An FDA official explained that ISO 13485 is directly used in the regulation of many other countries and could become the U.S. regulatory standard in the future. Telephone Interview with David Kalins, *supra* note 347. The official further explained that FDA's current QS regulation is similar in many ways but demands more evidence that the quality system is being effectively implemented. *Id.*

3. Compare the Benefits and Drawbacks of Third-Party Programs with Other Approaches

Agencies that are considering third-party compliance assessment programs to achieve regulatory goals should compare this approach with others. Most importantly, the agency should compare a third-party approach with direct governmental compliance assessment and with requiring regulated entities to make a self-declaration of compliance.

An evaluation that EPA undertook when it decided not to require third-party certification of greenhouse gas emissions reports provides a good example.⁶¹⁰ EPA commissioned a report that evaluated three options: (1) facility self-certification and third-party verification paid for by the reporting companies (i.e., third-party certification), (2) facility self-certification with EPA verification of submitted data (i.e., direct governmental compliance assessment), and (3) facility self-certification with little or no independent verification of submitted data (i.e., self-declaration of compliance).⁶¹¹

There may be situations in which self-declaration can serve the regulatory purpose at hand.⁶¹² Some regulatory programs may involve “[l]ow- to medium-risk areas in which market mechanisms . . . can mitigate the negative consequences associated with non-compliances before those consequences are intolerable to society.”⁶¹³ Some voluntary regulatory programs that confer marketing labels may fit this description well. However, if an agency is considering a third-party program, there may have already been a determination that self-declaration is insufficient. In the Energy Star program, for example, self-declaration had been used previously and a GAO audit had revealed that the self-declaration system opened the program to fraud and abuse.

Also, self-declaration with little or no verification is rarely considered sufficient for mandatory standards that relate to public health and safety. Indeed, laws to protect health and safety—and their effective enforcement—are often necessary precisely because market mechanisms are

610. Memorandum from Ruth Mead et al., ERG, to Suzanne Kocchi and Kong Chiu, U.S. Evtl. Prot. Agency Headquarters, Wash., D.C., Review of Verification Systems in Environmental Reporting Programs (Feb. 10, 2009) available at [http://www.epa.gov/ghgreporting/documents/pdf/archived/tsd/Verification%20approaches%20memo%20\(2-10-09\)%20Final.pdf](http://www.epa.gov/ghgreporting/documents/pdf/archived/tsd/Verification%20approaches%20memo%20(2-10-09)%20Final.pdf) [hereinafter EPA Verification System Memo].

611. *Id.*

612. *Cf.* Johnson, *supra* note 605, at 29 (stating that businesses prefer self-declaration of compliance (SDoC), and citing an economist who states that because SDoC “is surely the cheapest form of conformity assessment, it is to be preferred except when it cannot be trusted”).

613. Gillerman, *supra* note 605/605.

ineffective in protecting against harm. For example, consumers are generally unable to tell if children's products contain lead or if food is infected by salmonella. Environmental protection and other societal interests are similar: consumers cannot tell if a product came from a highly polluting facility or an unsafe workplace.

As such, the question to be considered becomes whether the agency should directly assess compliance or rely on third parties. An agency should consider which would be less costly and which would provide greater benefits. The EPA report, for example, found that setting up a third-party program would impose significant costs on the agency.⁶¹⁴ Costs would be incurred in developing the program, approving third parties and training them, ensuring that conflicts of interest were not present, and performing ongoing oversight. The report also observed that, even with third-party certification, the EPA would probably need to develop specialized software to receive and review the data and accompany third parties on site visits.⁶¹⁵ In EPA's decision not to require third-party verification, EPA also emphasized that the activities necessary to set up a third-party program would "slow down implementation of the [greenhouse gas reporting] rule."⁶¹⁶ Several of the third-party programs reviewed above also suggest that program establishment may be costly and slow.⁶¹⁷

On the other hand, even if there are significant set-up costs, they may be justified in light of the cost savings or benefits generated in later years. For example, with its reliance on TCBs, the FCC now oversees the issuance of more than four times the number of equipment authorizations annually as it did fifteen years ago with roughly the same number of staff (seven to ten employees).⁶¹⁸ If the program had not been established, it can be

614. EPA Verification System Memo, *supra* note 610, at 26.

615. *Id.*

616. Mandatory Reporting of Greenhouse Gases, *supra* note 502, at 56,283 ("[D]eveloping the third party verification approach would require EPA to establish and develop emissions verification protocols and a system to qualify and accredit the third party verifiers, and to develop and administer a process to ensure that verifiers hired by reporting facilities do not have conflicts of interest. Such a program could require EPA to review numerous individual conflict of interest screening determinations made each time a reporter hires a third party verifier. Even if EPA were to partner with an existing program or organization to accredit verifiers, EPA would still need to develop the criteria and systems described above to implement this rule and ensure high quality emissions verification given the unique reporting requirements of this rule. These efforts would slow down implementation of the rule and sharing of data.").

617. See generally *supra* notes 515–29 and accompanying text (on the shrimp aquaculture pilot) and notes 570–79 and accompanying text (on the FDA AP Inspections program).

