Voluntary Codes and Standards

Introduction to Voluntary Codes and Standards: A Teaching Guide and Resources

Cary Coglianese
University of Pennsylvania

www.pennreg.org/codes-standards

This material was developed under the auspices of the Penn Program on Regulation using federal funds under awards 70NANB15H343 and 70NANB15H344 from the National Institute of Standards and Technology (NIST), U.S. Department of Commerce. Any statements, findings, conclusions, and recommendations are those of the individual authors and do not necessarily reflect the views of the Penn Program on Regulation, the University of Pennsylvania, NIST, or the U.S. Department of Commerce.

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I. Introduction

Most law students and lawyers associate codes and standards with legally binding rules. The typical law school curriculum pays very little, if any, attention to another type of codes and standards: ones that are voluntary. Voluntary codes and standards are not created by government agencies, but are documents developed by nongovernmental organizations to guide the design and functioning of industrial processes and commercial products and services. Notwithstanding their voluntary nature, these nongovernmental codes and standards influence industry behavior and can have wide-reaching impacts on modern products and industry practices. Furthermore, voluntary codes and standards may be made legally binding through their incorporation by reference into binding law by governmental lawmaking bodies.

The current degree of emphasis placed upon voluntary codes and standards in law school curricula—virtually none—does not serve law students well. Voluntary codes and standards can and sometimes do substitute for government regulations. They can also interact in other important ways with a wide variety of domains of the law, including tort law, contracts, criminal law, intellectual property, environmental law, and international trade. The goal of this module is to provide law instructors with the resources to give their students an opportunity within existing courses on legal subjects to learn about voluntary codes and standards. This module explains how voluntary codes and standards are developed and implemented so students can better understand what they are. It also explains ways that voluntary codes and standards are relevant to legal practice. This module is meant to provide instructors with a level of detail sufficient to teach students how voluntary codes and standards operate, what organizations create these codes and standards, and how these codes and standards interact with the law.

II. Learning Objectives

This Guide will provide faculty with the background material needed to introduce students to the ecosystem of voluntary codes and standards, allowing them to fulfill one or more of the following four major learning objectives:

- *Voluntary Codes & Standards*. Students will learn:
    - the difference between binding law and voluntary codes and standards

* Edward B. Shils Professor of Law and Professor of Political Science, and Director, Penn Program on Regulation at the University of Pennsylvania. I am grateful for exceedingly helpful comments from Emily Bremer on an earlier draft of this teaching guide, as well as for extensive research support from Lily Moran, other excellent research assistance from Audrey Adams, Neharika Goyal, Kat Hefter, Stephanie Haenn, Brianna Rauenzahn, Angel Reed, and Timothy von Dulm, and instrumental efforts by Andrew Coopersmith to bring this guide to completion.

- the difference between voluntary codes and voluntary standards
- how voluntary codes and standards are developed
- how voluntary codes and standards interact with law and legal practice

These materials will also afford instructors an opportunity to encourage students to think critically about both the advantages and disadvantages of voluntary codes and standards as a governance tool.

- *Standard-setting organizations*. Students will learn what standard-setting organizations are and how they develop voluntary codes and standards. Although each standard-setting organization will be different from others, students will also learn the common steps that these organizations follow to create voluntary codes and standards.

- *Federal Law and Voluntary Codes and Standards*. Although voluntary codes and standards are not binding law, some traditional sources of law do speak to these standards and their relationship with federal regulation. Specifically, students will learn about:
  - The National Technology Transfer and Advancement Act of 1995 (NTTAA)
  - Office of Management and Budget (OMB) Circular A-119
  - The Consumer Product Safety Improvement Act of 2008 (CPSIA)

- *Incorporation by Reference:* Students will learn what incorporation by reference is and how the process of incorporation brings voluntary codes and standards into the law. Students will also be introduced to the legal rights that standard-setting organizations have to copyright their documents. Another teaching guide in the Penn Program on Regulation's online collection of teaching materials on voluntary codes and standards explores incorporation by reference in depth.[1] This present introductory module only briefly touches on incorporation by reference and raises just one basic question that students might wish to discuss, namely whether members of the public should be expected to purchase copyrighted voluntary codes and standards to know what has been incorporated by reference into the law.

