Third-Party Programs to Assess Regulatory Compliance

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This report was prepared for the consideration of the Administrative Conference of the United States. The views expressed are those of the author and do not necessarily reflect those of the members of the Conference or its committees.

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[Revised] Draft Report Prepared for the Administrative Conference of the United States[*]

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I. Introduction

Federal 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. With oversight by the responsible federal agency, third parties are charged with assessing the safety of imported food, children's products, medical devices, cell phones and other telecommunications equipment, and electrical equipment used in workplaces. Third parties also ensure that products labeled as organic, energy-efficient, and water-efficient meet applicable federal standards. In these regulatory third-party programs, third parties carry out product testing, facility inspections, and other regulatory compliance activities in the place of regulatory agencies. Regulatory agencies take on new roles in coordinating and overseeing these private actors.

Third-party programs operated by federal agencies for regulatory purposes vary in important ways. In many cases, Congress provided legislative authority for the third-party program and set forth certain design elements in statute. 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.

There are several reasons why third-party programs are being increasingly incorporated into regulation. Some regulatory problems are difficult to address using traditional regulatory approaches such as ensuring the safety or correct labeling of food and other products manufactured in complex international chains of production. Third-party programs may extend the reach of regulators by enabling third parties around the globe to participate in compliance assessment. Another motivating factor is that agency resources are often inadequate to address the ever-growing number of problems and entities subject to regulation. Third-party programs may have the effect of shifting some regulatory costs to private parties and thereby conserving governmental resources.

Regulatory third-party programs raise a host of significant theoretical and practical questions. Representing a partial privatization of the public function of implementing and enforcing regulatory law, they are a form of "public-private governance," in which private actors play roles that are traditionally viewed as governmental in nature.[2] While they may enable innovation, efficiency, and quality in the provision of governmental services, third-party programs may also jeopardize the fulfillment of public purposes and commitments. Difficult issues are presented regarding considerations such as the competence and independence of third-party actors, the extent of governmental control and oversight, and the management and coverage of third-party program costs.

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

A variety of sources inform this paper. Information about particular programs was gathered primarily from relevant statutes, regulations, agency guidance documents, and agency reports. The author also conducted twenty phone interviews, mostly with agency staff responsible for, or otherwise very knowledgeable about, third-party programs (see Appendix A). The paper also draws from relevant academic literature.[3]

The rest of the paper is divided into four sections. Section II introduces the language of conformity assessment. Many regulatory third-party programs, particularly newer ones, explicitly incorporate terminology and concepts from private-sector conformity assessment systems. Older programs do not as much, but the vocabulary of conformity assessment remains helpful in understanding their structure.

Section III surveys eight programs in which federal agencies rely on private third parties to provide information about the compliance of regulated entities. The programs are diverse. They are operated by six different regulatory agencies. Half assess compliance with mandatory standards, and the other half assesses compliance with voluntary standards. The use of third parties is required in six and optional in two.

Section IV identifies five metrics to assess the success of third-party programs. These metrics include the reliability of third-party determinations, the rate of compliance, agency capacity to administer the third-party program, public acceptance, and industry acceptance. They are discussed with examples drawn from the surveyed programs.

In the final section, recommendations are made to federal agencies. The first set of recommendations regards how an agency should consider whether or not to establish a third-party program. The second set of recommendations is directed towards agencies that have decided to establish such a program.

II. Conformity Assessment in a Regulatory Context

Regulatory third-party programs are often built using the terminology and practices of a broad "conformity assessment" framework that has been developed by standards bodies in the private sector. Conformity assessment is defined as "demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled."[4] It is commonly used in the private sector by purchasers who want to verify that a potential supplier's product or service conform to their requirements.[5]

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[3] *See especially* Lesley K. McAllister, *Regulation by Third-Party Verification*, 53 B.C. L. REV. 1 (2012); Friederike Albersmeier et al., *The Reliability of Third-Party Certification in the Food Chain: From Checklists to Risk-Oriented Auditing*, 20 FOOD CONTROL 927, 930 (2009); Stepan Wood, *Voluntary Environmental Codes and Sustainability*, *in* ENVIRONMENTAL LAW FOR SUSTAINABILITY 229, 230 (2006); Errol E. Meidinger, *The New Environmental Law: Forest Certification*, 10 BUFF. ENVTL. L.J. 211, 284 (2002).

[4] 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.

[5] Margaret M. Blair et al., *The New Role for Assurance Services in Global Commerce*, 33 J. CORP. L. 325, 329-30 (2008) (tracing the origins of the third-party assurance industry and many of its most important firms back to the

Given the importance of conformity assessment to business transactions, the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) have published a series of standards relating to conformity assessment. Also, a large number of private organizations have been established to perform conformity assessment-related services. As federal agencies have recognized that verifying compliance with regulatory requirements can be viewed as a form of conformity assessment, they have built relevant international standards and the work of related organizations into their compliance programs.

The vocabulary of conformity assessment has thus become essential to understanding third-party programs operated by federal agencies. Indeed, the term "third party" is part of that vocabulary. International standards divide conformity assessment into three major types. [6] First-party conformity assessment is performed by the manufacturer or supplier itself and is also referred to as "supplier's declaration of conformity" (SDoC). [7] Second-party conformity assessment is performed by the purchaser or customer. Third-party conformity assessment is performed by an independent entity, which may (in this general terminology) be a government agency or a private party.[8] This report is concerned with third-party conformity assessment conducted by private parties under the direction of federal agencies for regulatory purposes.

Definitions of the various types of activities and organizations related to conformity assessment are also set forth in international standards.[9] "Testing" means the "determination of one or more characteristics of an object of conformity assessment, according to a procedure."[10] "Certification" means "third party attestation related to products, processes or persons that conveys assurance that specified requirements have been demonstrated."[11] Testing is usually conducted by laboratories (which may also be referred to as testing bodies), while certifications are conducted by certification bodies (which may also be laboratories). Both testing bodies and certification bodies are referred to as conformity assessment bodies.[12]

In the language of conformity assessment, testing is often necessary for certification but it is distinct. Unlike testing, certification is always performed by a third party, and it requires that the third party conduct not just initial testing but also the surveillance necessary to attest to the

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1800s when marine insurance companies hired private inspectors to make sure that ships carrying insured goods were seaworthy).

[6] Christopher Johnson, U.S. International Trade Commission, Technical Barriers to Trade: Reducing the Impact of Conformity Assessment Measures 4 (2008), *available at* http://www.usitc.gov/publications/332/working_papers/ca-dft-rev-final082008.pdf.

[7] *Id.* (defining SDoC as a procedure by which a manufacturer (or other supplier) provides written assurance of the conformity of its products to specified requirements.)

[8] *Id.* at 7.

[9] ISO/IEC 17000 sets out standard definitions of conformity assessment terms.

[10] ISO/UNIDO, Building Trust: The Conformity Assessment Toolbox 34 (2010), http://www.iso.org/iso/casco_building-trust.pdf.

[11] ANSI, *supra* note 4, at 5.

[12] Another type of conformity assessment body that could be relevant to third-party programs for regulatory purposes is an inspection body. ISO/IEC 17000 defines inspection as an "Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements." ISO/UNIDO, *supra* note 10, at 35. The international standard for inspection bodies is ISO/IEC 17020, *General criteria for the operation of various bodies performing inspection.* None of the third-party programs surveyed in this report have incorporated the standard for inspection bodies.

continuing conformity of a product, process, system, or person.[13] "Surveillance" is defined by ISO as a "systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity."[14] 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.[15]

Accreditation is another important element of private conformity assessment systems. "Accreditation" is defined as "third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks."[16] Accreditation bodies decide whether to accredit conformity assessment bodies by using auditing techniques to assess their organizational and technical capabilities.[17] They are often appointed by national governments, but not all countries have a national accreditation body and some countries have one or more private accreditation bodies in addition to or instead of a national accreditation body.[18]

Accreditation bodies are often members of an international association of accreditation bodies, such as the International Accreditation Forum (IAF) or the International Laboratory Accreditation Cooperation (ILAC).[19] 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 (MLA) and the ILAC Mutual Recognition Agreement (MRA).[20] IAF and ILAC use a system of peer evaluation to assess accreditation bodies for membership and to perform reassessments every four years.[21] Their objective is that conformity assessment bodies accredited by member accreditation bodies would be recognized

[13] Interview (by phone), Gordon Gillerman, Chief, Standards Services Division, National Institute of Standards and Technology, Aug. 15, 2012. *See also* IAF FAQ, http://www.iaf.nu/articles/FAQ/288 (last visited Sept. 11, 2012) (stating that ISO/IEC defines certification as a "third-party attestation related to products, processes, systems or persons"); ISO/UNIDO, *supra* note 10, at 52-55 (setting forth various systems that include surveillance and meet the definition of product certification).
[14] ISO/UNIDO, *supra* note 10, at 44.
[15] *Id.* at 45.
[16] ANSI, *supra* note 4, at 5; ISO/UNIDO, *supra* note 10, at 24.
[17] ISO/UNIDO, *supra* note 10, at 44.
[18] ISO/UNIDO, *supra* note 10, at 25, 86-88.
[19] *See e.g.*, International Laboratory Accreditation Cooperation, https://www.ilac.org/.
[20] Office of the United States Trade Representative (USTR), Technical Barriers to Trade (TBT Report) 28 (2012), http://www.ustr.gov/about-us/press-office/reports-and-publications/2012/technical-barriers-trade-tbt-report (last visited Sept. 11, 2012). *See also* IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Narrative Framework for Reporting on the Performance of an Accreditation Body (AB) A Tool for the Evaluation Process, IAF/ILAC-A3:07/2011 (2011), http://www.compad.com.au/cms/iafnu/workstation/upFiles/IAFILACA3072011.pdf (last visited Sept. 11, 2012).
[21] *Id.*

as competent in multiple jurisdictions and markets.[22] In the words of the accreditation industry, "tested or certified once - accepted everywhere."[23]

It is useful to understand that private conformity assessment encompasses a spectrum of rigor and independence.[24] 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, an SDoC based on the manufacturer's own inspection or testing may be adequate. When the purchaser needs more assurance, it may require an SDoC supported by testing in an accredited third-party laboratory. When the purchaser needs much more assurance, it may require certification by an accredited third party, perhaps with testing conducted in an accredited third-party laboratory.

Importantly, conformity assessment requirements impose costs, and those costs are higher in systems that are more rigorous and independent. More complete and frequent conformity assessment adds rigor, but it also increases the cost to the party required to demonstrate conformity. Similarly, the involvement of a third party increases not just a system's independence, but also its cost. Redundancy in accreditation has also been observed to add costs to conformity assessment: a laboratory or certification body may need to get different accreditations to perform similar assessment in different localities, states and countries.[25] These costs may then result in higher market prices for products and services subject to conformity assessment requirements. Also, differences in conformity assessment requirements across global markets can act as non-tariff barriers, a type of technical barrier to trade.[26] The Agreement on Technical Barriers to Trade requires that conformity assessment procedures adopted by the US and other member governments be non-discriminatory and avoid creating unnecessary obstacles to international trade.[27]

Federal agencies have often 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, to be replaced by ISO/IEC 17065); and how accreditation bodies should conduct accreditations (ISO/IEC 17011)

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[22] ISO/UNIDO, *supra* note 10, at 89. *See also* USTR, *supra* note 20, 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.").

[23] United Kingdom Accreditation Service, IAF: What is the International Accreditation Forum, INC.?, http://www.ukas.com/technical-information/international-role/iaf.asp (last visited Sept. 11, 2012); *see also* http://www.iaf.nu/ (showing the slogan "certified once, accepted everywhere" in the bottom right hand corner of the page).

[24] Interview (by phone), Gordon Gillerman, Chief, Standards Services Division, National Institute of Standards and Technology, Aug. 15, 2012.

[25] National Research Council, Standards, Conformity Assessment, and Trade: Into the 21st Century (1995, National Academy Press), *available at* http://www.nap.edu/openbook.php?record_id=4921.

[26] Johnson, *supra* note 6.

[27] Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Legal Instruments--Results of the Uruguay Round, *available at* http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm .

(see Appendix B).[28] Agencies have also tapped into the international networks of accreditation bodies, certification bodies, and testing bodies that seek to operate in conformity with these standards and do the work of conformity assessment.

In regulatory third-party programs, third parties determine whether the products or production processes of regulated entities conform to certain standards. Most often these standards are established by the responsible governmental agencies, referred to as "government-unique" standards. In other regulatory programs, agencies have required compliance with privately-established "voluntary consensus standards." Voluntary consensus standards are standards developed or adopted by domestic or international voluntary consensus standard-setting bodies, such as the American Society for Testing and Materials (ASTM) or ISO.[29] Pursuant to the National Technology Transfer and Advancement Act of 1995 and OMB Circular A-119, federal agencies are required to adopt voluntary consensus standards instead of government-unique standards when available and appropriate.[30] Also, since the passage of the NTTAA, federal employees have become much more involved in the private sector organizations that establish voluntary consensus standards. In FY2010, more than 2,800 federal agency staff participated in more than 500 private-sector standards organizations.[31]

In most of the programs reviewed 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, Telecommunication 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. The applicable standard may be a mandatory standard, such as a product safety rule, or a voluntary standard, as for an organic labeling scheme. In some programs, regulated entities are required to contract with a third party; in others, they have an option to do so.

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. Or 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.

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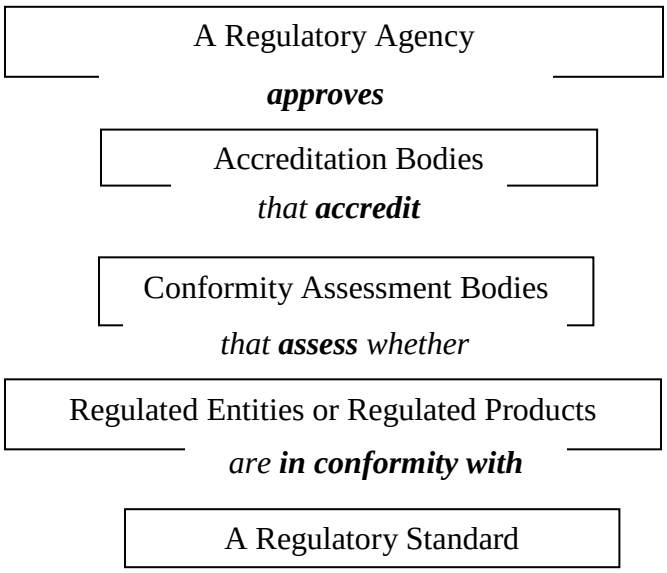
[28] *See* Appendix A.
[29] OMB Circular No A-119-Revised (Feb. 10, 1998), *available* at http://www.whitehouse.gov/omb/circulars_a119.
[30] *Id.*; National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, 110 Stat. 775 (1996) (codified in scattered sections of 15 U.S.C.).
[31] First Responder Technologies - Ensuring a Prioritized Approach for Homeland Security Research and Development: Hearing Before the Subcomms. on Emergency Preparedness, Response and Communications & Cybersecurity, Infrastructure Protection, and Security Technologies of the H. Comm. on Homeland Security, 112th Cong. (May 9, 2012) (testimony of Mary H. Saunders, Director, Standards Coordination Office, National Institute of Standards and Technology), http://homeland.house.gov/sites/homeland.house.gov/files/Testimony-Saunder.pdf (last visited Sept. 11, 2012).

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



III. Review of Federal Third-Party Programs

This paper surveys the most significant regulatory third-party programs implemented by federal agencies.[32] In these programs, federal agencies directly rely on private third parties to provide information about regulatory compliance with mandatory or voluntary standards. Several types of programs that share some similarities but do not meet this description are outside the scope of this report. Examples include: (1) where a federal agency places responsibility for inspecting and providing information about compliance directly on regulated entities;[33] (2) where a federal agency relies on state agency personnel to inspect and provide information about compliance;[34] (3) where a federal agency takes into account whether a regulated entity is certified as meeting an ISO/IEC standard or another similar privately-established standard in determining its inspection priorities;[35] and (4) where an agency uses

[32] A significant program is one that is large, long-standing, well-documented, or some combination thereof. Several other programs implemented by the EPA may fall within the scope of this report but are relatively small and/or very recent. These include EPA's requirement of attest engagements in its regulation of fuels (see http://www.epa.gov/otaq/fuels/reporting/attestengage.htm); EPA's program regarding formaldehyde in wood (see http://www.epa.gov/opptintr/chemtest/formaldehyde/); and its Design for Environment label (DfE) (http://www.epa.gov/dfe/).

[33] *See, e.g.*, USDA's proposed rule, Modernization of Poultry Slaughter Inspection, 77 Fed. Reg. 4408 (Jan. 27, 2012).

[34] An example is provided by USDA's Good Agricultural Practices/Good Handling Practices (GAP/GHP) Audit Program, in which auditors from USDA and related state agencies certify on a fee-for-service basis the compliance of farms and food facilities with voluntary standards set by FDA. *See* USDA, Fresh Fruit and Vegetable Audit Programs, http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&page=GAPGHPAuditVerificationProgram (last visited Sept. 11, 2012).

[35] An example is provided by a program in which FDA intends to use the results of a voluntary ISO 13485 audit as part of its risk assessment to determine whether that establishment can be removed from FDA's routine inspection work plan for one year from the last day of the audit. *See* FDA, Guidance for Industry, Third Parties and Food and Drug Administration Staff, Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program

private third parties to assess compliance with its own procurement or federal assistance policies.[36]

The eight third-party programs that are surveyed have been implemented by six different federal agencies (see Table 1). In four of the programs, third parties are called upon by regulatory agencies to assess compliance with mandatory regulatory standards. In the other four, third parties assess compliance with voluntary regulatory standards. In two of the eight programs, regulated entities have a choice about whether or not to use third parties to assess their compliance. In the others, 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 third-party programs were established before 2003 (with one dating to the late 1980s), and four others have been established since 2008.