618. Telephone Interview with George Tannahill, *supra* 390. Between 2000 and 2011, the number of equipment authorization applications grew from 3,168 to 13,645. In the year 2000, FCC processed 83.5 percent of the applications (2,645 applications). In 2011, FCC

expected that more staff would have been hired. Also, even high set-up costs might be justified if the long-term alternative is not having the program at all. Due to EPA resource constraints, the WaterSense program might not have been pursued without a third-party approach.

In some situations, set-up costs may not be as high because third parties are already doing similar assessments for other purposes. An agency may not have to do as much in terms of identifying suitable third parties and training them. Also, the costs to industry may be lower because they are already contracting with these third parties. In WaterSense, for example, one of the most important types of products—toilets—was already often the subject of private conformity assessment. Manufacturers were engaging third parties to certify that their products met certain operational standards set by the Canadian government or state and local governments in the United States. When WaterSense established its third-party program to assess conformity with water efficiency standards, the existing conformity assessment networks could be leveraged. Similar networks may already be present in the arena of food safety due to the prevalence of private conformity assessment.⁶¹⁹

An agency should also consider the different benefits that derive from either directly verifying compliance or relying on third-party verification. The outputs of the two approaches differ in ways that may be important. For example, FDA staff does not view the compliance data acquired through the AP Inspection Program as equivalent to the compliance data acquired directly through an FDA inspection of a medical device facility. If the AP inspection suggests there may be violations, FDA must follow up with its own inspections to collect the evidence needed for a formal enforcement action.⁶²⁰ Similarly, in PMAP, FDA's pilot program for medical device facility inspections established in coordination with Canada, FDA found that "the level of detail in the narrative needs to be greater in order for the regulators to have a more complete picture of the audit/inspection and the manufacturer's organization and operation."⁶²¹ The narrative portion of the auditors' reports under the PMAP varied in length from

processed only 1.6 percent of applications (218 applications), and TCBs processed the rest (13,427 applications). *Id.*

619. In terms of food safety and possibly other areas of product safety, it is important to note that the private conformity assessment processes that exist are often not considered to be reliable. *See supra* note 250 and accompanying text. An agency that seeks to incorporate existing networks into its compliance assessment program would need to be particularly careful to set third-program rules that enhance the reliability of third-party determinations and otherwise instill public confidence.

620. Telephone Interview with David Kalins, *supra* note 347.

621. PMAP Report, *supra* note 344, at 3.

three to twenty pages, with large variability in the format and level of detail.⁶²²

Direct governmental verification may also enable more consistency in compliance data and quicker release of data to the public. Rather than adopt a third-party approach for greenhouse gas emission reporting, EPA decided to have facilities submit data electronically and to perform a series of automated data checks with follow-up questions to regulated entities and facility audits as necessary. EPA found that “the combination of comprehensive electronic review and a flexible and adaptive program of on-site auditing will enable us to effectively target verification resources while also providing the necessary consistency and quality in the data.”⁶²³ EPA also found that the direct verification approach would enable it to make data available to the public more quickly. With third-party verification, three to six months might be needed for third-party verifiers to perform their verification role, and EPA “would still need to review [the data] and perform consistency checks after third-party verification was complete.”⁶²⁴

Third-party verification programs generally have the drawback of adding complexity and principal-agent problems to the regulatory process. With a third-party program, many decisions must be made about the roles and responsibilities of new actors, namely certification bodies, testing bodies, and accreditation bodies. The regulatory agency must also assume a new role in overseeing these actors. The new roles seem likely to make the regulatory framework more complicated, thus potentially hindering public understanding and participation. Also, the introduction of new actors creates a “principal-agent problem.” A principal-agent problem arises when a principal (here, the regulatory agency) chooses an agent (the third party) to act on its behalf. Because the two parties have different interests and the agent has more information, the principal has difficulty ensuring that the agent is acting in the principal’s best interest.⁶²⁵ In third-party programs, such principal-agent problems are likely to be exacerbated by the fact that the third parties are not only agents of the regulatory agency but also paid agents of the regulated entities.⁶²⁶

622. *Id.*

623. 74 Fed. Reg. 56,282 (Oct. 30, 2009).

624. *Id.* at 56,283.

625. See Paul M. Johnson, *Agency Problem*, in A GLOSSARY OF POLITICAL ECONOMIC TERMS, http://www.auburn.edu/~johnspm/gloss/agency_problem (last visited Feb. 11, 2014).

626. See Amy Shapiro, *Who Pays the Auditor Calls the Tune?: Auditing Regulation and Clients’ Incentives*, 35 SETON HALL L. REV. 1029, 1031 (2005) (arguing that the problem of auditing in the financial sector is that auditors have two masters and that the law needs to be written “so that auditors recognize proper incentives and serve only one master, a master whose own interests are aligned with those of the investing public”).