III. Materials in this Course Module

The materials listed below may be used both to help prepare instructors to teach a class on voluntary codes and standards and to provide materials for students to review ahead of class discussion. All of the following materials for this module can be found online at www.codes-and-standards.org:

- Teaching guide (this document)
- "Teaching Voluntary Codes and Standards to Law Students," 7-page overview by Cary Coglianese & Caroline Raschbaum (suitable for assignment to students in advance)
- Selected Reading Materials (either for assignment to students or preparation of the instructor—or both)

[1] Emily S. Bremer, When Technical Standards Meet Administrative Law: A Teaching Guide on Incorporation by Reference, available at https://www.law.upenn.edu/live/files/7770-bremer-ibr-teaching-guidepdf.

- PowerPoint Slides (optional if the instructor chooses to lecture for some or all of the class session)
- Videos available on the website under the module for "Introduction to Voluntary Codes and Standards" (suitable for assignment to students in advance or for display during class)
- Primer on Voluntary Codes and Standards (possible handout for students to read in preparation for class discussion or simply as supplemental reading)

IV. Background for Instructors

Voluntary codes and standards are documents or statements that specify norms for behavior or product design or performance that are developed by standard-setting organizations. In the United States, these standard-setting organizations are nongovernmental entities. Voluntary codes and standards are often written in the same form as binding legal rules but, unlike statutes created by legislatures or regulations adopted by administrative agencies, they do not by themselves constitute binding law.

Although many provisions in voluntary codes and standards can be extremely technical, many also read much like the provisions of public regulatory codes and standards. Consider the following sample provisions from actual voluntary codes and standards:

- "Combustible waste material creating a fire hazard shall not be allowed to accumulate in buildings or structures or upon premises."[2]
- "Emergency personnel and equipment must be able to access the building."[3]
- "The organization shall identify training needs. It shall require that all personnel whose work may create a significant impact upon the environment, have received appropriate training."[4]
- "No open-flame producing devices or equipment shall be permitted within the confines of the crop maze."[5]
- "Common use circulation paths within employee work areas shall be accessible routes."[6]

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[2] I INT'L CODE COUNCIL, INT'L FIRE CODE § 304.1, GENERAL REQUIREMENTS COMBUSTIBLE WASTE MATERIAL, (2021) available at https://codes.iccsafe.org/content/IFC2021P1/chapter-3-general-requirements (last visited July 15, 2021).

[3] AM. SOC'Y OF HEATING, REFRIGERATING, & AIR-CONDITIONING ENG'R, ASHRAE 29-2019, GUIDELINE FOR THE RISK MANAGEMENT OF PUBLIC HEALTH AND SAFETY IN BUILDINGS. § 5.41. BUILDING PLANNING AND DESIGN: GENERAL CONSIDERATIONS, (2019) available at https://www.ashrae.org/technical-resources/standards-and-guidelines/read-only-versions-of-ashrae-standards (under the headline Current Popular ASHRAE Standards and Guidelines, click on Guidelines 29-2019) (last visited July 15, 2021).

[4] INT'L ORG. FOR STANDARDIZATION, ISO 14001: STANDARDS ON ENVIRONMENTAL MANAGEMENT SYSTEMS, (1996), available at https://www.iso.org/standard/23142.html?browse=tc (last visited July 17, 2021), as quoted in GREGORY JOHNSON, THE ISO 14000 EMS AUDIT HANDBOOK (CRC Press 2006).