The reviewed programs are discussed with attention to the following questions: What is the overall purpose of the third-party program and the nature of the standard applied (voluntary or mandatory, governmentally-set or privately-set)? What is the authorizing law for the program? Who are the regulated entities that are subject to the third-party program? Who are the third parties and how are they accredited? What measures are in place to prevent conflicts of interest between third parties and regulated entities? How does the agency exercise oversight? And what funding exists for the administration of the third-party program? For each program, Table 1 summarizes 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.

(March 19, 2012), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM212798.pdf [hereafter "FDA 13485 Program Guidance"]. The program is authorized by statute at 21 U.S.C. § 374(g)(7)(F) (providing that "For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality system standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice.")

[36] Since 1965, the Department of Health and Human Services has relied on third parties such as the Joint Commission on Accreditation of Hospitals (now the Joint Commission) to certify that hospitals meet the Medicare Conditions of Participation (CoP) and are thus eligible to receive providing Medicare-funded services. *See generally* 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); Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543 (2000).

Table 1: Federal Regulatory Third-Party Programs with Selected Program Attributes

Federal Agency	Program Name	Authorizing Legislation and/or Year Established	Regulated Product or Activity	Third-Party Assessment Activities	Use of Third Parties: Required or Voluntary	Standard-setting Entity: Government or Private	Accreditation Entity: Agency or Accreditation Bodies
Programs to Assess Compliance with Mandatory Standards							
Food & Drug Administration (FDA)	Import Certification Program and Voluntary Qualified Importer Program (VQIP)	Food Safety Modernization Act of 2011	Imported Food	- Certification of foreign food facilities; - Laboratory testing of imported food products	Required	Government	Accreditation Bodies (*for both certification bodies and laboratories*)
Consumer Product Safety Commission (CPSC)	Third Party Testing and Certification	Consumer Product Safety Improvement Act of 2008	Children's Products	- Laboratory testing of children's products	Required	Government and Private	Accreditation Bodies (*for laboratories*)
FDA	Premarket Notification 510(k) Third Party Review Program/ Inspections by Accredited Persons (AP) Program	FDA Modernization Act of 1997 (premarket program)/ Medical Device User Fee and Modernization Act of 2002 (inspection program)	Medical Devices	- Review of premarket notifications/ - Inspection of medical device production facilities	Voluntary	Government	Agency
Federal Communications Commission (FCC)	Telecommunication Certification Body (TCB) Program	N/A (established by regulation in 1999)	Telecom-munication Equipment	- Certification of telecom products	Voluntary	Government	Accreditation bodies (*for certification bodies*)
Programs to Assess Compliance with Voluntary Standards							
Occupational Safety & Health Administration (OSHA)	National Recognized Testing Laboratory (NRTL) Program	N/A (established by regulation in 1988)	Labeling of electrical and other types of equipment in workplaces	- Certification of equipment - Inspection of equipment production facilities	Required	Private	Agency
Agricultural Marketing Service (USDA AMS)	National Organic Program (NOP)	Organic Foods Production Act of 1990 (implemented by regulation in 2000)	Labeling of Organic Products	- Inspection and certification of organic production facilities	Required	Government	Agency
Environmental Protection Agency (EPA)/ Department of Energy (DOE)	Energy Star	N/A (established through agency guidance in 2011)	Labeling of Energy Efficient Products	- Certification of products - Laboratory testing of products	Required	Government	Accreditation Bodies (*for both certification bodies and laboratories*)
EPA	WaterSense	N/A (established through agency guidance in 2009)	Labeling of Water Conservation Products	- Certification of products	Required	Government	Accreditation Bodies (*for certification bodies*)

A. Programs for Mandatory Standards

Several federal laws enable regulatory agencies to rely on third parties to assess compliance with mandatory standards. Mandatory standards must be complied with in order for a regulated entity to legally operate or sell a regulated product. In two of the programs—imported food programs administered by the Food & Drug Administration's (FDA) and children's product safety rules administered by the Consumer Product Safety Commission's (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. 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. In the FCC's program for telecommunications equipment, the use of a third party is optional for most types of equipment.

1. FDA, Imported Food Programs

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.[37] Overall, the FDA is responsible for ensuring the safety of about 80% of US food supply.[38] Increasingly, much of this food supply is imported, including 80% of seafood, 50% of fresh fruits, and 20% of fresh vegetables.[39]

FSMA significantly strengthened FDA's authority to regulate imported food, [40] and it relies on accredited third-party auditors in two different ways. First, 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 is certified by a third-party auditor.[41] Second, 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.[42] The third-party auditors that issue these certifications have to be accredited by either an accreditation body recognized by FDA or by the FDA directly.[43]

In both programs, the third-party auditors would be responsible for performing an audit to assess and certify compliance with the mandatory requirements of the law.[44] While VQIP is a voluntary program in the sense that importers are not required to participate, it is likely that for

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[37] *See* FDA Food Safety Modernization Act (FSMA), Pub. L. No. 111-353, 124 Stat. 3885 (2011).
[38] Silliker, Inc., FDA Food Safety Modernization Act: Marking a New Era in U.S. Food Safety, *available at* http://www.foodsafetymagazine.com/article.asp?id=4005&sub=sub2.
[39] Dina ElBoghdady, *Taking New Look at Food Inspection*, WASH. POST, March 5, 2012, at A1.
[40] *Id.*
[41] 21 U.S.C. § 384b (also known as FDCA § 806 and FSMA §302).
[42] 21 U.S.C. § 381(q) (also known as FDCA § 801(q) and FSMA § 303).
[43] 21 U.S.C. § 384d (also known as FDCA § 808 and FSMA § 307).
[44] In the case of the import certification program, certification involves an assessment of whether a food satisfies the requirements of section 801(q) [21 U.S.C. § 381(q)]. *See* 21 U.S.C. § 384d(c)(2)(B)(i). In the case of the VQIP program, certification involves an assessment of whether a facility is eligible to be part of the program. *See* 21 U.S.C. § 384d (c)(2)(B)(ii).

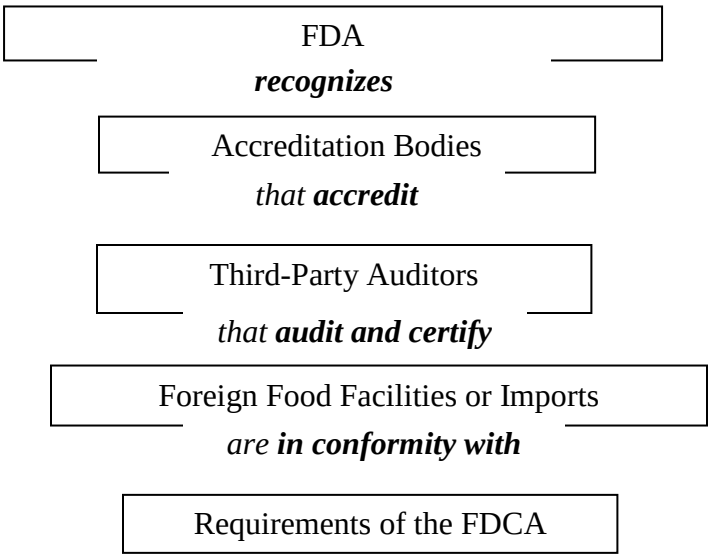
an importer to participate, it will be required to contract with a third-party auditor.[45] Similarly, it is likely that the import certification program will also require the participation of a third party, which in this case may be the government of the country from which the food originated.[46]

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 third-party auditors to audit and certify foreign food facilities or imports.[47] Under the law, an accreditation body is "an authority that performs accreditation of third-party auditors," and a third-party auditor refers to a foreign government (or an agency thereof), a foreign cooperative, or any other third party as deemed appropriate by the FDA in its regulations."[48] Private third-party auditors can be single individuals, but are more likely to be companies that employ "audit agents."[49] FDA is required by law to establish the system for the recognition of accreditation bodies by January 4, 2013 (two years after the enactment of the law).[50] If the FDA has not recognized any accreditation bodies within two years of the establishment of such system, it may directly accredit third-party auditors.[51]

The law directs FDA to develop model standards for becoming an accredited third-party auditor and for preparing audit reports by July 4, 2012 (18 months after the enactment of the law).[52] The statute itself contains several relevant requirements, including that the FDA should look to standards already in place (existing voluntary consensus standards, for example)[53] and an audit report should be submitted within 45 days of conducting an audit.[54] As of May 2012, FDA was in the process of drafting such regulations.[55]

[45] The law provides that the FDA may provide the certification, 21 U.S.C. § 384d(c)(2)(C)(ii), but based on the experience of other federal third-party programs it seems likely that forthcoming regulations will generally require the use of an accredited third-party auditor.
[46] 21 U.S.C. § 381(q)(3). It should be noted that the law also allows the FDA to provide the certification, per 21 U.S.C. § 384d (c)(2)(C)(ii), but it seems likely that forthcoming regulations will generally require the use of a third party.
[47] 21 U.S.C. § 384d(b)(1)(A)(i).
[48] *Id*. § 384d(a)(3).
[49] The law provides that a third-party auditor may be a single individual. 21 U.S.C. § 384d (a)(3).The law also states that third-party auditors may employ "audit agents," defined 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." 21 U.S.C. § 384d(a)(1).
[50] 21 U.S.C. § 384d(b)(1)(A)(i).
[51] *Id*. § 384d(b)(1)(A)(ii).
[52] *Id*. § 384d(b)(2).
[53] *Id*. § 384d(b)(2).
[54] *Id*. § 384d(c)(3)(A).
[55] Interview (by phone), Charlotte Christen, U.S. Food and Drug Administration, May 16, 2012.

Figure 2: Structure of Third-Party Program for Imported Food Certifications

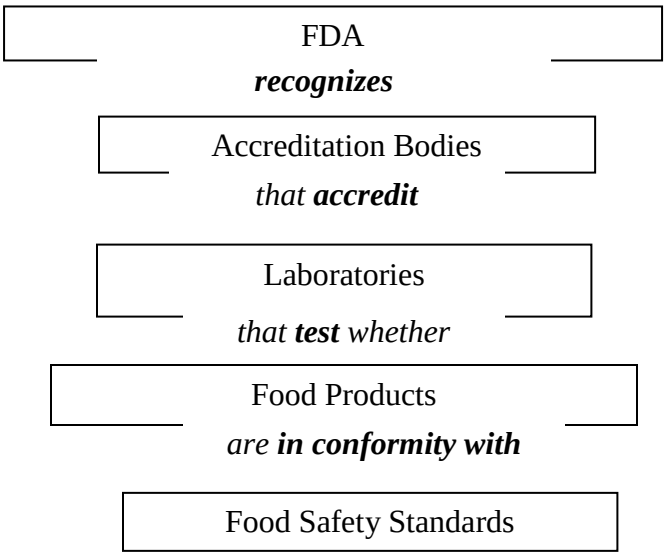


It is also important to note that FSMA also requires the establishment of a system for the accreditation of laboratories to conduct food safety tests. [56] Figure 3 illustrates the third-party structure for laboratories. Accredited labs must be used to satisfy a variety of testing requirements, such as testing required by FDA to address an identified or suspected food safety problem and testing to support admission of an imported food.[57] The law directs FDA to establish a program for the testing of food by accredited laboratories and a public registry of accreditation bodies and accredited laboratories by January 4, 2013.[58] The law also states that the FDA shall develop model accreditation standards that include, for example, appropriate sampling methods, quality system requirements, and employee training requirements.[59]

Importers may choose to seek certification from a third-party auditor in order to participate in the VQIP program, or they may be required to seek certification because FDA imposes an import certification requirement on the food they import. Under the statute, the audits for such certifications are termed "regulatory audits."[60] Importers and other regulated entities may also contract with an accredited third-party auditor to conduct a "consultative audit," defined in the law to be for internal purposes only.[61]

[56] 21 U.S.C. § 350k.
[57] *Id*. § 350k(b)(1).
[58] *Id*. §350k(a)(1).
[59] *Id*. § 350k(a)(6).
[60] *Id*. § 384d (a)(7).
[61] *Id*. § 384d (a)(5).

Figure 3: Structure of Third-Party Program for Food Safety Testing



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.[62] 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.[63]

With its import certification authority, the FDA may require that certain food imports be accompanied by a certification that they comply with the requirements of U.S. food safety law.[64] To determine that 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, and to make a scientifically-supported finding that the "food safety programs, systems, and standards in the country, territory, or region of origin of the 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 Act."[65]

Recognized accreditation bodies ensure that third-party auditors and their audit agents meet the accreditation standards.[66] The law defines the types of entities that can become third-party auditors and sets forth certain requirements for their accreditation. In particular, the law states that foreign governments may be accredited based on a review of their food safety programs to

[62] 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). Elsewhere the law defines an importer as "the US owner or consignee of the food article at the time of entry," or if none, "the US agent of a foreign owner or consignee at the time of entry." 21 U.S.C. § 384a.
[63] 21 U.S.C. § 384b(d). *See* also Silliker, *supra* note 38.
[64] *See generally* 21 U.S.C. § 381(q).
[65] 21 U.S.C. § 381(q) (2).
[66] *Id*. § 384d (b)(2).

ensure that the foreign government is capable of determining that U.S. requirements are met.[67] 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.[68]

The law addresses the potential of conflicts of interest between accredited third-party auditors and the companies that contract with them to perform audits. It sets forth several specific provisions and also requires FDA promulgate regulations to further protect against conflicts of interest. The law directly 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 13 months.[69] 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 complied with conflicts-of-interest rules and procedures.[70] 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.[71]

According to the statute, FDA's conflict of interest regulations shall require that audits performed by accredited third-party auditors be unannounced and shall place limits on the extent to which there may be financial affiliations between auditors and audit agents and the entities they certify.[72] The regulations must also establish timing, disclosure, fee payment and other rules that decrease the potential for conflicts of interest.[73]

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,[74] and the FDA is required to establish a public registry of all accreditation bodies and accredited third-party auditors.[75] FDA must reevaluate accreditation bodies at least once every four years[76] and must revoke the recognition of an accreditation body that is out of compliance with its rules.[77]

Accredited third-party auditors are directly answerable to 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.[78] 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

[67] *Id*. § 384d (c)(1)(A).
[68] *Id*. § 384d (c)(1)(B).
[69] *Id*. § 384d (c)(4)(C)(i).
[70] *Id*. § 384d(c)(5)(A).
[71] *Id*. § 384d(c)(5)(B).
[72] *Id*. § 384d(c)(5)(C)(i) and (iii).
[73] *Id*. § 384d(c)(5)(C)(ii).
[74] *Id*. § 384d(b)(1)(B).
[75] *Id*. § 384d (g).
[76] *Id*. § 384d (f)(1)
[77] *Id*. § 384d(b)(1)(C).
[78] *Id*. § 384d(c)(3)(B).

that an article of food "presents a threat of serious adverse health consequences or death to humans or animals."[79] 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.[80]

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.[81] The FDA may also conduct its own onsite audit of any certified entity whether or not the certifying third-party auditor is present.[82] The FDA may withdraw accreditation from an auditor if food from a facility it has certified is linked to a serious outbreak of foodborne 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 FDA revokes the recognition of the accreditation bodies which accredited it.[83] 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.[84]

The law provides that FDA will establish a user-fee program to make operating the accredited third-party auditor program revenue neutral.[85] With the user fees, accredited third-party auditors and audit agents are to reimburse the FDA for "the work performed to establish and administer the accreditation system."[86]

2. CPSC, Children's Product Safety Rule

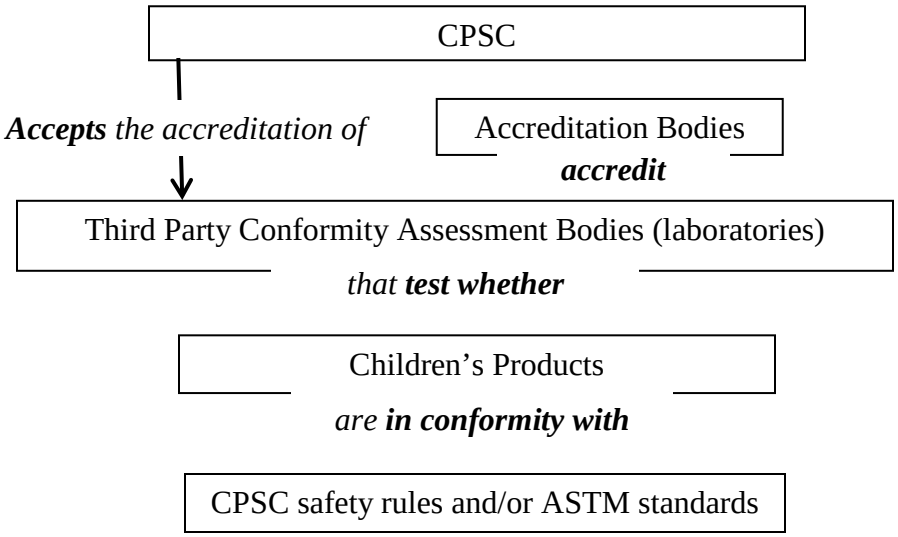
Pursuant to the Consumer Product Safety Improvement Act of 2008 (CPSIA), the CPSC requires manufacturers and importers of children's products to demonstrate that they meet mandatory product safety standards through third-party testing. [87] Testing must be conducted by a ''Third Party Conformity Assessment 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."[88] Based on the results of the third-party testing, the manufacturer or

[79] 21 U.S.C. § 384d(c)(3)(C) (referring to FDA's authority to inspect records at 21 U.S.C. § 350c).
[80] *Id*. § 384d(c)(4)(A); *see also* FDA, Imports, http://www.fda.gov/Food/FoodSafety/FSMA/ucm257980.htm (last visited Sept. 11, 2012) (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?").
[81] 21 U.S.C. § 384d(f)(2).
[82] *Id*. § 384d(f)(3).
[83] *Id*. § 384d(c)(6)(A) and (B).
[84] *Id*. § 384d(e). *See* also Charles F. Woodhouse, Imported Food Provisions of the Food Safety Modernization Act, 2001, http://www.food-label-compliance.com/Sites/5/Downloads/White-Paper-FSMA-IMPORT-PROVISIONS-Woodhouse-Nov-8-2011.pdf (last visited Sept. 11, 2012) (a white paper emphasizing the significance of specific inclusion of provisions relating to False Statements).
[85] 21 U.S.C. § 384d(c)(8).
[86] *Id.*
[87] Pub. L. No. 110-314, 122 Stat. 3016 (2008); 15 U.S.C. § 2063(a)(2). The law defines a "children's product" as a consumer product designed or intended primarily for children 12 years of age or younger. 15 U.S.C. § 2052(a)(2).
[88] Testing and Labeling Pertaining to Product Certification, 76 Fed. Reg. 69482 (Nov. 8, 2011) (codified at 16 C.F.R. Part 1107); *see also* 15 U.S.C. § 2063(f)(2)(A) (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

importer submits a Children's Product Certificate indicating compliance.[89] 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 4.