4. If Third-Party Verification Would Be Optional, Evaluate the Incentives for its Use

If a third-party program is being contemplated in which regulated entities would have the choice of contracting with third parties or being assessed directly by the agency, the agency should consider whether regulated entities are likely to use the program. The low level of participation in the AP Inspection Program exemplifies the problem. The FDA invested significant resources into its establishment, but it was seldom used by industry.⁶²⁷ While the program offered several incentives for participation, they were outweighed by a series of disincentives including the cost of hiring the third party and the perceived risk that FDA would ultimately take a harder look at its facility.⁶²⁸

Agencies should evaluate whether sufficient incentives can be created for the use of a voluntary third-party program in light of the costs and risks the program would impose. A program may attract more participation if the regulated entity is able to avoid paying an agency-assessed user fee if it contracts with a third party. Another incentive would be provided if the third-party conformity would satisfy the regulatory requirements of other jurisdictions in which a manufacturer operates or sells products. This would generally require a federal agency to coordinate with its counterparts in other countries to harmonize standards and assessments procedures. In this vein, the FDA is currently developing a Medical Device Single Audit Program (MDSAP) in coordination with Canada, Brazil, and Australia.⁶²⁹ The goal of the program is to enable a single audit/inspection of a medical device manufacturer's quality management system to satisfy the regulatory requirements of all the jurisdictions.

B. Establishing a Third-Party Program

1. Calibrate the Third-Party Program to the Level of Risks Associated with Noncompliance

An important principle of private third-party conformity assessment is that the design of the conformity assessment system should be driven by

627. Cf. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, THIRD PARTIES AND FOOD AND DRUG ADMINISTRATION STAFF: MEDICAL DEVICE ISO 13485:2003 VOLUNTARY AUDIT REPORT SUBMISSION PILOT PROGRAM 5 (2012) (stating that "FDA has committed significant resources to creating the AP for Inspections program and continues to maintain it"). It is worth noting that this program was required by statute.

628. See generally *supra* notes 556–562 and accompanying text.

629. Telephone Interview with Kim Trautman, *supra* note 345.

the degree of assurance its user needs.⁶³⁰ In some cases, a user—such as a product purchaser—wants some independent assurance of conformity, but occasional instances of nonconformity will not cause major problems to the purchaser’s manufacturing process or business interests. The purchaser might be satisfied with occasional third-party testing of the product. In other cases, a purchaser may be at risk of incurring high costs due to nonconformity in a purchased product. The purchaser might instead impose a variety of special requirements on the supplier and require third-party certification.

The same principle applies in third-party verification programs. If the risks associated with noncompliance are very high, a third-party program should be designed to provide a maximal degree of reliability in the determinations by third parties. This could be accomplished in a regulatory third-party program through accreditation rules that set high standards for third parties to be accredited, selection rules that carefully guard against conflicts of interest and the use of subcontractors, performance rules that require a rigorous and complete set of assessment activities, reporting rules that furnish ample information about the outcomes of the assessment, and a full array of governmental oversight and enforcement actions. Such rules can be expected to enhance the competence and independence of third-party activities and thus the reliability of their determinations.

Yet, such rules are also likely to entail high costs for both the regulatory agency and regulated entities. Such rules may, in some cases, represent an instance of “over-design” that adds costs to the system and potentially to the products or processes assessed, without compensating benefits.⁶³¹ In some cases, the regulatory objective can be achieved with less intensive conformity assessment activities and with third parties who are not trained as thoroughly as they could be or who are not completely independent.

For example, in several programs detailed above, the agency does not require that the laboratory that tests products be completely independent of the manufacturer. Under the CPSC’s rules, manufacturers’ laboratories can test products if they meet certain “firewalled” criteria. For Energy Star and WaterSense, products can be tested in a manufacturer’s lab under certain circumstances. More generally, the programs vary quite a bit in the extent they have adopted rigorous accreditation, selection, performance, and reporting rules. In some programs, governmental oversight has been sporadic and little evidence exists of active enforcement of third-party program rules.

630. See *supra* note 119 and accompanying text.

631. Gillerman, *supra* note 605.

It bears emphasis, however, that many types of regulations for which third-party programs are considered may be in the high-risk category, where noncompliance implies risks to health, safety, and other valued regulatory goals. For such regulatory purposes, a relatively complete third-party conformity assessment may indeed be appropriate despite its costs.

2. Incorporate Existing Conformity Assessment Standards and Activities When Possible

Agencies should strongly consider relying on existing conformity assessment standards and related activities when they establish third-party programs.⁶³² Doing so can reduce the costs of the program for both the regulatory agency and regulated entities. Relevant conformity assessment standards and activities may be occurring through other governmental agencies or in the private sector.

Sometimes a new third-party program may be able to rely on another governmental agency's conformity assessment activities. During development of the WaterSense program, for example, companies were concerned that participation in WaterSense would require them to duplicate testing and reporting required for DOE plumbing standards and the Federal Trade Commission (FTC) appliance labeling standards.⁶³³ In response, the WaterSense program made its reporting requirements similar or identical to what manufacturers already had done for DOE and FTC.

Extensive private sector conformity assessment standards and activities are also available to be incorporated into regulatory third-party programs.⁶³⁴ Most significantly, as described above, ISO/IEC have developed a set of international conformity assessment standards, and an international

632. Cf. NIST Guidance, *supra* note 592, § 287.4(c) (advising agencies to “[u]se the results of other governmental agency and private sector organization conformity assessment activities to enhance the safety and efficacy of proposed new conformity assessment requirements and measures”); *id.* at § 287.4(f) (advising agencies to “[c]onsider using the results of other agencies’ conformity assessment procedures”).