[5] NAT'L FIRE PROT. ASS'N, NFPA 1: FIRE CODE § 10.14.12.3.1 (2021), available at https://www.nfpa.org/codes-and-standards/all-codes-and-standards/list-of-codes-and-standards/detail?code=1 (last visited July 15, 2021).

[6] INT'L CODE COUNCIL, INT'L BLDG. CODE: § 1104.3.1 ACCESSIBILITY: ACCESSIBLE ROUTES, (2021), available at https://codes.iccsafe.org/content/IBC2021P1/chapter-11-accessibility (last visited July 17, 2021).

- "Materials, systems, and equipment shall be identified in a manner that will allow a determination of compliance with the applicable provisions of this code." [7]

Voluntary codes and standards like these are referred to by a variety of terms, such as "consensus standards," "industry codes," "private standards," or just plain "codes and standards." They are created by entities that can be variously referred to as standard-setting organizations (SSOs), standards developing organizations (SDOs), or even just standards-developers. As noted above, whatever the label used, voluntary codes and standards do not by themselves constitute binding law.

This background section of the teaching guide provides an overview of the world of voluntary codes and standards to aid the instructor in introducing law students to this world. It is a world that comprises the work of hundreds of standard-setting organizations and which involves the work of engineers and other professionals as much as, if not more than, lawyers. Still, lawyers need to know about voluntary codes and standards.

A. Why Law Students Should Learn about Voluntary Codes and Standards

Perhaps because they are not directly binding, voluntary codes and standards are seldom introduced to prospective lawyers during law school. But voluntary codes and standards can and do affect lawyers' work and the work of their clients; they may sometimes matter as much as if not more than the binding laws that make up the main focus of study in law school. These voluntary codes and standards can also provide a source for the content of binding law. When these voluntary norms are formally incorporated into public law, they can become binding on anyone.

Voluntary codes and standards can affect clients in a variety of ways and across many practice settings.[8] These voluntary codes and standards often define methods for conducting business operations, the qualities of manufactured materials and goods, or requirements for the delivery of services. They can thus become the basis for contractual disputes. But they can have a wide-ranging impact on a variety of legal realms, including intellectual property, international trade, and risk regulation. They can even determine the handling procedures for evidence in criminal law. In a wide range of substantive areas of the law, voluntary codes and standards can affect both clients and the work of lawyers in representing those clients.

Overall, voluntary codes and standards can be important tools for advancing larger societal goals, such as safety, health, and consumer protection. The work performed by standard-setting organizations can affect the economy and society in countless ways. Without voluntary codes and standards, consumer products would likely be less safe. Cell phones and other digital products would not be able to interact with one another. Houses would be more prone to damage and collapse in the face of hurricanes, earthquakes, and other natural disasters. These are just a few of the ways in which voluntary codes and standards help produce value to society.

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[7] INT'L CODE COUNCIL, INT'L ENERGY CONSERVATION CODE § C303.1 GENERAL REQUIREMENTS, (2021) available at https://codes.iccsafe.org/content/IECC2021P1/chapter-3-ce-general-requirements#IECC2021P1_CE_Ch03_SecC303 (last visited July 17, 2021).

[8] For a series of extended examples, see Part IV.E *infra*.

Just by their numbers alone, voluntary codes and standards may rival if not exceed annually the number of laws passed by legislatures or regulations adopted by administrative agencies. And despite their technically voluntary nature, in practice these private standards can shape behavior as much as any public law.

A consideration of voluntary codes and standards, and the manner in which they interact with the law, presents an opportunity for students to consider an alternative set of governing mechanisms. It even allows them to learn more about legal mechanisms by engaging in a comparison with voluntary, private approaches to governance.

Although voluntary codes and standards are not binding in nature, they do not operate altogether independently of the law. Instead, they often work alongside, and sometimes in place of, formal legislation. Codes and standards permeate business contracts as parties grapple with questions about conformity, tort law as they are used to establish a duty of care, and criminal law as they guide the handling of evidence. Voluntary codes and standards have led to standard essential patents in intellectual property law. They are closely intertwined with administrative and regulatory law in a range of substantive fields, and the procedures used by private organizations to create voluntary codes and standards often similar to those followed by government agencies.