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,[90] bunk beds,[91] infant bath seats,[92] and electrically operated toys or articles.[93] CPSC product safety rules containing standards for flammability,[94] small parts,[95] and lead content[96] may also apply. In addition, CPSC has mandated compliance with a variety of toy safety standards established by the ASTM regarding, for example, toy chests, stuffing materials, and sound producing toys.[97]

Figure 4: 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.[98] 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

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noting that while the statute uses the term certification, the third-party program that it requires is a third-party testing program rather than a certification program under the definitions of international standards.

[89] 15 U.S.C. § 2063(a)(2). *See also* Certificates of Compliance, 73 Fed. Reg. 68328 (Nov. 18, 2008); 16 C.F.R. Part 1110, Certificates of Compliance.

[90] 16 C.F.R. pt. 1203, Bicycle Helmets (effective date Feb. 10, 2010).

[91] *Id*. pt. 1513, Bunk Beds (effective date Feb. 10, 2010).

[92] *Id*. pt. 1216, Infant Walkers (effective date Dec. 21, 2010).

[93] *Id*. pt. 1505, Electrically Operated Toys or Articles (effective date Jul. 29, 2010).

[94] *Id*. pts. 1610, 1611, 1615, 1616, 1630, 1631, 1632, and 1633.

[95] *Id*. pt. 1501.

[96] Test Method CPSC-CH-E1001-08 and/or CPSC-CH-E1001-08.1

[97] ASTM F963 Standard Consumer Safety Specifications for Toy Safety, http://www.cpsc.gov/cgi-bin/labsearch/Default.aspx (last visited Sept. 11, 2012) (list of rules that require third-party testing and certification).

[98] 15 U.S.C. § 2063(a)(3).

laboratories to assess conformity with a children's product safety rule.[99] 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.[100] In total, CPSC published 19 notices of requirements between August 14, 2008 and August 14, 2011.[101] 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 on February 10, 2009 for new total lead content limits, phthalates limits for certain products, and mandatory toy standards, among other things.[102] As of January 1, 2012, almost all stays had been lifted, and third-party certification and testing was required for nearly all the children's product safety rules.[103]

Rulemaking for the CPSC third-party program has also progressed. On November 8, 2011, the CPSC issued a final rule establishing protocols and standards for certification and testing of children's products and also detailing requirements for the labeling of certified products.[104] The final rule applies to products manufactured after February 8, 2013.[105] On May 24, 2012, the CPSC published its final rule, "Audit Requirements for Third Party Conformity Assessment Bodies." Also on May 24, 2012, the CPSC published a proposed rule, "Requirements Pertaining to Third Party Conformity Assessment Bodies."[106] The proposed rule, if finalized, would establish the requirements related to CPSC acceptance of the accreditation of laboratories for purposes of testing children's products.[107] The proposed requirements are largely the same as the requirements that the CPSC has set forth in the various notices of requirements that it has published since August 2008.

Nearly all children's products are required to undergo third-party testing.[108] In 2011, Congress enacted amendments to the CPSIA that, among other things, provided an exemption from third-party testing for "small batch manufacturers."[109] Small batch manufacturers are those that produced fewer than 7500 units and collected less than $1 million in consumer products

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[99] 15 U.S.C. § 2063(a)(3)(A) (stating that the third-party testing requirement does not commence "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.).
[100] In brief at http://www.cpsc.gov/library/foia/foia10/brief/102testing.pdf .
[101] In brief at http://www.cpsc.gov/library/foia/foia12/brief/tprequirements.pdf at 6.
[102] Press release at http://www.cpsc.gov/cpscpub/prerel/prhtml09/09115.html; *see* Notice of Stay of Enforcement of Testing and Certification Requirements, 74 Fed. Reg. 6396 (staying the enforcement of certain provisions of section 14(a) of the CPSA); 74 Fed. Reg. 68588 (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).
[103] CPSC, FAQs: Certification and Third Party Testing, http://www.cpsc.gov/info/toysafety/3ptfaq.html#foot1 (last visited Sept. 11, 2012).
[104] Testing and Labeling Pertaining to Product Certification, 76 Fed. Reg. 69482 (Nov. 8, 2011) (codified at 16 C.F.R. pt. 1107).
[105] *Id.* at 69482.
[106] Requirements Pertaining to Third Party Conformity Assessment Bodies, 77 Fed. Reg. 31086, 31087-88 (May 24, 2012), *available at* http://www.gpo.gov/fdsys/pkg/FR-2012-05-24/pdf/2012-10923.pdf.
[107] *Id.*
[108] *Id.*
[109] Pub. L. No. 112-28, § 2(a)(4), 125 Stat. 273 (2011) (codified at 15 U.S.C. 2063(d)).

revenues in the previous year. According to CPSC, small batch manufacturers are still required to third-party test for compliance with some children's product safety rules but not others.[110] An exemption was also provided for ordinary books for children aged 4 to 12.[111]

There are three types of third-party testing: (1) initial certification testing (2) material change testing; and (3) periodic testing.[112] Initially, each children's product must be third-party tested by a CPSC-accepted laboratory for compliance with all applicable children's product safety rules. 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. Periodic testing applies to continuing production of a children's product. If a children's product initially is certified, and then additional production continues, periodic testing is required for all the applicable children's product safety rules, even if there are no material changes. The requirements to test children's product when there is a material change and to undertake periodic testing become effective on February 8, 2013.[113]

The law provides that accreditation of TPCABs may be conducted either by the CPSC or by a designated accreditation body.[114] 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")[115]; and (3) those owned or controlled, in whole or in part, by a government ("governmental laboratories").[116]

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.[117] To be an ILAC-MRA signatory, an accreditation body must, *inter alia*, operate in accordance with ISO/ IEC 17011.[118] To make an accreditation determination, the accreditation body assesses the laboratory's conformity with ISO/IEC 17025. As described by 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.[119] It also includes management requirements relating to organization, management systems, document

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[110] CPSC, Small Batch Manufacturers and Third Party Testing, http://www.cpsc.gov/info/toysafety/smallbatch.html (last visited Sept. 11, 2012).
[111] 15 U.S.C. § 2063(i)(5)(A)(i).
[112] CPSC, FAQs: Certification and Third Party Testing, http://www.cpsc.gov/info/toysafety/3ptfaq.html#foot1 (last visited Sept. 11, 2012).
[113] *Id*.
[114] 15 U.S.C. § 2063(a)(3)(C).
[115] *See infra* notes 127 - 129 and accompanying text.
[116] Requirements Pertaining to Third Party Conformity Assessment Bodies, 77 Fed. Reg. 31086, 31087-88 (May 24, 2012); *see* also 15 U.S.C. § 2063(f)(2).
[117] Third Party Conformity Assessment Body Accreditation Requirements for Testing Compliance with 16 C.F.R. pt. 1501 (Small Parts Regulations), 73 Fed. Reg. 54564 (Sept. 22, 2008), available in unpublished form at http://www.cpsc.gov/library/foia/foia09/brief/smallparts.pdf; *see also* Requirements Pertaining to Third Party Conformity Assessment Bodies, 77 Fed. Reg. 31086, 31088 (May 24, 2012).
[118] ILAC, ILAC MRA and Signatories, http://www.ilac.org/ilacarrangement.html (last visited Sept. 11, 2012).
[119] *Id*.

controls, audits, and management reviews. [120]

Laboratories are accredited with a defined "scope of accreditation," which indicates the children's product safety rules and/or test methods for which it is accredited to test.[121] As required by the CPSIA, the commission maintains an online listing of accredited TCPABs and their scopes of accreditation.[122] The current list includes hundreds of laboratories in about 35 countries.[123] For example, the U.S.-based laboratory NSF International is accredited by International Accreditation Services Inc. (IAS) and its scope of accreditation includes about 45 different product safety rules and ASTM standards.[124]

Several measures exist to address conflicts of interest that might raise doubt about the impartiality of product certifications. As part of being accredited to ISO/IEC 17025, laboratories must "have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity."[125] A laboratory must "demonstrate that it is impartial and that its personnel are free from any undue commercial, financial, and other pressures that might influence their technical judgment." CPSC has also stated in its Notices of Requirements that 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.[126]

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

> (I) its test results are protected from undue influence by the manufacturer, private labeler or other interested party;
> (II) the Commission is notified immediately of any attempt by the manufacturer, private labeler or other interested party to hide or exert undue influence over test results; and
> (III) allegations of undue influence may be reported confidentially to the Commission.[127]

In CPSC's published Notices of Requirements, the CPSC has required that firewalled labs seeking approval submit copies, in English, of their training documents showing how employees are trained to notify the CPSC immediately and confidentially of any attempt by the

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[120] *Id*.
[121] *See* CPSC, CPSC Form 223 - Lab Accreditation, http://www.cpsc.gov/cgibin/labregentry/ (last visited Sept. 11, 2012).
[122] 15 U.S.C. § 2063(a)(3)(E) (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.)
[123] CPSC, List of CPSC-Accepted Testing Laboratories, http://www.cpsc.gov/cgi-bin/labsearch/ (last visited Sept. 11, 2012).
[124] *Id.* (detailed information displayed by highlighting the laboratory name and clicking "submit").
[125] Requirements Pertaining to Third Party Conformity Assessment Bodies, 77 Fed. Reg. 31086, 31093 (May 24, 2012).
[126] *See, e.g.*, Third Party Conformity Assessment Body Accreditation Requirements for Testing Compliance with 16 C.F.R. Part 1501 (Small Parts Regulations), 73 Fed. Reg. 54564 (Sept. 22, 2008), available in unpublished form at http://www.cpsc.gov/library/foia/foia09/brief/smallparts.pdf
[127] 15 U.S.C. § 2063(f)(2)(D)(ii).

manufacturer, private labeler, or other interested party to hide or exert undue influence over the TCPAB's test results.[128] This additional requirement applies to any laboratory in which a manufacturer or private labeler of a children's product to be tested by it owns an interest of ten percent or more.[129]

Similarly, the CPSIA contains five criteria that a governmental laboratory must satisfy for its accreditation to be accepted by the CPSC.[130] The CPSC must determine that to the extent practicable, manufacturers located in any nation are permitted to choose a laboratory that is not owned or controlled by the government of that nation; that the testing results are not subject to undue influence by any other person; that the governmental laboratory and its testing results do not receive more favorable treatment than other accredited laboratories in the same 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.[131] The CPSC's proposed rule requires governmental labs seeking CPSC acceptance to submit a variety of relevant information to assist it in making these determinations.[132]

The CPSIA requires the CPSC to establish "requirements for the periodic audit of third party conformity assessment bodies as a condition for the continuing accreditation of such conformity assessment bodies."[133] CPSC's final rule, "Audit Requirements for Third Party Conformity Assessment Bodies," implements this provision.[134] It provides that the periodic audit of TCPABs consists of two parts.[135] The first part is a reassessment by the same accreditation body that it received its initial accreditation from to determine whether it continues to meet accreditation criteria. The second part is the resubmission to the CPSC of the CPSC's "Consumer Product Conformity Assessment Body Acceptance Registration Form" and its review by the CPSC. The rule 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."[136] 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.[137] In this case, the time between reassessments must be no more than 5 years.[138]

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[128] Third Party Conformity Assessment Body Accreditation Requirements for Testing Compliance with 16 C.F.R. Part 1501 (Small Parts Regulations), 73 Fed. Reg. 54564 (Sept. 22, 2008), available in unpublished form at http://www.cpsc.gov/library/foia/foia09/brief/smallparts.pdf ; *see also* Requirements Pertaining to Third Party Conformity Assessment Bodies, 77 Fed. Reg. 31086, 31088, 31133 (May 24, 2012) (stating that the requirement is that the laboratory "train employees that they may notify the CPSC immediately, and that a report to the CPSC may be confidential.")

[129] *Id*.

[130] 15 U.S.C. § 2063(f)(2)(B); summarized in Requirements Pertaining to Third Party Conformity Assessment Bodies, 77 Fed. Reg. 31086, 31088, 31133 (May 24, 2012).

[131] *Id*.

[132] Requirements Pertaining to Third Party Conformity Assessment Bodies, 77 Fed. Reg. 31086, 31133-34 (May 24, 2012).

[133] 15 U.S.C. § 2063(i)(1) (before amendments in H.R. 2715, this provision was located instead at 15 U.S.C. § 2063(d)(1)).

[134] Audit Requirements for Third Party Conformity Assessment Bodies, 77 Fed. Reg. 31074 (May 24, 2012).

[135] *Id*. at 31083.

[136] *Id*. at 31085.

[137] *Id*. at 31083.

[138] *Id*.

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 section; or (B) such conformity assessment body failed to comply with an applicable protocol, standard, or requirement established by the Commission…."[139] 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.[140] In May 2012, CPSC published a proposed rule, "Requirements Pertaining to Third Party Conformity Assessment Bodies," which would implement these provisions.[141] The rule would establish whether, when and how the CPSC may deny a TCPAB's application; suspend accreditation; and withdraw accreditation.[142] It would also establish how a person may submit to the CPSC information alleging a ground for denial, suspension, or withdrawal.[143]

The CPSC's third-party program has been funded with appropriated funds. The statute contains no provisions regarding the assessment of user fees to cover the costs of program development and implementation.

3. FDA, Medical Device Inspections

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. Through the second program, third parties may conduct inspections of facilities that manufacture certain medical devices. In both, third-party organizations recognized by FDA evaluate a manufacturer's compliance with mandatory standards in the Federal Food, Drug, and Cosmetic Act (FDCA). [144]

Premarket Notification 510(k) Third Party Review Program

The FDA Modernization Act of 1997 (FDAMA) directed the FDA to accredit third parties (referred to as either Accredited Persons or Recognized Third Parties) in the private sector to conduct the 510(k) pre-market review for low risk (Class I) and certain moderate risk (Class II) devices.[145] Pursuant to this authorization, the FDA established accreditation criteria (including

[139] 15 U.S.C. § 2063(e)(1). *See* also 15 U.S.C. § 2063(e)(2) (setting forth procedures for accreditation withdrawals).
[140] 15 U.S.C. § 2063(e)(3).
[141] Requirements Pertaining to Third Party Conformity Assessment Bodies, 77 Fed. Reg. 31086 (May 24, 2012).
[142] *Id*. at 31119.
[143] *Id*.
[144] As used in the program, the term "Persons" refers to organizations. *See* GAO, Report to Congressional Committees, Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations 3 (January 2007) [hereinafter "Status of FDA's Program"].
[145] *See generally* FDA, Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications, (Sept. 28, 2004), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082191.htm; FDA, Implementation of Third Party Programs under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry and Third Parties (February 2, 2001), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/

criteria to prevent conflicts of interest) and conducted accreditations,[146] published a list of Accredited Persons,[147] and conducted a training program for Accredited Persons.[148] 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."[149]

Post-Market Inspections by Accredited Persons Program

The rest of this section provides an in depth discussion of the post-market Inspections by APs Program, in part because it involves facility inspections in addition to document review, and in part because information was more readily about this program. The overall structure of the third-party program for medical device facility inspections is shown in Figure 5.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) authorized FDA to establish the "Inspection by Accredited Persons" program (AP Program).[150] Under the AP 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. FDA considers an inspection by an AP to be "an alternative to the traditional inspection by an FDA official."[151] With the AP Program, accredited third parties may conduct these inspections "in lieu" of the FDA.[152] In requiring its establishment, Congress sought to address the FDA's inability to meet its inspection burden.[153] The program also purported to offer an advantage to manufacturers that produce for both the US market and foreign markets by providing the opportunity to undergo a single inspection process that satisfies multiple jurisdictions.[154]

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ucm094459.pdf (noting that FDA's policy permitted third party review of class II devices only if device-specific guidance or recognized consensus standards existed) [hereinafter Implementation of Third Party Programs]; *see also* 21 U.S.C. §360m (containing the statutory requirement).