633. WATERSENSE, U.S. ENVTL. PROT. AGENCY, COMMENTS ON THE MAY 2007 DRAFT WATERSENSE CERTIFICATION SCHEME 14 (2007), available at http://www.epa.gov/WaterSense/docs/cert_scheme_comments508.pdf; cf. *EnergyGuide Labeling: FAQs for Appliance Manufacturers*, FED. TRADE COMMISSION, <http://www.business.ftc.gov/documents/bus-82-energyguide-labels-faqs> (last visited Feb. 11, 2014); *Energy Efficiency and Renewable Energy, Building Technologies Program*, U.S. DEP’T ENERGY, http://www1.eere.energy.gov/buildings/appliance_standards/residential/plumbing_products.html (last visited Feb. 11, 2014).

634. See NIST Guidance, *supra* note 592, § 287.4(e) (directing agencies to “[i]dentify appropriate private sector conformity assessment practices and programs and consider the results of such practices and/or programs as appropriate in existing regulatory and procurement actions”).

conformity assessment industry has emerged to conduct related activities.⁶³⁵ These standards set forth how testing bodies, certification bodies, and accreditation bodies should function.

Regulated entities have expressed a preference for agencies to incorporate private conformity standards and activities rather than creating “government-unique” conformity assessment.⁶³⁶ Regulated entities fear that government-unique standards would be duplicative of private sector conformity assessment activities that they already undertake for business reasons. They also opine that government-unique conformity assessment standards “may be expensive to develop and maintain, may impose additional costs on the private sector, and may not be recognized beyond national boundaries.”⁶³⁷

Using international standards of conformity assessment enhances the possibility that the same conformity assessment might serve regulatory needs in other countries. For example, a federal agency may require that a certain product be tested by a lab accredited to ISO 17025 for conformity with a particular safety standard. If another country has the same safety standard or otherwise considers the U.S. standard equivalent and it respects the international accreditation of the lab, then the manufacturer may not need to undertake any further action to legally market its product in that other country.

A significant way in which an agency can rely on existing conformity assessment standards and activities is by recognizing private sector accreditation bodies to accredit certification and testing bodies rather than accrediting them directly. As in some existing programs, an agency may require that the private accreditation body operate in accordance with ISO/IEC 17011 and be a member of an international organization like IAF or ILAC that coordinates a peer-review process to evaluate accreditation

635. NIST Guidance, *supra* note 592, § 287.4(d) (directing agencies to “[u]se relevant guides or standards for conformity assessment practices published by domestic and international standardizing bodies as appropriate in meeting regulatory and procurement objectives”).

636. *See, e.g.*, Comments of Air-Conditioning, Heating & Refrigeration Inst. on Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, (April 26, 2012), at 1, *available at* <https://law.resource.org/pub/us/cfr/regulations.gov.docket.02/0900006480ffd5af.pdf>.

637. *See id.* at 3; *see also* Comments of Am. Nat’l Standards Inst. on Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, (June 1, 2012), at 4, (advocating solutions based on voluntary consensus standards to reduce the costs of compliance for industry) *available at* http://publica.a.nsi.org/sites/apdl/Documents/Standards%20Activities/Critical%20Issues/FederalRegister_OMBA119/ANSI%20Response%20OMB-A119_FINAL.pdf.

bodies for membership.⁶³⁸ When an agency relies on the ISO/IEC standards for recognition, it avoids having to set all such standards itself. Also, if the agency requires that the accreditation be a member of IAF or ILAC, those organizations conduct periodic assessments of the accreditation body.

If an agency decides to accredit certification bodies directly, it may still find ISO/IEC 17011 to be useful as a guide for its own accreditation activities. The NOP regulations initially required that the NOP assemble a peer review panel pursuant to Federal Advisory Committee Act (FACA) to evaluate its accreditation procedures.⁶³⁹ In its 2010 review of the program, USDA OIG found that the NOP had never established the panel, reportedly due to budget constraints. In response to the OIG report, the NOP proposed an alternative, namely that it would amend its regulations and instead develop “a quality management system that complies with the criteria set forth in NIST’s National Voluntary Conformity Assessment Evaluation program (NVCASE) as well as the requirements of ISO/IEC 17011:2004.”⁶⁴⁰

The FDA’s aquaculture pilot illustrated some of the challenges faced by agencies that directly accredit certification bodies, particularly in an international context.⁶⁴¹ FDA reports that after it announced the pilot, it received applications from candidate certification bodies. It found, however, that the candidate CBs did not reliably submit supporting documentation in their applications and determining whether CBs were qualified required a greater investment of resources than it had anticipated. FDA recommended that “in any future program, FDA should be clearer in its expectations for the amount and type of information needed to adequately evaluate a firm’s application.”⁶⁴²

Notably, programs that anticipate reliance on certification bodies in other countries may be particularly well served by relying on private accreditation bodies. Such accreditation bodies may have more institutional competence than the agency in dealing with foreign companies and may even be located in that country or the same region of the world. Of course, the issue then arises of how the agency will oversee the foreign activities of private accreditation bodies and the foreign certification bodies they accredit.