The study of voluntary codes and standards can raise challenging and thought-provoking questions for law students. Since businesses create and control the decisions of standard-setting organizations, they can present questions about the risks of private regulatory capture—that is, when businesses take over regulatory power and use it to their own advantage at the expense of public interest. These questions—and others—take on even deeper significance when governmental bodies incorporate private standards into law, through a process known as incorporation by reference. When private voluntary codes and standards are incorporated by reference, they become binding law, even though their exact content is not copied into the law itself. Although they are referred to in binding law, and become themselves binding law, they are still copyrighted and owned by the standard-setting organization that created them. This raises the question of whether it is reasonable to require regulated businesses and members the public to pay a fee to the standard-setting organization to read what has become law. Should copyright law take precedence over our right to freely view the law? What would be the consequences if the government disregarded intellectual property rights in such a manner?

These are just some of the questions that law students can explore in the course of being exposed to the world of voluntary codes and standards. Given the extensive role these private codes and standards can play in society and the economy, no legal education should be considered complete without at least some awareness being imparted about the existence of voluntary codes and standards and the ways they touch the world and affect the work of lawyers and their clients.

B. Key Terminology

In introducing students to the world of voluntary codes and standards, instructors should be mindful of basic terminology. What the professionals who develop voluntary codes and standards mean by “codes” and “standards” differs from what lawyers and legal scholars often mean by these same terms. In fact, your law students will have already encountered other uses of the terms

"codes" and "standards." For codes, they will have certainly heard of the U.S. Code, which contains all federal statutory law. They will know that many of the judge-made principles of criminal law have been *codified* and can now be found in criminal *codes* adopted by state legislatures.

With respect to "standards," students will have heard of a *standard* of care from their study of torts. Students who have taken administrative law may know that some government agencies develop regulatory *standards*: e.g., the National Highway Traffic Safety Administration (NHTSA) issues motor vehicle safety standards and the Consumer Product Safety Commission (CPSC) issues product safety standards. All of these regulatory standards comprise binding rules adopted by governmental bodies.

Students may have also encountered the jurisprudential distinction between *rules*, which are stated with precision (such as "do not exceed 55 miles per hour"), and *standards*, which are stated in a more open-textured fashion (e.g., "do not drive at an unreasonable speed").[9] But standards in the jurisprudential context are still binding law; the only difference is the degree of precision with which such law is expressed.

To facilitate learning, instructors will want to distinguish voluntary codes and standards from these other uses of the terms "codes" and "standards" that law students will encounter.

The key difference with voluntary codes and standards is that they are not binding law—hence, they are "voluntary." They also emanate from nongovernmental organizations, rather than from legislatures, administrative agencies, or courts. Ultimately, instructors should aim to illuminate the underlying concepts rather than dwell on mere semantics. But because semantics can sometimes stand in the way of conceptual clarity, it is worth taking some time to make a point about nomenclature.

Some caution is in order, though, as matters are further complicated by the fact that a variety of different terms are used by professionals in the world of voluntary standards to refer to the same basic normative materials. It has even been said that "[n]omenclature in the standards area has its pitfalls."[10]

The term used in this teaching guide—"voluntary codes and standards"—is actually a variation on a several different terms used in the field. Sometimes both "codes" and "standards" are referred to simply as "standards." Such codes and standards may also be referred to as "private standards," "nongovernmental standards," "industry standards," and "voluntary consensus standards." Because many voluntary codes and standards deal with product engineering or other technical issues, they are also commonly referred to as "technical" standards.