[146] 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. 28388 (May 22, 1998) (publishing these criteria); Implementation of Third Party Programs Under the FDA Modernization Act of 1997 - Final Guidance for Staff, Industry and Third Parties (Feb. 2, 2001), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094450.htm (last visited Sept. 9, 2012).

[147] Current List of Accredited Persons for 510(k) Review under the FDA Modernization Act of 1997 (updated Sept. 5, 2012), http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm (last visited Sept. 9, 2012).

[148] Implementation of Third Party Programs, *supra* note 145.

[149] *Id*.

[150] 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)) (amended section 704 of the Federal Food, Drug, and Cosmetic Act by adding subsection (g)).

[151] *See* FDA, Medical Devices, Accredited Persons Inspection Program, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm125410.htm (last visited Sept. 11, 2012).

[152] *Id*.

[153] Medical Devices - Challenges for FDA in Conducting Manufacturer Inspections: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 110th Cong. (Jan. 29, 2008) (statement of Marcia Crosse, Director, Health Care, United States General Accountability Office) (citing H.R. Rep. No. 107-728, pt. 1, at 35-36 (2002)) [hereinafter "Challenges for FDA"].

[154] *Id*.

The mandatory standard that applies in such inspections is the Quality System (QS) regulation and other device requirements in the FDCA and its regulations.[155] 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 finished medical devices intended for human use" in the United States.[156] In a QS inspection, FDA inspectors examine manufacturing controls, processes, and records.[157] When a manufacturer participates in the AP program, the AP prepares and submits its reports to FDA, which remains responsible for making a final compliance assessment.[158]

FDA has also implemented the MDUFMA's third-party inspection provisions through its Pilot Multi-purpose Audit Program (PMAP).[159] 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.[160] PMAP aimed to include 10 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.[161] In total, eleven such inspections were conducted, and the agencies produced a final joint report to summarize lessons learned.[162]

Importantly, the AP by Inspections 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.[163] If a manufacturer is inspected by an AP, FDA removes the manufacturer from its routine inspection work plan for two years.[164] In effect, the manufacturer receives a two-year

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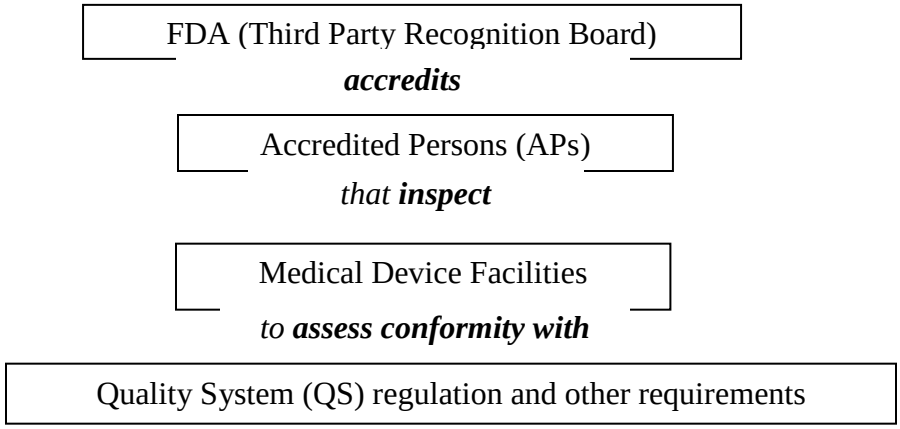
[155] 21 C.F.R. pt. 820 (2007).
[156] *Id.* § 820.1(a)(1).
[157] Status of FDA's Program, *supra* note 144, at 1.
[158] *See* FDA, Medical Devices, Accredited Persons Inspection Program, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm125410.htm (last visited Sept. 11, 2012). *See* also 21 U.S.C. § 374(g)(7)(A) (stating that APs shall prepare an inspection report and that "any official classification of the inspection shall be determined by the Secretary.")
[159] FDA, Pilot Multi-Purpose Audit Program (PMAP) - Questions and Answers Related to the Pilot, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm125453.htm (last visited Sept. 11, 2012) [hereinafter PMAP Q&A]; *see* also Challenges for FDA, *supra* note 153, at 9, 19-21.
[160] Pilot Multi-Purpose Audit Program, *supra* note 159 (stating that Health Canada's CMDCAS was established several years before FDA established the AP Program).
[161] On international cooperation in regulation, *see* Administrative Conference of the United States, Recommendation 2011-6, International Regulatory Cooperation (Dec. 8, 2011), *available at* http://www.acus.gov/acus-recommendations/international-regulatorycooperation/.
[162] FDA, Medical Devices, Final Joint Report of the Pilot Multipurpose Audit Program (PMAP), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm232806.htm (also available in PDF format at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/md-im/activit/int/md_pmap_rep_im_ppafm_rap-eng.pdf) [hereinafter PMAP report]; Interview (by phone), Kim Trautman, Associate Director, International Affairs, Office of the Center Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration, Jun. 5, 2012 (reporting that eleven PMAP inspections were conducted).
[163] *See* FDA, Medical Devices, Accredited Persons Inspection Program, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm125410.htm (last visited Sept. 9, 2012).
[164] Interview (by phone), David Kalins, Office of Compliance, CDRH, FDA, July 31, 2012.

"inspection holiday" from regular FDA inspections unless FDA receives a complaint or has other cause to inspect.

Figure 5: Structure of Third-Party Program for Medical Device Facilities



Only certain manufacturers are eligible to participate in the program. The manufacturer must manufacture a Class II or Class III device.[165] 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.[166] Also, the program was "limited to establishments whose most recent inspection was classified by FDA as either 'No Action Indicated' or 'Voluntary Action Indicated.'"[167] The Food and Drug Administration Amendments Act (FDAAA) of 2007 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 eliminating the limit of two consecutive Third-Party Inspections unless FDA granted a waiver.[168] After the amendments, eligible manufacturers may simply submit notification of their intent to use the program.[169]

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[165] FDA, 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), 4 (Mar. 2, 2009), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm ,

[166] *Id.* (stating "At 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." *Id.* at 6). *See* also 21 U.S.C. § 374(g)(6)(A)(ii)(IV)(bb).

[167] 21 U.S.C. § 347(g)(6)(A)(i). *See also* Status of FDA's Program, *supra* note 144, at 6 (stating "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)."); FDA, 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 (Aug. 6, 2009), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089702.htm (last visited Sept. 9, 2012) [hereinafter "Guidance for Industry"].

[168] Guidance for Industry, *supra* note 167, at 4.

[169] Agency Information Collection Activities; Proposed Collection; Comment Request; Manufacturer's Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program Authorized by Section

Unlike the two programs reviewed above, FDA does not utilize independent accreditation bodies in this program. Rather, accreditation determinations are made by FDA's Third Party Recognition Board (TPRB), which was established in 1998 to make accreditation determinations for the 510(k) pre-market review program.[170] MDUFMA required FDA to establish criteria for the accreditation of Accredited Persons and to conduct further activities to approve their employees to conduct inspections.[171] 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.[172]

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.[173] 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 to protect confidential information.[174]

After an organization is approved as an AP, its employees must complete classroom training conducted by the Association for the Advancement of Medical Instrumentation (AAMI) and the FDA.[175] Upon successfully completing the classroom training, AP employees must then successfully complete three joint inspections with FDA including 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

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228 of the Food and Drug Administration 76 Fed. Reg. 29764 (May 23, 2011); *see also* Guidance for Industry, *supra* note 167, at 4 (noting the specific information that the notice must include).

[170] Guidance for Industry, *supra* note 167, 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. 22400, 22402-03 (Apr. 28, 2003). On the 510(k) program generally, *see supra* notes 145 - 148 and accompanying text.

[171] 21 U.S.C. § 374(g)(2). These criteria were published at 68 Fed. Reg. 22400 (Apr. 28, 2003). On October 4, 2004, FDA published revised accreditation criteria at 69 Fed. Reg. 59250 to incorporate changes to MDUFMA made by the Medical Devices Technical Corrections Act (MDTCA), Pub. L. No. 108-214, signed into law on April 1, 2004.

[172] 21 U.S.C. § 374(g)(3); *see also* Guidance for Industry, *supra* note 167.

[173] Guidance for Industry, *supra* note 167, at 6-8.

[174] *Id*.; *see* also 21 U.S.C. § 374(g)(2); Guidance for Industry, Food and Drug Administration Staff, and Third Parties; Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria; Availability, 69 Fed. Reg. 59250 (Oct. 4, 2004) (providing that the qualifications for APs' personnel will be equivalent to that of FDA personnel); *see* also 21 U.S.C. § 374(g)(3)(E)(iii) (providing 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).

[175] Guidance for Industry, *supra* note167, at 9-10.

inspection that is observed and evaluated by an FDA inspector).[176]

FDA instructs APs to prepare an inspection report to be submitted to both the manufacturer and the FDA using the format defined in its Investigations Operations Manual (IOM).[177] The report must describe in detail each significant non-conformity found and identify any other matters that relate or that may influence compliance with the Act.[178] The report must also describe any recommendations made by the AP to the manufacturer during the inspection or at the closing meeting and describe any promised corrective actions or other discussions with the manufacturer at the conclusion of the inspection.[179] APs are required to maintain certain records regarding their initial and continuing qualifications to be APs and regarding each inspection.[180] The law requires also an AP that discovers a condition that it believes could cause or contribute to an unreasonable risk to public health to report the problem to FDA immediately.[181]

Since 2003, the FDA has accredited 16 organizations as APs and conducted classroom training for the AP auditors.[182] FDA maintains a list of Accredited Persons with contact information online.[183] For example, US-based organizations that have been recognized as APs include: Intertek Testing Services; Lloyd's Register Quality Assurance, Inc.; TUV Rheinland of North America, Inc.; and Underwriters Laboratories, Inc. (UL).[184] Some of the recognized firms based outside the U.S. include AMTAC Certification Services Limited, in the United Kingdom; Center for Measurement Standards/Industrial Technology Research Institute (CMS/ITRI), in China; and Quality Management Institute (QMI), in Canada.[185] The list sets forth the types of device manufacturing facilities that each AP is recognized to inspect (often "all medical devices") and the foreign countries that certify, accredit, or otherwise recognize the AP as having the authority to conduct device inspections.[186]

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

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[176] *Id*. *See also* 21 U.S.C. § 347(g)(2); Guidance for Industry, Food and Drug Administration Staff, and Third Parties; Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria; Availability, 69 Fed. Reg. 59250, 59291 (providing that APs are not eligible to conduct independent inspections until they successfully complete FDA's training program and perform a satisfactory inspection under FDA's observation).

[177] *See* FDA, Inspections, Compliance, Enforcement, and Criminal Investigations, Investigations Operation Manual, http://www.fda.gov/ora/inspect_ref/iom/ (last updated March 2, 2012); *see* also 21 U.S.C. § 374(g)(7)(A) (stating that APs are required to prepare inspection reports in the form and manner designated by FDA).

[178] Guidance for Industry, *supra* note 167, at 12-13.

[179] *Id*.

[180] *Id*. at 13-14.

[181] 21 U.S.C. § 374(g)(7)(E).

[182] Guidance for Industry, *supra* note 167, at 3-4 (noting that the law required that no more than 15 firms be accredited during the first year of the AP Program).

[183] *See* FDA, Medical Devices, Accredited Persons Inspection Program, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm125410.htm (last visited Sept. 9, 2012).

[184] *Id*.

[185] *Id*.

[186] *Id*.

affect the inspection process or the preparation of reports.[187] APs may not be owned, operated or controlled by a manufacturer, supplier or vendor of any article regulated under the Act, and no personnel of an AP involved in inspections, nor their spouses or minor children, may have ownership of or other financial interest in any product, manufacturer, supplier or vendor regulated under the Act.[188] 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 Act; 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.[189]

When applying to become APs, organizations are required to submit a copy of the written policies, procedures and sample certification/compliance statements established to prevent conflicts of interest. FDA uses a rating criteria checklist to evaluate whether APs have established, documented, and executed policies and procedures to prevent individual and organizational conflicts of interest.[190] FDA states that APs should either adopt the conflict of interest standards that apply to federal agency employees,[191] use the Model Conflict of Interest Policy that it provides in guidance,[192] or "explain alternative equivalent procedures" to safeguard against conflicts of interest.

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.[193] As described by FDA, business relationships that may undermine the 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.[194] 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.[195] 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.[196]

The Act sets forth several prohibited acts including the knowing failure of an AP to

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[187] *See* 21 U.S.C. § 374(g)(2) and (3); Guidance for Industry, Food and Drug Administration Staff, and Third Parties; Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria; Availability, 69 Fed. Reg. 59250, 59252 (Oct. 4, 2004).
[188] 21 U.S.C. § 374(g)(2); Guidance for Industry, Food and Drug Administration Staff, and Third Parties; Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria; Availability, 69 Fed. Reg. 59250, 59252 (Oct. 4, 2004).
[189] Guidance for Industry, *supra* note167.
[190] *Id.* (*see especially* the checklist contained in Appendix 3.)
[191] *See* "Standards of Ethical Conduct for Employees of the Executive Branch," *available at* http://www.oge.gov/Laws-and-Regulations/Employee-Standards-of-Conduct/Standards-of-Ethical-Conduct-for-Employees-of-the-Executive-Branch-(PDF)/ (last visited Sept. 11, 2012) (compiling ethics standards codified in 5 C.F.R. pt. 2635 as amended at 76 Fed. Reg. 38547 (July 1, 2011)).
[192] Guidance for Industry, *supra* note 167 (see especially the Model Conflict of Interest Policy contained in Appendix 2).
[193] Guidance for Industry, *supra* note 167.
[194] *Id.*
[195] 21 U.S.C. § 374(g)(5).
[196] *Id*. § 374(g)(3)(E).

immediately notify FDA of a condition noted during an inspection that could cause or contribute to an unreasonable risk to the public health, the knowing inclusion by an AP of false information in an inspection report, and the knowing failure of an AP to include material facts in such a report.[197] With respect to public disclosure, FDA states that inspection records and information collected from the manufacturer and submitted to FDA by APs will generally be available for disclosure after the agency issues a compliance decision, unless such information is exempt from disclosure by law.[198] 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 AP Program inspections.[199]

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.[200] 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.[201] Before FDA withdraws an AP's accreditation, it notifies the AP and provides an opportunity for an informal hearing.[202]

The FDA's design and implementation of the AP program has been funded with appropriated funds. The statute contains no provisions regarding the assessment of user fees to cover the costs of program development and implementation. As of 2012, the program was largely inactive and a single FDA employee administered the program as a collateral duty.[203] Also as of 2012, the 510(k) premarket review program had no full-time positions committed to it. Administrative responsibilities are spread over three employees as part of their other workload.[204]

4. FCC, Telecommunication Certification Body Program

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.[205] FCC requirements generally apply to all

[197] 21 U.S.C. § 331(gg). *See also* 21 U.S.C. § 374(g)(7)(E); Guidance for Industry, *supra* note 167, at 13 (providing that "If at any time during an inspection the AP discovers a condition that it believes could cause or contribute to an unreasonable risk to public health, the AP must report the problem to FDA immediately").
[198] Guidance for Industry, *supra* note 167, 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 FDCA (21 U.S.C. § 331(j)) and FDA regulations implementing these statutes (*see e.g.*, the FDA regulations implementing the Freedom of Information Act in 21 C.F.R. pt. 20 and FDA's FOIA web page at http://www.fda.gov/RegulatoryInformation/foi/default.htm).
[199] 21 U.S.C. § 374 (g)(5)(A)(i); Guidance for Industry, *supra* note 167, at 5, 11 (further stating that it audits APs on a periodic and "for cause" basis).
[200] 21 U.S.C. § 374(g)(5); Guidance for Industry, *supra* note 167, at 14.
[201] *Id*.
[202] Guidance for Industry, *supra* note 167, at 14.
[203] Email from Jean Cooper, Senior Staff Fellow, U.S. Food and Drug Administration, July 17, 2012 (on file with author).
[204] *Id*.
[205] 64 Fed. Reg. 4995 (Feb. 2, 1999); 47 C.F.R. §§ 2.960-2.962 & 68.160-68.162. The applicable telecommunications equipment regulations are at 47 CFR pts. 0 through 101. The requirements for Telecommunication Certification Bodies (TCBs) were specified in the Commission's Report and Order (R&O) in

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.[206]

Only certain types of equipment require certification, and often the certification can be conducted by either a TCB or the FCC.[207] Examples of devices which 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.[208] Some devices may only be submitted to the FCC (such as certain new technologies) or TCBs (all computers and computer peripherals). When a manufacturer seeks certification directly from the FCC, equipment authorization fees apply.[209]

Figure 6 shows the third-party structure of the TCB program. TCBs are required to be accredited as operating in accordance with ISO/IEC Guide 65 (1996), *General Requirements for Bodies Operating Product Certification Systems* and FCC's technical requirements for TCBs.[210] Under its National Voluntary Conformity Assessment Evaluation (NVCASE) program, 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).[211] Certification bodies located outside the US 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 US. In that case, the TCB is accredited by appropriate authorities in that country.[212] An online list of recognized TCBs is maintained by FCC.[213] The TCB program went into effect in June 2000 with 13 recognized TCBs, and as of 2012, there are 34 recognized TCBs.[214]

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.[215] TCBs are accredited with certain scopes, which indicate the product types they may approve (e.g., Scope A: Unlicensed Radio Frequency Devices; Scope B:

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.

[206] 47 CFR §§ 2.1091, 2.1093; *see also* http://transition.fcc.gov/oet/rfsafety/ (last visited Sept. 11, 2012).