638. See *supra* notes 116–18 and accompanying text.

639. USDA OIG, *supra* note 531, at 3.

640. *Id.* at 19; cf. GRADING & VERIFICATION DIV., U.S. DEP’T OF AGRIC., QUALITY MANUAL FOR ACCREDITING CONFORMITY ASSESSMENT BODIES (2001), available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5073714>.

641. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, *supra* note 479.

642. *Id.* at 7.

Importantly, when an agency incorporates international standards into its requirements for certification, testing, or accreditation bodies, it can supplement those standards in various ways. An agency, for example, may require that a certification body be accredited by a private accreditation body to ISO/IEC 17065 and also meet a certain set of requirements specific to a third-party program. The accreditation body might be given responsibility for assessing conformity with the program-specific requirements, or the agency might do its own assessment as part of “recognizing” an accredited certification body for participation in the program.

Through these program-specific requirements, the agency can put flesh on the sometimes bare-bones requirements of the international standard. For example, ISO/IEC 17065 contains a basic requirement that certification bodies conduct surveillance of certified companies or products. Through program-specific requirements for accreditation of the certification body, the agency could require it to undertake particular types of surveillance activities at particular times. Similarly, an agency might specify particular conflict-of-interest rules that supplement ISO/IEC 17065’s general requirement that certification bodies be independent and impartial.

3. Ensure that the Agency and the Public Have Appropriate Access to Information

Private third-party conformity assessment systems differ from regulatory third-party verification programs in a key respect. In the latter, the user of the system is ultimately the public, and the regulatory agencies that establish third-party programs are accountable to the public for their outcomes. As a result, the responsible agency and the public should have access to a variety of types of information about the operation of the third-party program.

The public should have access to and input into the procedures by which a regulatory third-party program is run. The development of program rules and guidance should include public notice and participation. When agencies incorporate international conformity assessment standards into their regulatory processes, important concerns arise about the public availability of those standards.⁶⁴³ Because ISO/IEC standards are copyright protected, they are not easily accessible to interested members of the public. ACUS has recommended that when an agency considers “incorporating copyrighted material by reference, the agency should work with the copyright owner to ensure the material will be reasonably available to regulated

643. See especially ADMIN. CONFERENCE OF THE U.S., ADMINISTRATIVE CONFERENCE RECOMMENDATION 2011-5: INCORPORATION BY REFERENCE, *supra* note 604, at 2, 5–6.

and other interested parties both during rulemaking and following promulgation.”⁶⁴⁴

The public should also have access to certain types of information about the compliance of regulated entities. If a third-party program replaces a regulatory compliance program, the same types of information that were accessible to the public before the implementation of the third-party program should remain accessible after. In some cases, however, it may be appropriate and desirable to provide additional compliance information to the public that was not systematically available before the third-party program came into effect.

The public should have access to certain types of information about the third parties that participate in the regulatory program. The agency should make clear the roles and identities of the various third-party actors. In several programs discussed above, Congress has required that agencies maintain a public list of the private bodies associated with the program. Other information about the characteristics and activities of the private bodies may also be important to create public confidence in the integrity of the third-party program.

For effective oversight, the government agency will also need certain types of information from accreditation, certification, and testing bodies. For example, testing and certification bodies might be required to report potential conflicts of interest before performing the conformity assessment. They might also be required to report the dates of their conformity assessment activities so that agency officials can conduct a site visit for oversight purposes. In addition to the positive or adverse determination that is the ultimate outcome of the conformity assessment process, bodies can be required to submit documents gathered or generated during the process that explain and support the determination. To the extent that information required of third parties constitutes confidential business information, it can be held back from the public in accordance with the Freedom of Information Act and other applicable laws.

Information disclosure requirements may have the effect of enhancing the degree to which third-parties answer directly to the agency rather than just the regulated entity that has contracted it. For example, FSMA requires that accredited labs send their test results directly to the FDA.⁶⁴⁵ One commentator has called this “a game-changing requirement” that “alters the whole dynamic between labs and their clients,” making them

644. *Id.* at 5.

645. 21 U.S.C. § 350k(b)(2) (2012).

“directly responsible to the public (i.e., the government) to ensure that information is disclosed about their client.”⁶⁴⁶

Importantly, international conformity assessment standards include confidentiality provisions that may prevent the flow of information in a regulatory third-party program. When EPA requested comments on a draft of its rules for the recognition of accreditation bodies that would accredit laboratories, it received comments to the effect that several types of information that it initially wanted from the accreditation bodies were contrary to the confidentiality provisions of ISO 17011.⁶⁴⁷ For example, EPA initially wanted to be informed of the results of ILAC’s peer evaluation. After being informed that such information was against ISO 17011’s confidentiality rules, EPA struck the requirement.⁶⁴⁸

On the same basis, a commenter also objected to EPA’s requirement that recognized accreditation bodies provide EPA with copies of laboratory assessment documentation including corrective action plans and documentation about the resolution of deficiencies.⁶⁴⁹ In this case, however, EPA responded that the release of this information by the AB is an “integral aspect of EPA’s recognition of the laboratory” and suggested that the AB should seek the laboratory’s written consent to share this information with EPA.⁶⁵⁰ EPA’s response also indicates how an agency can use program-specific rules to essentially modify the default confidentiality rules contained in the international standards.