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[9] *See, e.g.,* Barbara Luppi & Francesco Parisi, *Rules Versus Standards,* in 7 ENCYCLOPEDIA OF LAW AND ECONOMICS 43, 49-50 (Gerrit De Geest ed., 2d ed. 2009); Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L.J. 557, 562 (1992); FREDERICK SCHAUER, PLAYING BY THE RULES: A PHILOSOPHICAL EXAMINATION OF RULE-BASED DECISIONMAKING IN LAW AND IN LIFE (1991); Colin S. Diver, *The Optimal Precision of Administrative Rules*, 93 YALE L.J. 65 (1983).

[10] Robert W. Hamilton, *Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety or Health*, 56 TEX. L. REV. 1329, 1331 n.1 (1978).

A few of these various terms are defined in law or other official government materials. For example, the National Technology Transfer and Advancement Act (NTTAA), a federal statute, defines "technical standards" that have been "developed or adopted by voluntary consensus standards bodies" as "performance-based or design-specific technical specifications and related management systems practices."[11] The Office of Management and Budget (OMB) has issued Circular A-119 to address federal agencies' involvement in voluntary standard-setting and their reliance on voluntary codes and standards.[12] Circular A-119 contains a section entitled, "What is a Standard?," that then answers this question as follows:

> The term "standard," or "technical standard," (hereinafter "standard") as cited in the NTTAA, includes all of the following: (i) common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices; (ii) the definition of terms; classification of components; delineation of procedures; specification of dimensions, materials, performance, designs, or operations; measurement of quality and quantity in describing materials, processes, products, systems, services, or practices; test methods and sampling procedures; formats for information and communication exchange; or descriptions of fit and measurements of size or strength; and (iii) terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process, or production method.
>
> The term "standard" does *not* include the following:
> (i) professional standards of personal conduct; or
> (ii) institutional codes of ethics.[13]

The OMB Circular further defines a "voluntary consensus standard" as "a type of standard developed or adopted by voluntary consensus standards bodies, through the use of a voluntary consensus standards development process," in accordance with criteria outlined in the Circular.[14]

Legal scholars have opted for somewhat more succinct definitions. For example, Professor Emily Bremer defines "voluntary consensus standards" simply as "technical standards developed by private sector organizations using an open process that respects due process, includes an appeals process, and results in a consensus among participants representing a balance of interests."[15] Professor Jorge Contreras states that "[t]echnical standards specify methods by which complex technologies interact and interoperate."[16]

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[11] National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, 110 Stat. 775, 783 (1996).
[12] OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, [https://perma.cc/EZB8-QLNT] (notice of availability published at 81 Fed. Reg. 4673 (Jan. 27, 2016)). A full copy of the Circular, as revised in 2016, can be found online at: https://www.nist.gov/system/files/revised_circular_a-119_as_of_01-22-2016.pdf.
[13] *Id*. at 15.
[14] *Id*. at 16
[15] Emily S. Bremer, *Incorporation by Reference in an Open-Government Age*, 36 HARV. J.L. & PUB. POL'Y 131, 1364 (2013).
[16] Jorge L. Contreras, *Standards, Patents, and the National Smart Grid*, 32 PACE L. REV. 642, 654 (2012).

Nongovernmental standard-setting organizations have also offered their own definitions. Training materials produced by the American National Standards Institute (ANSI), an organization which produces standards for how standard-setting organizations should operate, state:

> Simply put, a standard is an agreed-upon way of doing something. In practice, it is a document that sets specific guidelines for the design, operation, manufacture, and use of nearly everything produced by mankind. There are standards to protect human health, safety, and the environment, and others to ensure that different products work compatibly together.[17]

ASTM International, a standard-setting organization, describes a standard as "a document that has been developed and established through ASTM's consensus principles and which meets the requirements of our procedures and regulations. Full consensus standards are developed with the participation of stakeholders with an interest in their development and use."[18]