[207] *See* 47 CFR § 2.907 (on "certification"). Equipment with a low risk of causing harmful interference may generally satisfy FCC requirements through a manufacturer's "verification," 47 CFR § 2.902, or "Declaration of Conformity," 47 CFR § 2.906.

[208] *See* http://transition.fcc.gov/oet/ea/procedures.html (last visited Sept. 11, 2012).

[209] *See* http://apps.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?id=41712&switch=P (last visited Sept. 11, 2012) (showing fees ranging from $490-$1265 for certification of devices).

[210] TCB Program Rules and Responsibilities, FCC Office of Engineering and Technology (OET) Laboratory Division, (Jan. 6, 2011). *See also* 47 CFR § 68.160(b).

[211] *Id.*

[212] *Id. See also* 47 CFR § 68.160(b).

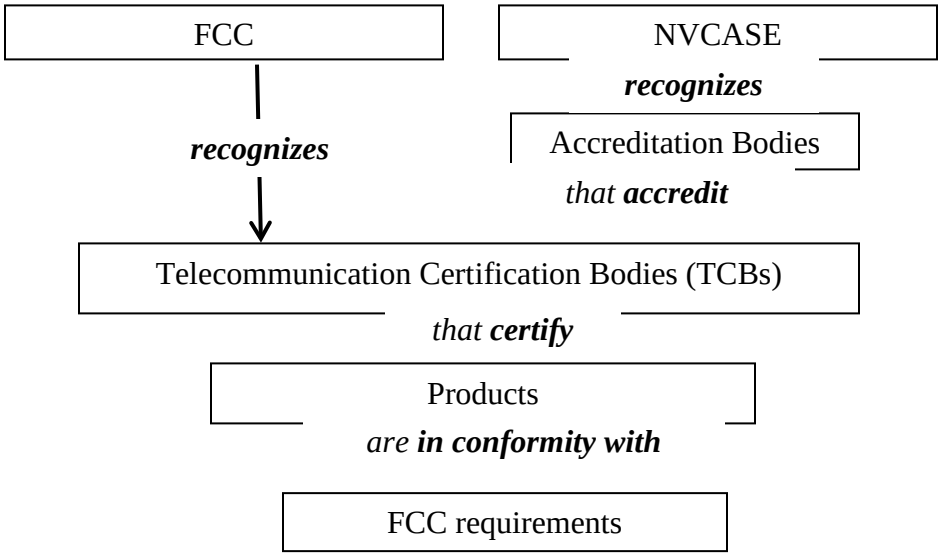
[213] *See* https://apps.fcc.gov/tcb/index.html (last visited Sept. 11, 2012).

[214] David A. Case & William Graff, Approval Options: A Look at the FCC and TCB Approval Processes (2001), http://www.ce-mag.com/archive/01/09/case.html (for 2001 number); Interview (by phone), George Tannahill, FCC Office of Engineering and Technology, August 27, 2012 (for 2012 number).

[215] TCB Program Rules, *supra* note 210, at 3; *see also* 47 C.F.R. § 68.162(b)(2).

Licensed Radio Service Equipment). For accreditation, TCBs must demonstrate expert knowledge of the regulations for the product types in each of their scopes. 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 17025 to demonstrate it is competent to perform such tests.[216] Testing of products may be performed by subcontractors of TCBs, but the TCB must maintain oversight and remains responsible for the test results.[217] The FCC has not established conflict-of-interest rules for TCBs beyond what is required for accreditation to ISO Guide 65.[218]

Figure 6: Structure of Third-Party Program for Telecommunication Equipment



Before a TCB can grant an equipment authorization, it must submit all required information to the FCC's online system.[219] After the system automatically performs certain validity checks, it can be used to grant the authorization. FCC reserves to itself 30 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.[220] TCBs must test additional equipment samples for at least 5% of the grants they issue

[216] 47 C.F.R. § 68.162(b)(3), TCB Program Rules, *supra* note 210, at 2.
[217] *Id*. § 68.162(d).
[218] 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."
[219] Interview (by phone), George Tannahill, FCC Office of Engineering and Technology, August 27, 2012.
[220] 47 C.F.R § 2.962(g)(2); *see* Federal Communications Commission, Office of Engineering and Technology Laboratory Division, TCB Post-Market Surveillance, 1 610077 D01 TCB Post Market Surveillance v05r03

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.[221] Subject to certain procedural requirements, the FCC retains authority to withdraw its recognition of TCBs and revoke the certification of products by TCBs.[222] 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.[223]

B. Programs for Voluntary Standards

In four programs, federal agencies rely on third parties to assess and certify compliance with voluntary standards established or endorsed by the agency. All these programs 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. OSHA, National Recognized Testing Laboratories Program

Since 1988, the Occupational Safety & 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.[224] The program's structure is illustrated in Figure 7. 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 affixes a label (or mark) on the products, which is visible to the OSHA workplace inspector.

The standards that the products must meet to be certified by a NRTL are voluntary consensus standards, rather than government-unique OSHA standards.[225] OSHA requires NRTL certification for many different types of products, such as printers and copiers, electric heater and air conditioners, alarm systems, fire extinguishers, acetylene torches, and liquefied petroleum gas ovens.[226] These standards are set by national standards-producing organizations such as

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(Oct. 25, 2011), http://apps.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?id=20540&switch=P (last visited Sept. 11, 2012).

[221] 47 C.F.R § 68.162(g)(3).

[222] *Id*. § 68.162(f)(6).

[223] Interview (by phone), George Tannahill, FCC Office of Engineering and Technology, August 27, 2012.

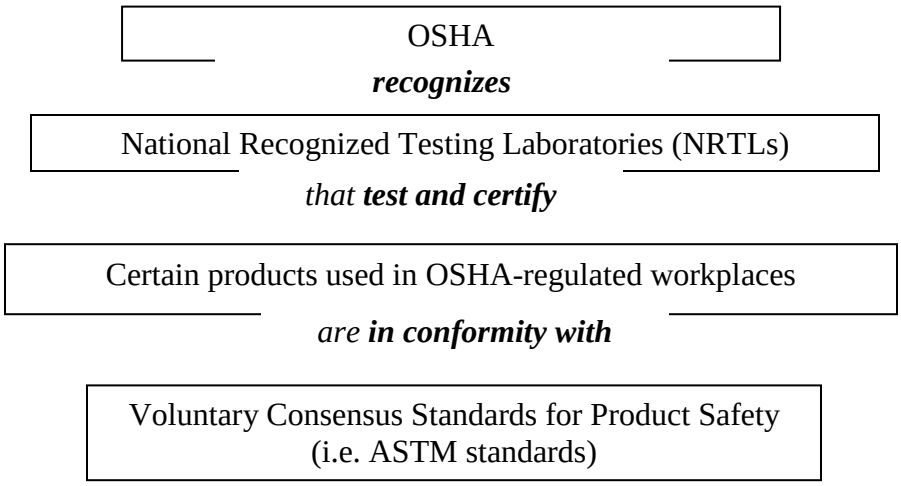
[224] 53 Fed. Reg. 12102 (Apr. 12, 1988); 29 CFR § 1910, subpart S. *See also* Bernard Pasquet, OSHA Requirements for Nationally Recognized Testing Laboratory Approval of Products, http://www.osha.gov/dts/otpca/nrtl/NRTLarticle.html (last visited Sept. 11, 2012) (stating that workplaces subject to OSHA's 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).

[225] *See* 29 C.F.R. § 1910.7(c) (defining the test standards used in the NRTL program).

[226] *See* Pasquet, *supra* note 224; OSHA, Type of Products Requiring NRTL Approval, http://www.osha.gov/dts/otpca/nrtl/prodcatg.html (setting forth 37 product categories, of which electrical equipment is the largest, and citing to General Industry Standards, 29 C.F.R. pt. 1910).

American National Standards Institute (ANSI), American Society for Testing and Materials (ASTM), Factory Mutual Research Corporation (FMRC), and UL.[227] 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 certified products.

Figure 7: Structure of Third-Party Program for Workplace Product Safety



NRTLs are private organizations that are recognized by OSHA to be qualified to perform safety testing and product certification.[228] OSHA regulations set forth the requirements for NRTLs.[229] 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.[230] 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.[231] 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.[232] NRTLs must maintain effective procedures for producing objective and unbiased reports and for fairly handling complaints and disputes.[233]

If its application is approved by OSHA, a NRTL's initial recognition is valid for five years.[234] OSHA approves NRTLs with certain "scopes of recognition" by specifying the test

[227] Occupational Safety & Health Administration, Nationally Recognized Testing Laboratory Program Application Guidelines, at 1, http://www.osha.gov/dts/otpca/nrtl/applguid.pdf (last visited Sept. 11, 2012) [hereinafter "OSHA Application Guidelines"]. A list of standards recognized by OSHA is at http://www.osha.gov/dts/otpca/nrtl/allstds.html.
[228] *See* OSHA, Frequently Asked Questions (FAQs), http://www.osha.gov/dts/otpca/nrtl/faq_nrtl.html#1 (last visited Sept. 11, 2012) (stating that "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).
[229] 29 C.F.R. § 1910.7.
[230] *Id*. § 1910.7(b)(1).
[231] *Id*. § 1910.7(b)(2).
[232] *Id*. § 1910.7(b)(3).
[233] *Id*. §§ 1910.7(b)(4)(i) & (ii).
[234] OSHA Application Guidelines, *supra* note 227 at 1.

standards with which they can certify conformity. OSHA maintains an online registry of NRTLs and their scopes of recognition.[235] Currently, 16 NRTLs are based in the United States, and three NRTLs are based in other countries.[236] 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 10 foreign countries.

NRTLs and applicants for NRTL recognition must pay fees.[237] 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 and Federal Register notices; and audits of sites."[238] Fees first went into effect on October 1, 2000.[239] They were revised in 2002, 2007 and 2011.[240] A current listing of the applicable fees is maintained online.[241] For example, currently, total fees to become recognized as a NRTL 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).[242] Substantial fees also apply when a 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.[243] Audit fees are significantly higher if non-conformances are found or if more than one day is required.

2. AMS, National Organic Program

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."[244] 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.[245]

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[235] List of NRTLs is available at http://www.osha.gov/dts/otpca/nrtl/ (last visited Sept. 11, 2012).
[236] *Id.*
[237] 29 C.F.R. § 1910.7(f).
[238] *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).
[239] OSHA, Fee Payment Instructions and Information, http://www.osha.gov/dts/otpca/nrtl/nrtlfees.html; *see* also Nationally Recognized Testing Laboratories -- Fees; Public Comment Period on Recognition Notices, 65 Fed. Reg. 46798 (July 31, 2000), *available at* http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=FEDERAL_REGISTER&p_id=15480.
[240] Nationally Recognized Testing Laboratories Fees, 76 Fed. Reg. 10500 (Feb. 25, 2011) http://www.gpo.gov/fdsys/pkg/FR-2011-02-25/html/2011-3937.htm (last visited Sept. 11, 2012) (revising the fee regulations).
[241] OSHA, Fee Schedule (effective March 28, 2011), http://www.osha.gov/dts/otpca/nrtl/nrtlschedule.html (last visited Sept. 11, 2012).
[242] *Id.*
[243] *Id.*
[244] 7 U.S.C. § 6503(d).
[245] 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. pt. 205.

These regulatory standards are voluntary in that food producers or handlers are only required to conform to them if they label their products 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. [246] 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.[247]

As shown in Figure 8, 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.[248] To be accredited, the entity must have sufficient expertise and adequately trained personnel to comply with the terms of the organic certification program.[249] Certifying agents must also conduct an annual program review of their certification activities and correct any noncompliances,[250] and they must maintain records of certification processes and make them available for inspection upon request.[251] As of 2012, 91 entities – 51 domestic and 40 foreign – were accredited by the NOP to act as certifying agents.[252] 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.[253] Overall, state agencies constituted 17 of the 51 domestic organic certifiers.[254] Examples of foreign domestic certifying agents include Argencert S.A., based in Argentina, and CAAE Certification Service, based in Spain.[255]

The NOP regulations include several provisions to avoid potential conflicts of interest.[256] Certifying agents are required to prevent conflicts of interest by not certifying operations that they have any commercial interest 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.[257]

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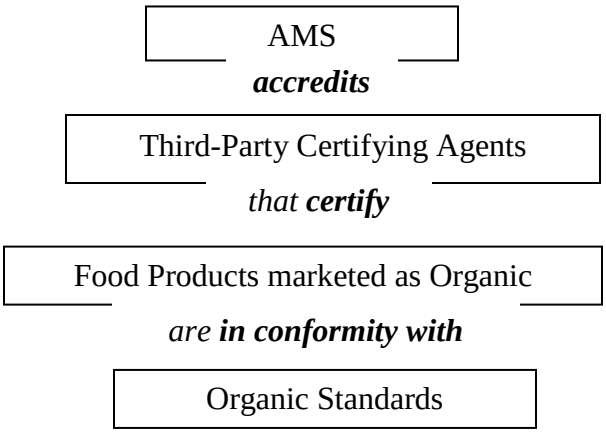
[246] USDA, National Organic Program, Organic Certification & Accreditation, http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=NationalOrganicProgram&leftNav=NationalOrganicProgram&page=NOPAccreditationandCertification&description=Accreditation%20and%20Certification&acct=nopgeninfo (last visited Sept. 11, 2012).
[247] 7 C.F.R §§ 205.403 - 205.406.
[248] *Id*. § 205.500(c)
[249] *Id*. § 205.501(a)(1)-(6).
[250] *Id*. § 205.501(a)(7).
[251] *Id*. § 205.501(a)(9).
[252] USDA, National Organic Program, Organic Certification & Accreditation, *supra* note 246.
[253] *See* the list of domestic certifying agents at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5074486 (last visited Sept. 11, 2012).
[254] *Id*.
[255] *See* the list of foreign certifying agents at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5074487 (last visited Sept. 11, 2012).
[256] 7 C.F.R. § 205.501(a)(11).
[257] *Id*.

Figure 8: 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."[258] 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.[259] NOP reports that 56 such onsite reviews or inspections occurred in 2012.[260]

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."[261] 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.[262] 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.[263]

3. EPA/DOE, Energy Star Program

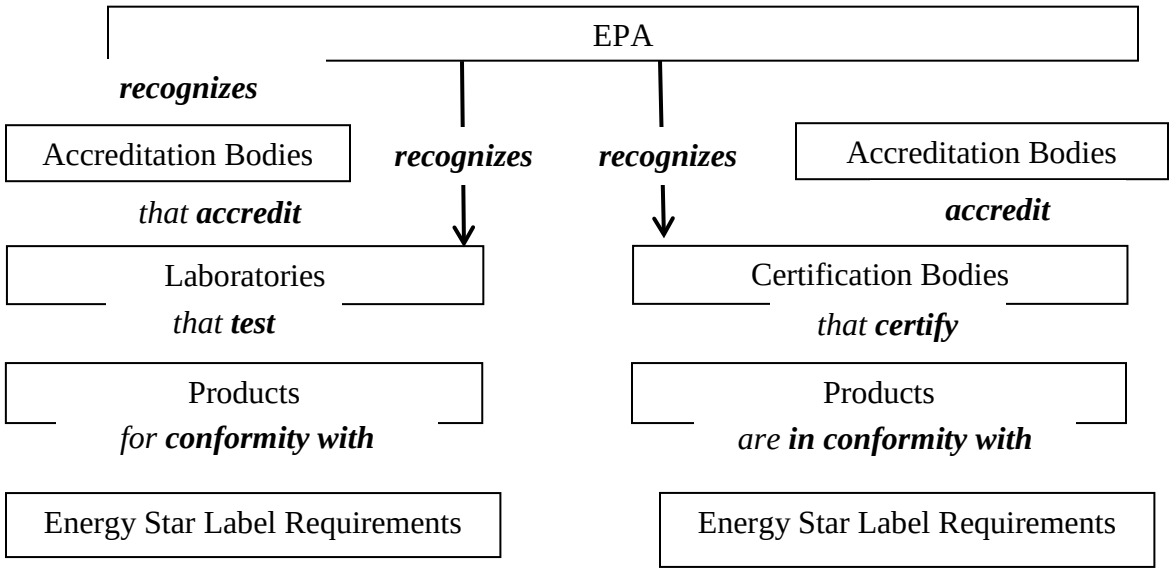
The Energy Star Program was established by the Environmental Protection Agency (EPA) in 1992 to provide a labeling system for products that voluntarily meet certain energy efficiency standards. The Department of Energy (DOE) has jointly administered the program since 1995, when labeled products expanded from computers and monitors to additional office equipment

[258] *Id*. § 205.508(a).
[259] *See* 7 C.F.R. §§ 205.508 (b), 205.500 (specifying that the duration of accreditation is five years)
[260] Interview (by phone), Cheri Courtney, Acting Director, Accreditation and International Activities Division, NOP (August 16, 2012). Some audit reports and corrective action reports can be found on the NOP website at http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateJ&page=NOPReadingRoomHome (last visited Sept. 9, 2012).
[261] 7 U.S.C. § 6506(a)(10).
[262] 7 C.F.R. § 205.640.
[263] USDA, National Organic Program, FAQ: Becoming a Certifying Agent, 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 Sept. 9, 2012).

and residential heating, ventilation, and cooling (HVAC) equipment.[264] Over 60 product categories may now carry the Energy Star label including major appliances, office equipment, lighting, home electronics, new homes, and commercial and industrial buildings. [265] As of 2010, more than 40,000 individual product models made by over 1,600 manufacturers had earned the Energy Star label.[266]

Effective in 2011, after a critical report by the Government Accountability Office, Energy Star was significantly restructured by EPA to require that products carrying the label be certified by third parties.[267] The new third-party structure for the program is shown in Figure 9. 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 have to be certified and submitted to EPA by an EPA-recognized certification body. EPA recognition, in turn, generally depends on accreditation to an appropriate ISO standard by an EPA-recognized accreditation body.