While confidentiality provisions should not hinder the flow of information that is necessary for adequate regulatory oversight and public accountability, some would argue that certain confidentiality assurances ultimately serve regulatory goals. For example, the FDA has provoked a negative reaction from industry by interpreting FSMA to require that an accredited auditor must immediately notify the FDA if it “discovers a condition that could cause or contribute to a serious risk to the public health”

646. Daniel R. Dwyer, *Third-Party Accreditation under the FDA Food Safety Modernization Act*, KKBLOG (Mar. 7, 2012, 5:31 PM), http://www.kkblaw.com/?p=206&option=com_wordpress&Itemid=5.

647. See U.S. ENVTL. PROT. AGENCY, ENERGY STAR COMMENTS MATRIX 2, http://www.energystar.gov/ia/partners/downloads/mou/AB_Comment_Matrix.pdf (last visited Feb. 12, 2014) (providing matrix that summarizes comments on the condition and criteria for recognition of accreditation bodies for Energy Star laboratory recognition); see also *Stakeholder Comments on the Enhanced Program Plan for ENERGY STAR Products*, ENERGY STAR, http://www.energystar.gov/index.cfm?c=partners.intro_conf_calls#accred (last visited Feb. 12, 2014) (listing of stakeholder comments on draft accreditation body requirements).

648. U.S. ENVTL. PROT. AGENCY, ENERGY STAR COMMENTS MATRIX, *supra* note 647, at 2.

649. *Id.* at 3.

650. *Id.*

during either a regulatory or a consultative audit.⁶⁵¹ As stated by one industry commenter, “[w]e disagree with this interpretation of the FSMA and maintain that such a position could undermine the purpose of the law, ultimately dissuading manufacturers from using third party auditors—a move that could negatively impact food safety and hinder FDA’s efforts to efficiently use its own resources.”⁶⁵² Agencies should consider pros and cons of limiting the types of confidentiality that regulated entities expect when they contract privately with third parties.

IT can play an important role in enabling the flow of information in a third-party program. Regulated entities, third-party conformity assessment bodies, and accreditation bodies can be required to e-report certain types of information. Also, with well-administered IT systems, information that should be public can be more promptly made public. In its shrimp aquaculture pilot, the FDA made a special note of the need for new “IT data systems to capture and report on results of assessments and audits.”⁶⁵³

In sum, a change in the “communicative energy” of third-party conformity assessment is required in a regulatory context.⁶⁵⁴ The default in the private sector is for the third party to disclose his audit report exclusively to his client.⁶⁵⁵ If interested parties external to the contractual relationship are privy to the audit’s results at all, they are likely to be told little more than whether the subject of the audit conformed or not.⁶⁵⁶ For an assessment to serve public regulatory purposes, much richer information about its process and outcomes is necessary.⁶⁵⁷

4. Commit to Undertaking Appropriate Oversight Activities

When an agency establishes a regulatory third-party program, its role often changes from being the inspector to overseeing the inspectors.⁶⁵⁸ Governmental oversight of third-party programs is essential to ensure that

651. 21 U.S.C. § 384d(c)(4)(A) (2012); *see also Imports*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/food/guidanceregulation/fsma/ucm257980.htm> (last updated Aug. 19, 2013) (answering in the affirmative the question, “I.4.2 Is the accredited auditor required to notify the FDA if a condition of concern is found during a consultative audit?”).

652. Comments of Int’l Dairy Foods Ass’n on U.S. Food & Drug Admin. Food Safety Modernization Act Import Provisions Rulemaking, Docket Nos. FDA-2011-N-0143 to -45, (Apr. 28, 2011), at 3, *available at* http://www.idfa.org/files/IDFA_FSMA_Import_Comments_042811.pdf.

653. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, *supra* note 479, at 26.

654. Christine Parker, *Regulator-Required Corporate Compliance Program Audits*, 25 LAW & POL’Y 221, 235–36 (2003).

655. *See id.* at 235.

656. *See id.*

657. *Id.* at 236.

658. Martin Shapiro, WHO GUARDS THE GUARDIANS? (1988).

they are fulfilling their regulatory purposes. In addition to exercising direct oversight, an agency can also require third parties to conduct and report surveillance activities that provide additional information to the agency about program operation.

For a successful third-party program, a regulatory agency must implement and enforce the rules it establishes for associated accreditation and conformity assessment bodies. In principal, many of the same enforcement strategies and tools would apply in enforcing third-party program rules as apply in enforcing other regulatory rules. The agency can require certain types of reporting, conduct inspections to verify compliance, and impose sanctions for noncompliance. One important sanction would be the removal of a noncompliant accreditation or conformity assessment from the program.