The key to understanding what makes a code or standard voluntary is to focus on two defining characteristics: (1) its non-binding nature, and (2) its source in a process undertaken by a nongovernmental organization. The late law professor Robert W. Hamilton captures these features when he notes that "standards produced by the nongovernmental sector are 'voluntary.'"[19] He contrasts voluntary standards with regulations (or regulatory standards) that are "produced by state or federal governmental action" and that "are 'mandatory.'"[20]

As should be apparent, although these definitions distinguish voluntary standards from binding regulations, they do not always distinguish between voluntary *standards* and voluntary *codes.* This may be because these terms can be thought of as largely coterminous. The main difference is that voluntary codes tend to be (just as with statutory codes) comprehensive collections of norms, such as a voluntary building code that addresses all facets of a building's construction. By comparison, most voluntary standards are more discrete and limited in their topical scope, such as by being focused on a specific product or even function of a product. The National Fire Protection Association, for example, defines a "code" as "[a] standard that is an extensive compilation of provisions covering broad subject matter or that is suitable for adoption into law independently of other codes and standards."[21] In addition to the difference in scope and form between voluntary codes and standards, many times voluntary codes are expressly developed and designed for the purpose of being incorporated into law—such as with voluntary model building codes—whereas

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[17] *Standards 101,* AM. NAT'L STANDARDS INST., https://share.ansi.org/shared%20documents/Education%20and%20Training/Committee%20on%20Education/2014_USA_Science_Engineering_Festival/Standards%20101%20flyer.pdf (last visited July 17, 2021).

[18] *Frequently Asked Questions*, ASTM Int'l, https://www.astm.org/FAQ/ (last visited July 18, 2021).

[19] Hamilton, *supra* note 10. Commenting on the second feature of a voluntary code or standards—that is, its source outside of government, Hamilton notes that "[t]he phrase 'private standards' is sometimes used as a synonym for 'nongovernmental standards,' but the former phrase has been objected to because it causes confusion with 'proprietary standards,' *i.e.,* standards developed by a single industrial firm for its exclusive use, and because some standards-setting organizations do not consider themselves 'private' in the usual sense of the term." *Id.*

[20] *Id.*

[21] *Terminology*, NAT'L FIRE PROT. ASS'N, available at https://www.nfpa.org/Codes-and-Standards/Resources/Terminology (last visited July 18, 2021).

voluntary standards are not necessarily developed with the intention that they be incorporated into law.[22]

At least two parallels to voluntary codes and standards might come to mind for law students. First, students are likely to see a parallel with the Model Penal Code, which is developed by a nongovernmental organization—the American Law Institute (ALI). The Model Penal Code is not itself binding law, but it can become so once it is adopted by a state legislature. In this respect, the Model Penal Code has many of the same properties as a voluntary code or standard, such as a voluntary building code developed by the International Code Council—also a nongovernmental organization. Despite this conceptual parallel, of course, the Model Penal Code is not generally considered part of the world of voluntary codes and standards because it is a criminal code, rather than dealing with technical matters of product design or operational management of industry activity, and it is intended solely for adoption by state legislatures. The Model Penal Code is mainly proposed legislation, rather than a voluntary code or standard aimed at guiding business behavior regardless of whether it is ever adopted into law.[23]

Second, students with a background in administrative law may see the distinction between *binding laws* versus *voluntary codes and standards* as parallel to the distinction between *legislative rules* versus *agency guidance* (that is, interpretative rules or policy statements). Legislative rules are binding law created by administrative agencies, while guidance documents are non-binding.[24] The main difference between agency guidance documents and voluntary codes and standards, though, is that the latter emanate from nongovernmental entities. That said, as will be discussed later in this guide, even with their provenance in nongovernmental standard-setting organizations, voluntary codes and standards can sometimes be transformed effectively into a legislative rule through a process known as *incorporation by reference.*[25] As Hamilton has noted, "many voluntary standards are adopted or incorporated by reference through governmental action, … thereby becoming mandatory in fact though voluntary in origin."[26]