Figure 9: 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

[264] US Government Accountability Office (GAO), ENERGY STAR PROGRAM: COVERT TESTING SHOWS THE ENERGY STAR PROGRAM CERTIFICATION PROCESS IS VULNERABLE TO FRAUD AND ABUSE, 3 GAO-10-470 (March 2010), *available at* http://www.gao.gov/products/GAO-10-470.
[265] For general information *see* Energy Star, History of Energy Star, http://www.energystar.gov/index.cfm?c=about.ab_history (last visited Sept. 11, 2012) (noting that labeled products include major appliances, office equipment, lighting and home electronics, among others).
[266] USEPA, ENERGY STAR® and Other Climate Protection Partnerships 2010 Annual Report 4, *available at* http://www.energystar.gov/ia/partners/publications/pubdocs/2010%20CPPD%204pgr.pdf.
[267] *See* GAO, *supra* note 264; *see generally* EPA Energy Star, Third-Party Certification, http://www.energystar.gov/index.cfm?c=third_party_certification.tpc_index.

accreditation body must be a signatory to the IAF MLA.[268] As of April 2012, there were 54 signatories to the IAF MLA based in about 50 different countries.[269] In the U.S., 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.[270] By May 2012, EPA had recognized 27 accreditation bodies around the world, including A2LA, IAS, and three others in the U.S. [271]

EPA-recognized certification bodies (CBs) play the role of certifying that eligible products meet the requirements of the Energy Star label. A key requirement for recognition is accreditation to ISO/IEC Guide 65 by an accreditation body that is an IAF MLA signatory. ISO/IEC Guide 65 requires, for example, that the CB make certification decisions impartially and based on information gathered during the evaluation process.[272] 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.[273] More specifically, CBs are required to annually select and test at least 10% of all models they have certified, with half the models being randomly selected and half selected based on EPA referrals. As of August 2012, Energy Star had recognized 21 certification bodies around the world.[274]

In general, Energy Star qualifying 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.[275] Recognized labs must also agree to a variety of other requirements such as reporting to EPA and otherwise enabling EPA oversight.[276] Recognized labs need not be independent; they may be owned by the manufacturers of the products they test.

Manufacturers' laboratories that are not accredited may also be used for testing under the Energy Star's Witnessed Manufacturers' Testing Laboratory (WMTL) or Supervised

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[268] Energy Star, Accreditation Body Resources, http://www.energystar.gov/index.cfm?c=third_party_certification.tpc_accred_bodies (last visited Sept. 11, 2012).
[269] *See* full list at http://www.iaf.nu/articles/IAF_MEM_USA__all/112, accessible from IAF, IAF MLA, http://www.iaf.nu/articles/IAF_MLA/14 (last visited Sept. 9, 2012).
[270] *See* EPA, Conditions and Criteria for Recognition of Accreditation Bodies for ENERGY STAR® Laboratory Recognition, http://www.energystar.gov/ia/partners/downloads/mou/Criteria_Accreditation_Bodies_Labs.pdf?e75e-ee91 (last visited Sept. 11, 2012).
[271] *See* Energy Star, EPA-Recognized Accreditation Bodies, http://www.energystar.gov/index.cfm?c=partners.epa_recognized_accreditation_bodies (last visited Sept. 9, 2012).
[272] *See* EPA, Conditions and Criteria for Recognition of Certification Bodies for the ENERGY STAR program, http://www.energystar.gov/ia/partners/downloads/mou/Conditions_and_Criteria_for_Recognition_of_Certification_Bodies.pdf (last visited Sept. 11, 2012).
[273] *Id*.
[274] Interview (by phone), Eamon Monahan, EPA Energy Star Program, August 6, 2012.
[275] EPA, Conditions and Criteria for Recognition of Laboratories for the ENERGY STAR program, at http://www.energystar.gov/ia/partners/downloads/mou/Criteria_Laboratories.pdf (last visited Sept. 9, 2012).
[276] *Id*.

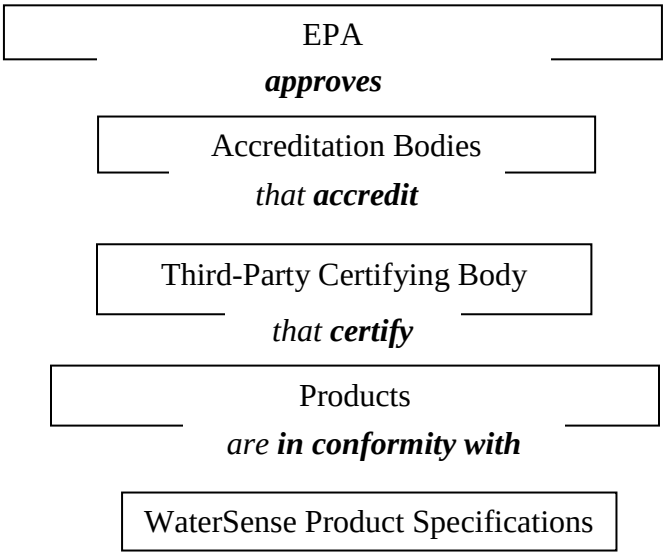
Manufacturers' Testing Laboratory (SMTL) programs.[277] Under these programs, a CB may operate a testing program to accept test data from such a lab if the CB commits to exercising and documenting a high degree of oversight, including on-site assessment and monitoring to ensure the laboratory's compliance 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.[278] About 200 of these labs were located in the Asia-Pacific region, most of which were fully accredited.[279]

EPA does not assess any user fees for participation in the Energy Star program. Funding for its development and maintenance has come from appropriated funds.

4. EPA, WaterSense Program

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 10. Modeled after Energy Star, WaterSense was launched in 2006 and has required third-party certification since 2009.[280] 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.

Figure 10: Structure of Third-Party Program for WaterSense Product Label



[277] *Id*. at 6-7.
[278] Interview (by phone), Eamon Monahan, EPA Energy Star Program, August 6, 2012.
[279] *Id*.
[280] *See* EPA WaterSense, Comprehensive List of all Frequent Questions, http://www.epa.gov/watersense/full_list.html (last visited Sept. 11, 2012). EPA issued the first WaterSense product certification system in 2009. WaterSense Product Certification System (March 23, 2009), http://www.epa.gov/watersense/docs/cert_system_revised508.pdf. EPA issued a revised version in 2009. EPA WaterSense, WaterSense®, Version 2.0 Product Certification System (Sep. 29, 2011), http://www.epa.gov/watersense/docs/cert_system_508.pdf [hereinafter "WaterSense 2.0"].

The applicable standards in WaterSense are EPA's "product specifications," which are currently finalized for five product categories: Tank-Type Toilets, Lavatory Faucets, Flushing Urinals, Showerheads, and Weather-Based Irrigation Controllers.[281] 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.[282] Manufacturers apply directly to the licensed certifying body for certification and to obtain the WaterSense label.[283]

To be approved by EPA, an accreditation body must be domiciled in the U.S. and show that it operates in accordance with the requirements of ISO/IEC 17011.[284] 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.[285] As of 2012, EPA had approved three accreditation bodies: A2LA, ANSI, and IAS.[286]

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.[287] As of May 2012, EPA had licensed seven certification bodies to provide product certifications for one or more of the five product categories.[288] Examples of licensed certification bodies include Intertek, NSF International, and UL, based in the U.S.; 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.[289] If a certifying body relies on testing data from a manufacturer's laboratory,

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[281] WaterSense, Compendium of Product & Program Specifications, http://www.epa.gov/watersense/partners/product_program_specs.html#final (last visited Sept. 9, 2012).
[282] WaterSense, Product Certification & Labeling, http://www.epa.gov/watersense/about_us/product_certification_labeling.html (last visited Sept. 9, 2012).
[283] *Id*.
[284] WaterSense 2.0, *supra* note 280, at 4. The requirement that the accreditation body be domiciled in the U.S. is not present in EPA's Energy Star program or other programs included in this review.
[285] *Id*. (noting that references to ISO/IEC Guide 65 will be superseded by ISO/IEC 17065 once ISO/IEC 17065 is published.)
[286] WaterSense, Accreditation & Licensed Certifying Bodies, http://www.epa.gov/watersense/about_us/cert_bodies.html#accreditation (last visited Sept. 9, 2012).
[287] WaterSense 2.0, *supra* note 280, at 4-5.
[288] WaterSense, Accreditation & Licensed Certifying Bodies, http://www.epa.gov/watersense/about_us/cert_bodies.html (last visited Sept. 9, 2012).
[289] WaterSense 2.0, *supra* note 280, at 8. *See also* EPA, Response to Public Comments Received on June 2011 WaterSense Draft Revised Product Certification System (September 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").

additional requirements are imposed.[290] 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.[291]

EPA does not assess any user fees for participation in the WaterSense program. Funding for its development and maintenance has come from appropriated funds.

IV. Evaluating Third-Party Programs

Given the growing prevalence of third-party programs in regulatory contexts, 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. Metrics of Success

1. Reliability of Third-Party Determinations

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.[292]

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

[290] *Id.* at 8-10.
[291] *Id*.
[292] *Cf. infra* notes 433 to 434 and accompanying text (recommending that agencies calibrate the design of third-party programs to the level of risks associated with noncompliance).

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 contamination.[293] 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 the FDA in which certification bodies (CBs) were selected to inspect establishments in the aquacultured shrimp industry for compliance with US 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.[294] Rather, they were using standards of other countries, which they had presumably used in other audits.[295] FDA concluded that it would have to conduct additional training to implement a full-scale third-party program.[296] 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."[297]

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."[298] In a similar vein, an FDA staffer who has worked with the AP Inspections program indicated that he perceived AP inspectors to be very competent, particularly in performing ISO 13485 facility inspections.[299] He noted, however, that because they do not usually do AP inspections, the information provided to the FDA through such inspection is generally not adequate to support an enforcement action. He opined that if the AP inspectors conducted a lot of inspections – for example, 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."[300] Indeed, FDA noted significant deficiencies when it observed and assessed third parties to see if they met eleven

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[293] Andrew Martin, *Peanut Plant says Audits Declared it in Top Shape*, New York Times (Feb. 4, 2009), *available at* http://www.nytimes.com/2009/02/05/business/05peanuts.html?_r=1&ref=peanutcorporationofamerica.
[294] FDA, Assessment of the Third-Party Certification Pilot for Aquacultured Shrimp (July 2011). *See also* 73 Fed. Reg. 39704 (Jul. 10, 2008) (announcing the pilot program and calling for applications from certification bodies).
[295] *Id.* at 7.
[296] *Id.* at 26.
[297] PMAP report, *supra* note 162, at 2. Note 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 US is similar, but not the same.
[298] *Id.* at 4.
[299] Interview (by phone), David Kalins, Office of Compliance, CDRH, FDA, July 31, 2012.
[300] FDA, *supra* note 294, at 26.

"critical audit performance elements." 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."[301] FDA conducted 28 audits and found that only 3 out of 11 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 4 out of the 28 audits met such critical elements as: "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?"[302]

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.[303] 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."[304] 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.[305] Also, the certain and immediate beneficial consequences of giving a positive audit opinion may outweigh the uncertain and distant negative consequences of not doing so.[306] Another threat to independence occurs when auditors provide their clients with additional "non-audit" consulting and tax services.[307] 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 programs for regulatory purposes. An example of an issue involving third-party independence is provided by the NRTL program. Curtis Straus LLC (CSL) was recognized as a NRTL in 1999 and applied to have its recognition renewed in 2004.[308] In 2007, OSHA informed Curtis Straus by letter that it did not appear to meet the NRTL program policy on independence because of a change in its ownership in 2005.[309] After the change in ownership, the investment firm (Wendel) owned 58% of CSL as well as 32% 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

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[301] *Id.*
[302] *Id.* at 31, app. B.
[303] Max H. Bazerman et al., *Why Good Accountants Do Bad Audits*, HARV. BUS. REV. 97-98 (Nov. 2002).
[304] *Id.* at 98.
[305] *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).
[306] *Id.*
[307] Keith A. Houghton & Christine A. Jubb, *The Market for Financial Report Audits: Regulation of and Competition for Auditor Independence*, 25 L. & POL'Y 299, 308–09 (2003).
[308] OSHA, Curtis-Straus LLC, Application for renewal of Recognition, 76 Fed. Reg. 62850 (Oct. 11, 2011).
[309] *Id.*

external and internal audits to ensure its independence.[310] 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.[311] In its continued efforts to persuade OSHA to renew, Wendel decreased its ownership stake in Legrand to11% in 2011.

In 2011, OSHA published notice of its preliminary finding to deny renewal, and a final finding is expected to be published in September 2012.[312] In the preliminary finding, OSHA explains 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.[313] CSL's substantial relationship with Legrand deriving from Wendel's partial ownership of both violates this independence requirement. OSHA's final determination on CSL's renewal has still not been published, suggesting that a lengthy process is required when an agency seeks to terminate the accreditation of a certification body.

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 the Environmental Protection Agency 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.[314] 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."[315]

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 observes 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."[316] 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 risks.[317] To standardize their task,

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[310] *Id.*
[311] *Id.*
[312] *Id.*; Interview (by phone), Robert Biersner, Department of Labor, Office of the Solicitor (Aug. 10, 2012).
[313] *Id.*
[314] Mandatory Reporting of Greenhouse Gases; Final Rule, 74 Fed. Reg. 56260, 56282 (Oct. 30, 2009).
[315] *Id.* at 56283.
[316] Maki Hatanaka, *Certification, Partnership, and Morality in an Organic Shrimp Network: Rethinking Transnational Alternative Agrifood Networks*, 38(5) World Development 706, 710 (2010).
[317] Albersmeier et al., *supra* note 3, at 930-933.

auditing organizations may develop detailed checklists, so there is lots of "ticking the boxes" but "crucial quality risks can go unnoticed at the same time because they are not specifically provided for on the checklist of technical requirements."[318] 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 it may be perceived as more standardized and fair.[319]

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.[320] 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 oversights mechanisms to make sure that third parties comply with program rules.

2. Rates of Compliance

Another metric to assess third-party programs for regulatory purposes 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.[321] With limited inspectorial resources (about 1,000 inspectors), FDA inspected only 6% of the 421,000 registered facilities in 2010.[322] Also, according to the FDCA, domestic manufacturers of a class II or III medical device shall be inspected by the FDA at least once in every two-year period.[323] 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.[324] 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 27 years.[325]

Third-party programs designed for regulatory purposes can enable more frequent inspections and more complete data about compliance. A program may be designed, for example, to require

[318] *Id.* at 933.
[319] *Id.*
[320] *Cf.* McAllister, *supra* note 3.
[321] Kathy Gombas & Howard Seltzer, *Regulatory Report, The Reportable Food Registry: A Valuable New Tool for Preventing Foodborne Illness*, FOOD SAFETY MAGAZINE (June/July 2011), *available at* http://www.foodsafetymagazine.com/article.asp?id=4117&sub=sub1.
[322] ElBoghdady, *supra* note 39.
[323] Guidance for Industry, *supra* note 167. *See also* 21 U.S.C §360(h) (containing the statutory requirement).
[324] Challenges for FDA, *supra* note 153, at 1st page (unnumbered).
[325] *Id.*

an assessment of the compliance status of all regulated entities or products each year or every few years. Importantly, the mere knowledge that a third party will inspect their activities can change the behavior of regulated firms. Evidence 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.[326] As such, the performance of an individual or group improves when it is singled out for observation and study by an outsider.[327] Also in third-party assessment processes, there may be opportunities for third parties to educate and persuade the regulated entity to comply.

Indeed, many third-party programs have been implemented by federal agencies in response to a perceived deficit in the agency's 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 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.