An agency should determine in advance how it intends to conduct oversight. The agency may decide, for example, that it will assess the performance of accreditation bodies every few years, that it will conduct a certain number of audits of accreditations or certifications, or that it will carry out a market surveillance program that will test a certain number of products off the shelf each year. Special program rules may be necessary to ensure an oversight activity. In the shrimp aquaculture pilot, for example, FDA found that entities subject to certification were not always willing to allow an FDA official to accompany the certification body on a site visit. FDA concluded that it should “[c]onsider requiring, as a condition for accreditation, that CBs maintain agreements with establishments they certify to allow FDA to monitor or otherwise participate in certification audits as necessary.”⁶⁵⁹

The agency should also retain direct enforcement authority over regulated entities, which could be used when the agency discovers through the third-party program or otherwise that a regulated entity is out of compliance. In the NOP program, for example, AMS uses its traditional enforcement powers to respond to situations where organic operations knowingly market nonorganic food as organic.⁶⁶⁰ Its enforcement actions play “a central role in maintaining the validity of the program and ensuring public trust” in the label.⁶⁶¹

As in traditional regulatory programs, agencies should be equipped to receive and respond to information about potential noncompliance from the public. In an investigation of the NOP program, the USDA OIG found that “NOP officials did not have adequate procedures or a system for track-

659. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, *supra* note 479, at 21.

660. USDA OIG, *supra* note 531, at 8.

661. *Id.* at 8.

ing the receipt, review, and disposition of complaints and any subsequent enforcement actions.”⁶⁶² When third parties have played a role in assessing compliance, the agency might be able to direct a public complaint to the relevant third-party body for an initial investigation. The agency, however, would remain ultimately responsible for ensuring that the complaint was resolved. The agency could also require that employees of accreditation bodies and conformity assessment bodies be given information about how to anonymously contact an official within the regulatory agency to report any potential problems.

The agency may require accreditation bodies and conformity assessment bodies to undertake certain activities that provide information for oversight purposes. For example, accreditation bodies may be required to conduct periodic audits of the certification bodies they accredit. Certification bodies may be required to conduct surveillance audits of the entities and products they certify.⁶⁶³ In either, the agency might also require that some or all of the audits be unannounced rather than announced.⁶⁶⁴ In its investigation of the NOP’s organic milk program, the OIG found that certifying agents were not performing unannounced inspections of organic dairy operations.⁶⁶⁵ While unannounced inspections are not required by NOP regulations, OIG and other stakeholders consider them to play a “critical role” in ensuring compliance.⁶⁶⁶ Notably, if the rules of a third-party program do not require unannounced audits, accreditation and certification bodies will have little incentive to do them for fear of offending clients. Unannounced audits of facilities can be facilitated by requiring regulated entities to agree to them as a condition of certification.

662. *Id.* at 1.

663. Energy Star requires CBs to operate a partner-funded verification testing program to ensure products meet Energy Star standards. DEPT. OF ENERGY, ENERGY STAR APPLIANCE VERIFICATION TESTING – PILOT PROGRAM SUMMARY REPORT 22 (2012), available at http://www1.eere.energy.gov/buildings/appliance_standards/pdfs/energystar_pilotprogram_report_02_03_12.pdf.

664. See Albersmeier et al., *supra* note 102, at 933 tbl.5 (showing that a superior risk-oriented approach includes “[r]andomly chosen audits without announcement” rather than “regular audits with announcements”).

665. OFFICE OF INSPECTOR GEN., U.S. DEP’T OF AGRIC., AGRICULTURAL MARKETING SERVICE: NATIONAL ORGANIC PROGRAM—ORGANIC MILK 16-17 (2012), available at http://www.usda.gov/oig/webdocs/01601-0001-Te.pdf?utm_source=Organic+Milk+Audit+Report+Published&utm_campaign=Organic+milk+audit+report&utm_medium=email.

666. *Id.* at 17.

CONCLUSION

Private regulation is pervasive. In a variety of contexts, private actors create, implement, and enforce rules that serve the traditional social goals of public regulation. This Article examines how these private actors and their work might be harnessed to build more effective regulatory regimes. After providing an overview of how private regulators perform the classic functions of regulation—standard setting, implementation, and enforcement—the first part of the Article focused on several forms of harnessing private regulation, namely the incorporation of private standards, the public endorsement of self-regulation, and third-party verification.

Having situated third-party verification in this broad context, the Article proceeded to describe and analyze the use of third-party verification by a diverse set of federal agencies responsible for health, safety, and environmental protection. Eight third-party programs established by six federal agencies are described with attention to the goals of the regulatory program, the authorizing laws and regulations, the roles and responsibilities of the third parties, and provisions for agency oversight. In doing so, the Article shows how the exercise of public and private authority is interwoven when federal agencies develop programs that enable private third-parties to assume primary responsibility for compliance monitoring and assessment.

The rich empirical information provided in the second part of the Article allows for the construction of a set of metrics of success in the third part and recommendations in the fourth part. As two scholars of private regulation recently explained, while there are many political forces pushing policymakers to prefer private regulation, there is “little or no guidance being given to policymakers about when, and under what circumstances [private regulatory schemes] can prove viable from a public policy perspective.”⁶⁶⁷ They further observed that “public bodies seem to have developed no means to design collaborative forms [to] control the evolution of public/private governance.”⁶⁶⁸ The metrics and recommendations for third-party verification answer this call for policy analysis and advice, enabling a much greater understanding of when and how third-party conformity assessment can be used for public regulatory purposes.