One final terminological note: Although lawyers speak of "compliance" with the law, those involved in the world of voluntary codes and standards instead refer to "conformity" with the provisions of voluntary codes and standards. ANSI defines a "conformity assessment" as a separate process which confirms whether products meet relevant voluntary codes and standards: an "activity concerned with determining directly or indirectly that relevant requirements are

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[22] The majority in the Fifth Circuit Court's en banc decision in Veeck v. Southern Building Code Congress Int'l, Inc., made a point to note that the voluntary code developer in that case actively "encourages local government entities to enact its codes into law by reference." 293 F.3d 791 (5th Cir. 2002).

[23] Students may also perhaps think of the Uniform Commercial Code (UCC) as another similar example. As with the Model Penal Code, the UCC is developed by the Uniform Law Commission, a separate organization comprising members who are selected as delegates from the states. But as with the Model Penal Code, it is developed specifically as proposed legislation, as its drafters aim to see all or most states adopt it. As a result, even though the UCC bears certain similarities to the kinds of voluntary codes and standards addressed in this teaching guide, it is oriented more toward state actors than the private actors that are the principal target of the guidance provided by voluntary codes and standards.

[24] For discussion of agency guidance, see, for example, Ronald M. Levin, *Rulemaking and the Guidance Exemption*, 70 ADMIN. L. REV. 263 (2018); Cary Coglianese, *Illuminating Regulatory Guidance*, 9 MICH. J. ENVTL. & ADMIN. L. 243 (2020).

[25] Further discussion of incorporation by reference can be found *infra* at notes 33-36 and accompanying text, as well as in Part IV.D.4.

[26] Hamilton, *supra* note 10.

fulfilled."[27] Conformity assessment encompasses testing of products, accreditation of test methods, and the accreditation of testers.[28]

C. The Institutional Ecosystem of Voluntary Codes and Standards

Voluntary codes and standards are developed by non-governmental standard-setting organizations. Hundreds (if not thousands) of such organizations exist worldwide.[29] The process of developing codes and standards can, though, involve the participation of representatives from governmental organizations. Moreover, several key governmental bodies have addressed issues related to standards are important for students and practicing lawyers to understand. This section of the teaching guide contains brief descriptions of some of the key organizations acting in the standards-development space.

Organizations noted with an asterisk (*) below have video interviews with representatives of these organizations available on the Penn Program on Regulation's Voluntary Codes and Standards website as part of the "Introduction to Codes and Standards" Module. These short clips may be useful additions to show as background during a lesson, or a short assignment for background research before class.

Within the world of voluntary codes and standards exist two main types of organizations: (1) those that provide oversight and even accreditation related to the development of standards; and (2) those that actually create standards themselves (that is, standard-setting organizations).

The first type of organization governs standard setting. One organization—the American National Standards Institute (ANSI), a nongovernmental body—provides standards and accreditation for the standards-developing process that other organizations use to create standards. Other organizations—governmental ones—establish rules or guidelines that govern how federal agencies can rely on standards.

- American National Standards Institute (ANSI)*

  ANSI is a private, not-for-profit stakeholder which develops frameworks for "fair standards development and quality conformity assessment systems."[30] ANSI itself is not a standard-setting organization, but it helps to facilitate and coordinate the U.S. standardization system overall by setting criteria for the processes that standard-setting organizations use in developing voluntary codes and standards and deploying conformity assessment activities. ANSI also helps ensure a voice for U.S. companies, other interested