3. Agency Capacity to Administer the Third-Party Program

Another metric for evaluating third party programs in regulatory contexts 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 the FDA AP Inspections program, selection and training of APs took many years to complete. FDA's aquacultured shrimp pilot further demonstrates the resource requirements of verifying the qualifications of third-parties, particularly when they are outside the US. As part of the application process, FDA asked candidate certification bodies (CBs) to assess their own conformity with certain attributes that FDA determined were necessary for CB certification programs.[328] These included, for example, that auditors should understand the food safety issues

[326] *See* ASEEM PRAKASH & MATTHEW POTOSKI, THE VOLUNTARY ENVIRONMENTALISTS: GREEN CLUBS, ISO 14001, AND VOLUNTARY REGULATIONS 60 (2006) (explaining that third-party inspections "mitigate shirking by creating incentives for managers within the firm to adhere to program obligations").
[327] *Id.* at 61–62, 181.
[328] Assessment of Pilot for Aquacultured Shrimp, *supra* note 294.

related to the processes and products 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. 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 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.[329] The FDA concluded that the onsite program assessments and associated discussions with CB personnel were critical to FDA's evaluation of the CB programs.[330]

Through this pilot, moreover, the 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 US.[331] 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 of the program attributes was limited."[332] For the CBs located outside the US, the overseas travel and need for translation services further complicated FDA's assessment efforts.[333]

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 (i.e. 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.[334] In addition, some changes in FDA's plans were necessitated by international crises and civil unrest in countries where audits had been planned.[335] Given the difficulties, some CBs conducted "mock audits" to accommodate the FDA. FDA concluded that the "coordination among multiple stakeholders demanded significant time and resources."[336]

Finally, the pilot made clear that agencies that implement third-parties program are likely to need to provide training to their own personnel and 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."[337] 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

[329] *Id.* at 13, tbl. 3
[330] *Id.* at 11.
[331] *Id.* at 11, 6 tbl. 1
[332] *Id.* at 12.
[333] *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 "It should be noted that the number of interpreters needed for a full-scale third-party certification program are likely to be substantial.")
[334] *Id.* at 16.
[335] *Id.* at 16
[336] *Id.* at 24.
[337] *Id.* at 25.

central coordinating point within the Agency."[338] 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.[339]

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.[340]

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.[341] OIG also found that NOP officials did not make required onsite assessments and did not identify inconsistencies in implementation of NOP regulations.[342] Lacking sufficiently specific rules and adequate oversight, certification agents developed different criteria for determining whether non-compliances were present and whether they were major or minor.[343] OIG concluded that "AMS did not ensure consistent oversight of organic operations by its certifying agents."[344] This lack of oversight, in turn, undermined the overarching goal of NOP "to assure consumers that products meet consistent, uniform standards."[345]

The OIG found even more serious deficiencies in AMS's oversight of foreign certifying agents.[346] AMS is required to make onsite reviews of foreign certifying agents, but 5 of 44 never received such a review and 24 of 44 received reviews more than two years after receiving their conditional accreditation. 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.[347] When NOP reviews were performed, NOP officials often found that certifying agents

[338] *Id.* at 23.
[339] *Id.* at 24-25.
[340] *See* EPA, Conditions and Criteria for Recognition of Certification Bodies, *supra* note 272, at 1(i) (authorizing EPA to conduct audits at its discretion); Interview (by phone), Eamon Monahan, EPA Energy Star Program, August 6, 2012 (mentioning that Energy Star picked at random some product categories and had CBs send all related certification files).
[341] USDA Office of the Inspector General (OIG), Oversight of the National Organic Program, Audit Report 01601-03-Hy (March 2010), at 29-30.
[342] USDA OIG, *supra* note 341, at 3.
[343] *Id.* at 21-27 (describing how NOP lacked clear and sufficiently focused rules and did not oversee their implementation).
[344] *Id.* at 21.
[345] *Id.*
[346] *Id.* at 28-29.
[347] *Id.*

committed major noncompliances such as failing to identify mislabeled products, maintain complete certification files, and complete annual conflict of interest disclosures.[348]

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 16, and that a 3.1 million dollar budget increase in 2010 would enable the program to grow to 31 staff members.[349] In 2007, the NOP had just nine staff members and an annual budget of $1.5 million.[350]

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 jurisdiction to do the kinds of oversight it would do in a domestic context.

4. 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 section that follows.

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 report 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."[351] The commenter then stresses the need for the agency to rigorously apply conflict-of-interest requirements and otherwise conduct oversight of third-party auditors. 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. It cites failures in the National Organic Program[352] and private food safety audits[353] to support its conclusion

[348] *Id.*
[349] *Id.* at appended back pages (AMS response).
[350] Uncle Matt's Organic Blog, http://unclematts.com/dev/how-to-add-oomph-to-organic/ (last visited Sept. 11, 2012).
[351] Comment of Make Our Food Safe and Safe Food Coalition, Docket Nos. FDA-2011-N-0145, § 303, Authority to require import certifications for food & FDA-2011-N-0146, § 307, Accreditation of Third-Party Auditors (Apr. 29, 2011).
[352] *Cf.* USDA OIG, *supra* note 341 (finding that AMS fails to adequately oversee NOP third parties).
[353] 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

that FDA "should invest its resources into doing as many as the imported food inspections itself and should avoid at all costs a reliance on a privatized inspection system."[354]

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.[355] In the aftermath of its passage, they have participated in the regulatory process to voice support for a strong third-party testing system.[356]

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 US 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."[357] 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."[358]

5. 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 inspection and compliance assessment from the government to industry.[359] 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

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Corp. *See* Jim Prevor's Perishable Pundit, Lessons From The Peanut Salmonella Outbreak: Audit System Broken, http://www.perishablepundit.com/index.php?date=02/19/09&pundit=1 (last visited Sept. 11, 2012).

[354] Comment of Food & Water Watch, Docket Nos. FDA-2011-N-0145, § 303, Authority to require import certifications for food & FDA-2011-N-0146, § 307, Accreditation of Third-Party Auditors (Apr. 29, 2011).

[355] Letter from Consumers Union to The Honorable Daniel K. Inouye (Oct. 26, 2007), *available at* http://www.consumersunion.org/pub/2007/10/005073print.html (last visited Sept. 11, 2012).

[356] Comments of Consumers Union, Consumer Federation of America, Kids in Danger, and the U.S. Public Interest Research Group to the U.S. Consumer Product Safety Commission on "Notice of 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 (last visited Sept. 11, 2012).

[357] Comment of Make Our Food Safe and Safe Food Coalition, *supra* note 351.

[358] Comment of Natural Resources Defense Council, NRDC's Comments on Energy Star's Proposed Enhanced Testing and Verification Program 4 (April 30, 2010) (emphasis on "complete transparency" removed from original), *available at* http://www.energystar.gov/ia/partners/downloads/mou/Natural_Resources_Defense_Council_Comments.pdf.

[359] *See* McAllister, *supra* note 3, at 27.

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.[360] 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.[361] In contrast, in the FDA's AP 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 8 APs out of 16 had completed all training.[362] 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 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 about the cost of the required third-parting testing. It was clear that these concerns had reached Congress when it amended the CPSIA in August 2011. [363] 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.[364] They recommended for example 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

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[360] *Cf.* Interview (by phone), Eamon Monahan, EPA Energy Star Program, August 6, 2012 (discussing that 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).

[361] Interview (by phone), Eamon Monahan, EPA Energy Star Program, August 6, 2012.

[362] U.S. Gov't Accountability Office, GAO-08-780T, Medical Devices: FDA Faces Challenges in Conducting Inspections of Foreign Manufacturing Establishments 19 (May 14, 2008), *available at* http://www.gao.gov/products/GAO-08-780T.

[363] H.R. 2715, Pub. L. No. 112-28 (Aug. 12, 2011) (creating a new section 14(i)(3)(A) of the CPSA); 15 U.S.C. § 2063(i)(3); Application of Third Party Testing Requirements; Reducing Third Party Testing Burdens, 76 Fed. Reg. 69596 (Nov. 8, 2011); Public Comments in response are available at regulations.gov, Docket No. CPSC–2011-0081 (listing 22 comments).

[364] Comments on Application of Third Party Testing Requirements; Reducing Third Party Testing Burdens, COSC Docket No. CPSC-2011-0081; available at www.regulations.gov.

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.[365]

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.[366] 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."[367] 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. [368] This manufacturer and others small manufacturers from Europe request that the CPSA exempt products tested to the European safety standards from CPSIA's third-party testing requirements.[369] Also, a manufacturer that describes itself as "medium-sized" 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.[370]

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, "Almost 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."[371] 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.[372]

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 than large companies. As stated by one commenter on the Watersense program, "High cost will discourage manufacturers, especially small ones, from participating in the process at all."[373] In effect, the costs of third-party certification may benefit larger companies at the expense of smaller ones.

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[365] *Id. (see especially* comments submitted by the Society of the Plastics Industry, Inc.; the Toy Industry Association; and Libbey).
[366] *Id. (see* comments submitted by the Fashion Jewelry and Accessories Trade Association).
[367] *Id.* at 11.
[368] *Id.* (*see* comments of Glueckskaefer).
[369] *Id.* (*see* comments of Fagus and Grimm's).
[370] *Id.* (see comments of Orbit Baby, Inc.).
[371] Comment, McGowan to Vokes (April 28, 2010) (in which the American Lighting Association reported that it had surveyed its members and 3/19 said the changes would cause them to end their participation in Energy Star and 15/19 said the changes would cause them to limit the number of fixtures they submit for certification).
[372] Interview (by phone), Eamon Monahan, EPA Energy Star Program, August 6, 2012.
[373] EPA Watersense, Comments on the May 2007 Draft WaterSense Certification Scheme 19 (Nov. 2007), *available at* http://www.epa.gov/WaterSense/docs/cert_scheme_comments508.pdf.

The Small Business Administration's Office of Advocacy has been concerned about third-party programs.[374] 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 30 to 90 days in the late 1990s to often just a few days.[375] In addition, a program may be designed such that a third-party assessment satisfies the regulatory requirements of both the US 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."[376]

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.

B. Incentives to Participate When Use of Third Parties is Voluntary

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 paper illustrate the situation: FDA's AP Inspections program for medical device production facilities; FDA's 510(k) Third-Party Review program for medical devices; and FCC's TCB program.

The FDA's Inspections by AP program has had a very low rate of participation. Despite an estimated 8,000 manufacturers that could use the program,[377] only 80 independent inspections (i.e. unaccompanied by FDA inspectors) have been conducted by APs in eight years of program operation.[378] The FDA had hoped that manufacturers would be attracted by the possibility that a single AP inspection might satisfy regulatory requirements in multiple jurisdictions.[379]

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[374] Interview (by phone), David Rostker, Assistant Chief Counsel, Office of Advocacy, U.S. Small Business Administration, Aug. 17, 2012.
[375] Interview (by phone), George Tannahill, FCC Office of Engineering and Technology, August 27, 2012.
[376] PMAP report, *supra* note 162, at 4.
[377] Agency Information Collection Activities; Proposed Collection; Comment Request; 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, 76 Fed. Reg. 29764, 29765 (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 program).
[378] Interview (by phone), David Kalins, Office of Compliance, CDRH, FDA, July 31, 2012.
[379] Status of FDA's Program, *supra* note 144, 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

However, the effect of this incentive has been limited because manufacturers have had doubts that APs could cover the multiple requirements of various standards in a single inspection.[380] Also, the program allows manufacturer to control the scheduling of inspections[381] and offers a two-year inspection holiday from regular FDA inspections.

Many disincentives to participation also exist. Under the AP 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.[382] 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."[383] 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.[384] 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 help FDA fulfill other responsibilities"[385]

The FDA's 510(k) pre-market third-party review program has attracted more participation than the AP Inspections program. As described above, this program enables certain manufacturers to contract with third parties to certify that products they intend to market. The FDA reported in July 2012 that about 8% of all 510(k) submissions are received from third parties, which is close to 300 submissions annually.[386] One difference between the AP inspection and pre-market programs is that in the latter, device manufacturers pay FDA a user fee if they do not go through an AP. In FY 2012, the fee is $4,049 ($2,024 for qualified small businesses).[387] However, it is likely that the user fee is lower than the amount that the manufacturer pays to a private third party.[388]

Another incentive that is present in the premarket program but not in the AP inspections 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% faster compared to 510(k)s reviewed entirely by

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13485: Medical devices -- Quality management systems -- Requirements for regulatory purposes," which many other countries use as their standard. *See also infra* note 430 and accompanying text.

[380] *Id.* 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* Interview (by phone), David Kalins, Office of Compliance, CDRH, FDA, July 31, 2012.

[381] Status of FDA's Program, *supra* note 144, at 13.

[382] *Id.* at 15.

[383] *Id.* at 16.

[384] *Id.*

[385] Challenges for FDA, *supra* note 153, at 6-7 (reporting 7 inspections between Mar. 2004 and Jan. 2008).

[386] Email from Jean Cooper, Senior Staff Fellow, U.S. Food and Drug Administration, July 17, 2012.

[387] FDA, Premarket Notification [510(k)] Review Fees, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134566.htm (last visited Sept. 11, 2012). MDUFMA, enacted in 2002, gave FDA authorization to charge manufacturers fees for premarket review. *See id.*

[388] Interview (by phone), David Kalins, Office of Compliance, CDRH, FDA, July 31, 2012.

FDA.[389] 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."[390]

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% of equipment authorization certifications (13,427 out of 13,645) were issued by TCBs rather than the FCC.[391] FCC staff explains that companies prefer going to TCBs because their products are approved more quickly and they can get to market faster.[392] In the late 1990s, product certifications were all conducted by the FCC and processing times tended to range from 30 to 90 days. Presently, certifications conducted by TCBs may take just a few days. The 1.5% of certifications that continue to be conducted by FCC tend to involve new technology that the FCC excludes from TCB approval until it published a measurement procedure.[393] 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 $1265.[394]

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 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.

V. Recommendations to Federal Agencies

This section sets forth recommendations to federal agencies regarding the use of private third parties for regulatory purposes. Regulatory third-party 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 report, four were explicitly required by

[389] FDA, Medical Devices, Third-Party Review, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ThirdParyReview/default.htm#3 (last visited Sept. 11, 2012).
[390] *Id.*
[391] Interview (by phone), George Tannahill, FCC Office of Engineering and Technology, August 27, 2012 (data on file with author).
[392] Interview (by phone), George Tannahill, FCC Office of Engineering and Technology, August 27, 2012.
[393] *Id.*; *see also* TCB Program Rules, *supra* note 210, at 4.
[394] Interview (by phone), George Tannahill, FCC Office of Engineering and Technology, August 27, 2012; *see also* http://apps.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?id=41712&switch=P.

Congress.[395] 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.[396] Moreover, the agency must make decisions about how it will conduct oversight and enforce these rules.[397]

When a third-party program is required by statute, certain characteristics of the third-party program may already be determined. Yet, within the 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 governmental and non-governmental resources relating to third-party 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.[398] Also, in 1998, the Office and 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.[399] NIST published this guidance in 2000.[400]

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

[395] 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.
[396] *Cf.* McAllister, *supra* note 3, at 47-59.
[397] *Id.* at 59-61.
[398] P.L. 104-113, § 12(d)(1) (codified at 15 U.S.C. § 272); *see also* NIST, Guidance on Federal Conformity Assessment Activities, 65 Fed. Reg. 48894 (Aug. 10, 2000).
[399] OMB Circular A-119 Revised §§ 8, 13(e) (Feb. 10, 1998).
[400] NIST Guidance, *supra* note 398.

relevant ISO standards and help establish the third-party program.[401] 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." 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 public interest; ensuring that agency participation in conformity assessment related activities is consistent with agency missions, authorities, priorities, and budgets; and establishing an ongoing process for identifying efficiencies that can be achieved through coordination with other agency and private sector conformity assessment activities.[402]

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.[403] Under its regulations, NIST accepts requests to perform these functions only in certain situations.[404] 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).[405]

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.[406] NIST has also expressed an interest in revising its 2000 guidance.[407]

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

[401] Interview (by phone), Stephanie Tanner, WaterSense Program, U.S. Environmental Protection Agency, Aug. 10, 2012.
[402] NIST Guidance, *supra* note 398, § 287.5. *See also* OMB Circular A-119, *supra* note 399, § 15 (setting forth the roles of the ICSP and standards executives).
[403] Interview, Ramona Saar (by phone), Standards Services Division, National Institute of Standards and Technology, 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).
[404] 15 C.F.R. § 286.2, *available at* http://gsi.nist.gov/global/docs/NVCASE_CFR.pdf (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").
[405] Interview (by phone), Ramona Saar, Standards Services Division, National Institute of Standards and Technology, Aug. 24, 2012 (explaining that NVCASE does a reassessment every two years whereas the IAF and ILAC do a reassessment every 4 years). *See also supra* notes 19 - 21 and accompanying text.
[406] 77 Fed. Reg. 19357 (Mar. 30, 2012).
[407] *Id.*

conformity assessment standards and guides, referred to collectively as the conformity assessment (or CASCO) toolbox.[408]

It is important to note, however, that ISO standards and guides are ordinarily subject to copyright restrictions. Some have suggested that this could potentially 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.[409] Several documents that provide context for and explain these standards are publicly available.[410]

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. While particular characteristics may not preclude or determine suitability, they may weigh in favor or against.

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.[411] 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.

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[408] ISO/UNIDO, *supra* note 10, at 170-174 (providing a chart of all standards and guides related to conformity assessment).

[409] *See* Administrative Conference of the United States, Recommendation 2011-5, Incorporation by Reference, 77 Fed. Reg. 2,257 (Jan. 17, 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, *Incorporation by Reference in Federal Regulations*, Report to the Administrative Conference 26-32 (Oct. 19, 2011) (discussing ways agencies have increased public access to copyrighted standards); Comments of Scott Rafferty in Response to Request for Information OMB-2012-0003 at 10-11 (posted May 18, 2012) (noting high cost of ISO standards and suggesting that "lack of meaningful access is a particularly serious barrier to wider use of standardized conformity assessment in federal regulatory programs… Agencies can be reluctant to delegate inspection or audit functions if the procedural and operational principles are not openly posted on the internet.").

[410] *See especially* ISO/UNIDO, *supra* note 10; ANSI, 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; USTR, *supra* note 20; Johnson, *supra* note 6; Gordon Gillerman, *Making the Confidence Connection: Conformity Assessment System Design*, ASTM Standardization News (December 2004), *available at* http://www.astm.org/SNEWS/DECEMBER_2004/gillerman_dec04.html; Maureen A. Breitenberg, NIST, The ABC's of the U.S. Conformity Assessment System (April 1997), *available at* http://gsi.nist.gov/global/docs/pubs/NISTIR_6014.pdf; National Research Council, *supra* note 25.

[411] Hatanaka, *supra* note 316, 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").

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 a NIST official, the more control that is needed, the greater the resources that are required.[412]

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.[413] 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 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 (VCS) rather than a governmental-unique standard. In the NRTL program, the standards are all VCSs; in the CPSC program, some of the standards are VCSs. When the standard is a VCS, private sector bodies may already 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.[414]

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.