Private regulation and attempts to harness it are likely to grow as government resources continue to fall short in fulfilling regulatory needs. This Article suggests that there is both promise and peril in harnessing private regulation. Third-party verification, in particular, seems likely to increase the comprehensiveness and reliability of safety testing in various regulatory

667. Cafaggi & Renda, *supra* note 144, at abstract.

668. *Id.* at 3.

contexts, particularly when regulated products are produced in international commodity chains. It also seems much more reliable than self-declaration to create trustworthy governmental labels for consumer products.

Yet Congress and agencies should tread carefully. They need to identify the contexts that are amenable to harnessing and establish third-party programs that keep “non-governmental regulators committed to public purpose.”⁶⁶⁹ As shown in this Article, not all programs have been successful, and public regulators will benefit greatly by understanding what has worked well and what has not. Perhaps most importantly, public regulators must have the resources and will to exercise serious and consistent oversight once a program is in place.⁶⁷⁰ Ensuring that public regulatory objectives are met remains their responsibility.

669. Balleisen, *supra* note 134, at 481.

670. Balleisen & Eisner, *supra* note 34, at 147.

APPENDIX

**ADMINISTRATIVE CONFERENCE
RECOMMENDATION 2012-7***Agency Use of Third-Party Programs to Assess Regulatory Compliance**Adopted December 6, 2012*

Federal agencies in diverse areas have developed third-party programs to assess whether regulated entities are in compliance with regulatory standards and other requirements. Through these programs, third parties assess 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, regulated entities generally contract with and pay third parties to carry out product testing, facility inspections, and other regulatory compliance assessment activities in the place of regulatory agencies. Regulatory agencies then adopt new roles in coordinating and overseeing these third-parties.¹

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. A third-party program is just one of many regulatory approaches that Congress and agencies may adopt.² Regulatory objectives may, for example, be adequately met by requiring regulated entities to self-assess and report their compliance (sometimes referred to as "first-party certification"). Also, statutory restrictions on information disclosure or other legal restrictions may preclude an agency from using third parties to conduct inspections and other compliance assessment activities. Some compliance assessment activities may be

1. Agencies may use third parties in connection with regulatory, procurement, and federal assistance programs. This recommendation addresses use of third parties in regulatory programs.

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

inherently governmental, and thus require performance by government personnel.³

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

Regulatory third-party programs raise a host of important questions. Because third-party programs represent 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.⁴ While third-party programs may increase regulatory compliance or otherwise improve the performance of regulated entities and products, these programs also pose risks.⁵ 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 a conformity assessment framework that has been developed by international 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.”⁶ International standards also set forth how the organiza-

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

4. 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).

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

6. 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>.

tions 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 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 own enforcement of regulatory requirements. The goal is to leverage private expertise and resources 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 government conformity assessment activities with similar activities of 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 in 2000 for federal agencies on conformity assessment activities.⁷ NIST: (1) provides advice, solutions, and program support for development of technical standards and conformity assessment programs to support agency missions; and (2) develops and conducts customized standards-related workshops and educational events for government.

Recognizing the growing use of third parties and the issues it raises, the Administrative Conference makes 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,

7. 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).

when considering a third-party program, agencies should 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 first determine that regulated entities will have sufficient 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 create efficiencies for both agencies and regulated entities. The agency should also ensure appropriate government and public access to information about program operation. Finally, the agency should undertake appropriate oversight activities to ensure that the third-party program fulfills 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, as appropriate. These include, but are not limited to, the National Institute of Standards and Technology (NIST); private conformity assessment standards, particularly the standards of the International Organization for Standardization (ISO); and conformity assessment bodies, for practical input on feasibility and the impacts on the regulated entities.

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 effective in practice and as a technical matter 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;

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

(g) 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. 2257, 2259 (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 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 a Federal Agency 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 regulato-

ry 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 and the public 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 and accreditation bodies. Incorporating existing standards may reduce costs for the agency and for the regulated entities. To evaluate the suitability of using existing standards, the agency should take into account the following considerations:

- (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 be cognizant of issues relating to incorporation by reference. (*See Administrative Conference of the United States, Recommendation 2011-5, Incorporation by Reference, 77 Fed. Reg. 2257 (Jan. 17, 2012)*);
- (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 the agency itself accrediting conformity assessment bodies;
- (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 to agencies and/or the public 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. Information about the compliance of regulated entities should be available from the agency to the public, comparable to what 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 agency oversight. For example, conformity assessment bodies can be required to report to the agency potential conflicts of interest before performing a conformity assessment, or provide the dates of their assessment activities so that the agency can conduct site visits;

(c) In certain circumstances, the agency might have reporting rules that require conformity assessment bodies to send assessment results directly to the agency; and

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

7. *Agency Oversight.* The agency has a duty to exercise oversight to ensure that the third-party program is fulfilling its regulatory purpose. An agency should generally set forth how it intends to conduct such oversight. For example, it may 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 take into account the following considerations:

(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 annually to 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 complaint of noncompliance. In any event, 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 accreditation, or permanently through a withdrawal of accreditation.