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[412] Interview (by phone), Gordon Gillerman, Chief, Standards Services Division, National Institute of Standards and Technology, Aug. 15, 2012.

[413] 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.

[414] 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 US regulatory standard in the future. Interview (by phone), David Kalins, Office of Compliance, CDRH, FDA, July 31, 2012. 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.[415] 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).

There may be situations in which self-declaration can serve the regulatory purpose at hand.[416] Some regulatory programs may involve "low to medium-risk areas in which market mechanisms… can mitigate the negative consequences associated with non-compliances before those consequences are intolerable to society."[417] 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 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 can't 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 imply significant costs to the agency.[418] Costs would be incurred in developing the program; approving third parties and training them; ensuring that conflicts of

[415] Memorandum from Ruth Mead et al., ERG, to Suzanne Kocchi and Kong Chiu, USEPA Headquarters, Washington DC, Review of Verification Systems in Environmental Reporting Programs (Feb. 10, 2009) (on file with author) [hereinafter "EPA Verification System Memo"].
[416] *Cf.* Johnson, *supra* note 6, at 29 (stating that businesses prefer 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").
[417] Gillerman, *supra* note 410.
[418] EPA Verification System Memo, *supra* note 415, at 26.

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. 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."[419] Several of the third-party programs reviewed above also suggest that program establishment may be costly and slow.[420]

On the other hand, even if there are significant set-up costs, they may be justified in light of 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 (7-10 employees).[421] If the program had not been established, it can be 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 Water Sense 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 Water Sense, 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 US. 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.[422]

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[419] 74 Fed. Reg. 56282 (Oct. 30, 2009) (stating "developing 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").

[420] *See especially* notes 328 to 336 and accompanying text (on the shrimp aquaculture pilot) and note 362 and accompanying text (on the FDA AP Inspections program).

[421] Interview (by phone), George Tannahill, FCC Office of Engineering and Technology, August 27, 2012. 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% of the applications (2,645 applications). In 2011, FCC processed only 1.6% of applications (218 applications), and TCBs processed the rest (13,427 applications). *Id.*

[422] 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 293 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.

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 Inspections 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.[423] Similarly in the 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."[424] The narrative portion of the auditors' reports under the PMAP varied in length from three to twenty pages, with large variability in the format and level of detail.[425]

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 on on-site auditing will enable us to effectively target verification resources while also providing the necessary consistency and quality in the data."[426] EPA also found that 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.[427]

Third-party 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, and possibly more difficult for the public to understand and participate in. 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.[428] In third-party programs for regulatory purposes, 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.[429]

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[423] Interview (by phone), David Kalins, Office of Compliance, CDRH, FDA, July 31, 2012.
[424] PMAP report, *supra* note 162, at 3.
[425] *Id*.
[426] 74 Fed. Reg. 56282 (Oct. 30, 2009).
[427] *Id*. at 56283.
[428] *See* A Glossary of Political Economic Terms: Agency Problem, http://www.auburn.edu/~johnspm/gloss/agency_problem (last visited Sept. 12, 2012).
[429] *Cf.* 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

4. If the use of third parties will be voluntary, evaluate whether sufficient incentives exist to attract participation

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 inspections program exemplifies the problem. The FDA invested significant resources into its establishment but it was seldom used by industry.[430] 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.[431]

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 their 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.[432] The goal of the program is to enable a single audit/inspection of a medical device manufacturer's quality management system would 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 the degree of assurance its user needs.[433] 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 a nonconformity in a purchased product. The purchaser might instead impose a variety of special requirements on the supplier and require third-party certification.

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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").

[430] *Cf.* FDA 13485 Program Guidance, *supra* note 35, at 3 (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.

[431] *See supra* notes 379 to 385 and accompanying text.

[432] Interview (by phone), Kim Trautman, Associate Director, International Affairs, Office of the Center Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration, Jun. 5, 2012.

[433] *See supra* note 24 and accompanying text.

The same principle applies in third-party programs for regulatory purposes. 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.[434] 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, governmental oversight has been sporadic and little evidence exists of active enforcement of third-party program rules.

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.[435] 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,

[434] Gillerman, *supra* note 410.

[435] *Cf.* NIST Guidance, *supra* note 398, § 287.4(c) (advising agencies to "Use 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 "Consider using the results of other agencies' conformity assessment procedures").

companies were concerned that participation in WaterSense would require them to duplicate testing and reporting required for Department of Energy plumbing standards and the Federal Trade Commission appliance labeling standards.[436] In response, the WaterSense program made its reporting requirements similar or identical to what manufacturers already had do for DOE and FTC.

Extensive private sector conformity assessment standards and activities are also available to be incorporated into regulatory third-party programs. [437] Most significantly, as described above, ISO/IEC have developed a set of international conformity assessment standards and an international conformity assessment industry has emerged to conduct related activities.[438] 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.[439] Regulated entities fear that government-unique standards with be duplicative of private sector conformity assessment activities that they already engage 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."[440]

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 US standard equivalent, and if 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.

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[436] EPA WaterSense, Comments on the May 2007 Draft WaterSense Certification Scheme 14 (Nov. 2007), *available at* http://www.epa.gov/WaterSense/docs/cert_scheme_comments508.pdf; *cf.* FTC, Labeling FAQs, http://www.ftc.gov/bcp/conline/edcams/eande/faq.htm (last visited Sept. 12, 2012); DOE, Energy Efficiency and Renewable Energy, Building Technologies Program, http://www1.eere.energy.gov/buildings/appliance_standards/residential/plumbing_products.html (last visited Sept. 12, 2012).

[437] *Cf.* NIST Guidance, *supra* note 398, § 287.4(e) (directing agencies to "Identify 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.")

[438] NIST Guidance, *supra* note 398, § 287.4(d) (directing agencies to "Use relevant guides or standards for conformity assessment practices published by domestic and international standardizing bodies as appropriate in meeting regulatory and procurement objectives").

[439] *See, e.g.*, Comment of Air-Conditioning, Heating and Refrigeration Institute (AHRI) on Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities (Apr. 26, 2012), *available at* https://law.resource.org/pub/us/cfr/regulations.gov.docket.02/0900006480ffd5af.pdf.

[440] *See id*. at 3; *see also* American National Standards Institute, ANSI Response to Request for Comments, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities 5, *available at* http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/Critical%20Issues/FederalRegister_OMBA119/ANSI%20Response%20OMB-A119_FINAL.pdf (advocating solutions based on VCS to reduce the costs of compliance for industry).

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 bodies for membership.[441] 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 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.[442] 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."[443]

The FDA's aquaculture pilot illustrated some of the challenges faced by agencies that directly accredit certification bodies, particularly in an international context.[444] 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 application 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."[445]

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.

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 an private accreditation body to ISO Guide 65 and also meet a certain set of requirements specific to a third-party program. The accreditation body might be given responsibility for assessing

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[441] *See supra* notes 19 to 23 and accompanying text.
[442] USDA OIG, *supra* note 341, at 3.
[443] *Id.* at 19; *Cf.* USDA, AMS, GV Division, "Quality Manual for Accrediting Conformity Assessment Bodies," http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5073714 (last visited Sept. 12, 2012).
[444] Assessment of Pilot for Aquacultured Shrimp, *supra* note 294.
[445] *Id.* at 7.

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 Guide 65 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 Guide 65'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 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 arises about the public availability of those standards.[446] 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 and other interested parties both during rulemaking and following promulgation."[447]

The public should also have access to certain types of information about the compliance of regulate entities. If a third-party program replaces a regulatory compliance program, the same types of information that were accessible to the public before the implantation 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

[446] *See especially* Administrative Conference of the United States, *supra* note 409.
[447] *Id.* at 5.

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-party answer directly to the agency rather than just the regulated agency that has contracted it. For example, FSMA requires that accredited labs send their test results directly to the FDA.[448] One commentator has called this "a game-changing requirement" that "alters the whole dynamic between labs and their clients," making them "directly responsible to the public (i.e., the government) to ensure that information is disclosed about their client."[449]

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.[450] 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.[451]

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. 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. 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 accredited auditor must immediately notify the FDA if it "discovers a condition that could cause or contribute to a

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[448] 21 U.S.C. § 350k(b)(2).
[449] Daniel R. Dwyer, Third-Party Accreditation under the FDA Food Safety Modernization Act (March 7, 2012), http://www.kkblaw.com/blog/archives/206.html (last visited Sept. 12, 2012).
[450] *See* http://www.energystar.gov/ia/partners/downloads/mou/AB_Comment_Matrix.pdf (providing matrix that summarizes comments on the condition and criteria for recognition of accreditation bodies for Energy Star laboratory recognition); *see also* http://www.energystar.gov/index.cfm?c=partners.intro_conf_calls#accred (listing of stakeholder comments on draft accreditation body requirements).
[451] *Id.* at 2.

serious risk to the public health" during either a regulatory or a consultative audit.[452] As stated by one industry commenter, "We 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."[453] Agencies should consider pros and cons of limiting the types of confidentiality that regulated entities expect when they contract privately with third parties.

Information technology (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."[454]

In sum, a change in the "communicative energy" of third-party conformity assessment is required in a regulatory context.[455] The default in the private sector is for the third party to disclose his audit report exclusively to his client.[456] 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.[457] For an assessment to serve public regulatory purposes, much richer information about its process and outcomes is necessary.[458]

4. Commit to undertaking appropriate oversight activities

When an agency establishes a regulatory third-party program, its role changes from being the guardian to guarding the guardians.[459] Governmental oversight of third-party programs is essential to ensuring that the program is fulfilling its regulatory purpose. 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 program actors. In principal, the same enforcement strategies and tools would apply in enforcing third-party program rules as apply in enforcing other regulatory rules. The agency must require certain types of reporting, conduct regulatory inspections to verify compliance, and impose sanctions as deemed necessary to respond to noncompliance. The

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[452] 21 U.S.C. § 384d(c)(4)(A); *see also* FDA, Imports, http://www.fda.gov/Food/FoodSafety/FSMA/ucm257980.htm (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?").
[453] Comment of International Dairy Foods Association, Re: Docket Nos. FDA-2011-N-0143, FDA-2011-N-0144, FDA-2011-N-0145, FDA 2011-N-0146; Food and Drug Administration; FDA Food Safety Modernization Act: Title 111—A New Paradigm for Importers (Apr. 28, 2011), *available at* http://www.idfa.org/files/IDFA_FSMA_Import_Comments_042811.pdf.
[454] Assessment of Pilot for Aquacultured Shrimp, *supra* note 294, at 26.
[455] Christine Parker, *Regulator-Required Corporate Compliance Program Audits*, 25 LAW & POL'Y 221, 235 (2003).
[456] *See id.*
[457] *Id.*
[458] *See id.*
[459] Martin Shapiro, WHO GUARDS THE GUARDIANS? (1988).

difference is that the agency's third-party program rules apply to the private bodies that form the third-party system rather than the regulated entities themselves.

An agency that establishes a third-party program should set forth, to the extent possible, how it intends to conduct such oversight. The agency may determine, 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 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 "consider 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."[460]

The agency would also retain 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.[461] Its enforcement actions "play a central role in maintaining the validity of the program and ensuring public trust" in the label.[462]

As in traditional regulatory programs, agencies should be equipped to receive and respond to information about potential noncompliances from the public. In an investigation of the NOP program, the USDA OIG found that that "NOP officials did not have adequate procedures or a system for tracking the receipt, review, and disposition of complaints and any subsequent enforcement actions."[463] 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 certain activities of accreditation bodies and conformity assessment bodies that provide information for oversight purposes. Accreditation bodies may be required for example, 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.[464] In both cases, the agency might also require that some or all of the audits be unannounced rather

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[460] Assessment of Pilot for Aquacultured Shrimp, *supra* note 294, at 21.
[461] USDA OIG, *supra* note 341.
[462] *Id.* at 8.
[463] *Id.* at 1.
[464] Energy Star requires CBs to operate a partner-funded verification testing program to ensure products meet Energy Star standards. DOE, Energy Star Appliance Verification Testing – Pilot Program Summary Report 22 (Feb. 3, 2012), http://www1.eere.energy.gov/buildings/appliance_standards/pdfs/energystar_pilotprogram_report_02_03_12.pdf (last visited Sept. 12, 2012).

than announced.[465] In its investigation of the NOP's organic milk program, the OIG milk found that certifying agents were not performing unannounced inspections of organic dairy operations.[466] While unannounced inspections are not required by NOP regulations, OIG and other stakeholders consider them to play a "critical role" in ensuring compliance.[467] 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.

[465] Albersmeier et al., *supra* note 3 , at 933, tbl. 5 (showing that a superior risk-oriented approach includes "randomly chosen audits without announcement" rather than "regular audits with announcements").
[466] USDA Office of Inspector General, Agricultural Marketing Service, National Organic Program – Organic Milk, Audit Report 01601-0001-Te (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.
[467] *Id.* at 17.

Appendix A: Interviews by Phone and Email

By Phone:

David Alderman, Standards Services Division, National Institute of Standards and Technology

Cheri Courtney, Director, Accreditation & International Activities Division, National Organic Program, U.S. Department of Agriculture

Bob Biersner, Office of the Solicitor, U.S. Department of Labor

Charlotte Christen, U.S. Food and Drug Administration

Bridget Dooling, Office of Information and Regulatory Affairs, U.S. Office of Management and Budget

Sandra B. Eskin, Director, Food Safety Campaign, The Pew Health Group

Jim Estep, Occupational Safety & Health Administration, U.S. Department of Labor

Gordon Gillerman, Chief, Standards Services Division, National Institute of Standards and Technology

David Hinden, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency

Eamon Monahan, Energy Star Program, U.S. Environmental Protection Agency

David Kalins, Office of Compliance, Center for Devices and Radiological Health, U.S. Food and Drug Administration

Kevin Robinson, Occupational Safety & Health Administration, U.S. Department of Labor

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Appendix B: ISO Standards for Conformity Assessment Activities

Conformity Assessment Activity	Relevant International Standard
Supplier's Declaration of Conformity (SDoC)	ISO/IEC 17050, "Conformity assessment - Supplier's declaration of conformity"
Testing	ISO/IEC 17025, "General requirements for the competence of testing and calibration laboratories."
Inspection	ISO/IEC 17020, "Conformity assessment -- Requirements for the operation of various types of bodies performing inspection"
Certification	ISO/IEC Guide 65, "General requirements for bodies operating product certification systems" (expected to be replaced by ISO/IEC 17065, "Conformity assessment -- Requirements for bodies certifying products, processes and services").
Accreditation	ISO/IEC 17011, "General requirements for accreditation bodies accrediting conformity assessment bodies."

Appendix C: List of Abbreviations

Abbreviation	Description
AAMI	Association for the Advancement of Medical Instrumentation
A2LA	American Association for Laboratory Accreditation
AMS	[USDA] Agricultural Marketing Service
ANSI	American National Standards Institute
AP	Accredited Person(s)
AP Program	Inspection by Accredited Persons Program
ASTM	American Society for Testing and Materials
CASCO toolbox	Collective term for conformity assessment standards and guides developed by the ISO Committee on Conformity Assessment
CB	Certification Body
CMS/ITRI	Center for Measurement Standards/Industrial Technology Research Institute (China)
CoP	Medicare Conditions of Participation
CPSC	Consumer Product Safety Commission
CPSIA	Consumer Product Safety Improvement Act of 2008
CSL	Curtis Straus LLC
DfE	EPA Design for Environment label
DOE	Department of Energy
EPA	Environmental Protection Agency
FACA	Federal Advisory Committee Act
FAQs	Frequently Asked Questions
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FDAMA	FDA Modernization Act of 1997
FDCA	Federal Food, Drug, and Cosmetic Act
FMRC	Factory Mutual Research Corporation
FOIA	Freedom of Information Act
FSMA	Food Safety Modernization Act of 2011
GAO	Government Accountability Office
GAP/GHP	[USDA] Good Agricultural Practices/Good Handling Practices Audit Program
HVAC	Heating, ventilation, and cooling equipment
IAF	International Accreditation Forum
IAS	International Accreditation Services Inc.
ICSP	Interagency Committee on Standards Policy
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
IOM	[FDA] Investigations Operations Manual
ISO	International Organization for Standardization
ISO/IEC	International Organization for Standardization/ International Electrotechnical Commission
ISO/UNIDO	International Organization for Standardization / United Nations Industrial Development Organization
IT	Information technology
MDSAP	Medical Device Single Audit Program
MDUFMA	Medical Device User Fee and Modernization Act of 2002
MLA	IAF Multilateral Recognition Agreement

Abbreviation	Description
MRA	ILAC Mutual Recognition Agreement
NIST	National Institute of Standards and Technology
NOP	National Organic Program
NRTL	National Recognized Testing Laboratory
NTTAA	National Technology Transfer and Advancement Act of 1995
NVCASE	[NIST] National Voluntary Conformity Assessment Evaluation program
OIG	Office of Inspector General
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
PMAP	Pilot Multi-Purpose Audit Program
RF	Radio frequency
QMI	Quality Management Institute (Canada)
QS	Quality System
SDoC	Supplier's Declaration of Conformity
SMTL	Supervised Manufacturers' Testing Laboratory
TCB	Telecommunication Certification Body
TPCAB	Third Party Conformity Assessment Body
TPRB	[FDA] Third Party Recognition Board
UL	Underwriters Laboratories, Inc.
UNIDO	United Nations Industrial Development Organization
USDA AMS	USDA Agricultural Marketing Service
USTR	Office of the United States Trade Representative
VCS	Voluntary consensus standard
VQIP	Voluntary Qualified Importer Program
WMTL	Witnessed Manufacturers' Testing Laboratory