[27] *National Conformity Assessment Principles for the U.S.*, AM. NAT'L STANDARDS INST., available at https://www.standardsportal.org/usa_en/conformity_assessment/conformity_assessment.aspx (last visited July 13, 2021).
[28] *The ABCs of Conformity Assessment*, NAT'L INST. OF STANDARDS & TECH., available at https://doi.org/10.6028/NIST.SP.2000-01 (last visited July 13, 2021).
[29] In the United States alone, more than 230 standard-setting organizations have been accredited by the American National Standards Institute (ANSI). *Homepage*, AM. NAT'L STANDARDS INST., https://ansi.org/ (last visited July 13, 2021).
[30] *Introduction*, AM. NAT'L STANDARDS INST., https://www.ansi.org/about/introduction (last visited July 13, 2021).

organizations, and persons in the international standard-setting community.[31] It advocates for the global use of voluntary codes and standards adopted by U.S. standard-setting organizations.[32]

- National Institute of Standards and Technology (NIST)*

  Part of the U.S. Department of Commerce, the National Institute of Standards and Technology (NIST) conducts research to advance technology infrastructure.[33] Section 12 (a)(3) of the National Technology Transfer and Advancement Act (NTTAA) amended the National Institute of Standards and Technology Act to task NIST with helping to facilitate federal government monitoring of and input into the processes of setting voluntary codes and standards.[34] Section 12 (b) (3) of the NTTAA created the same responsibility for conformity assessment activities.[35] NIST in general, then, assists federal agencies in how they might shape and rely on voluntary codes and standards.[36]

- Office of Management and Budget (OMB)

  The Office of Management and Budget (OMB) is an office within the White House tasked with budgetary responsibilities as well as other management-related issues such as the coordination and review of federal regulations issued by agencies across the federal government.[37] OMB has played a role with respect to voluntary codes and standards by issuing and periodically updating Circular A-119. This document, last updated in 2016, provides guidance to federal agencies as to their reliance on voluntary codes and standards. Its aim is to "improve the internal management of the Executive Branch with respect to the U.S. Government's role in the development and use of standards and conformity assessment."[38]

- Office of the Federal Register

  The Office of the Federal Register (OFR), situated within the National Archives and Records Administration, publishes a daily publication called the *Federal Register* that includes final and proposed agency rules, among other documents. Under Section 552(a) of the Administrative Procedure Act (APA) (a part of the APA that is also known as the

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[31] *U.S. Representation in ISO*, AM. NAT'L STANDARDS INST., https://ansi.org/iso/us-representation-in-iso/introduction (last visited, July 13, 2021).
[32] *Homepage*, AM. NAT'L STANDARDS INST. https://ansi.org/ (last visited July 13, 2021).
[33] *NIST Homepage*, NAT'L INST. OF STANDARDS & TECH., https://www.nist.gov/ (last visited, July 13, 2021).
[34] National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, 110 Stat. 775, 783 (1996) (noting NIST's role "[t]o coordinate the use by Federal agencies of private sector standards, emphasizing where possible the use of standards developed by private, consensus organizations").
[35] *Id.* (noting NIST's role "[t]o coordinate Federal, State, and local technical standards activities and conformity assessment activities, with private sector technical standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures"').
[36] *Key Federal Law and Policy Documents: NTTAA & OMB A-119,* NAT'L INST. OF STANDARDS & TECH., https://www.nist.gov/standardsgov/what-we-do/federal-policy-standards/key-federal-directives (last visited, July 13, 2021).
[37] *Office of Management and Budget*, THE WHITE HOUSE, https://www.whitehouse.gov/omb/ (last visited July 13, 2021).
[38] OMB Circular A-119, *supra* note 12.

Freedom of Information Act), agencies must publish both procedural and substantive rules adopted by the agency in the *Federal Register*.[39] Ordinarily, all agency rules must be published in the *Federal Register* to be considered binding federal law.[40] The APA, however, provides an option known as *incorporation by reference* that allows the content of a rule to become binding, even if that content does not appear in the *Federal Register.* Section 552(a)(1) of the APA provides as follows:

> For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the *Federal Register* when incorporated by reference therein with the approval of the Director of the *Federal Register*.[41]

Acting under this authority, the OFR has established regulations governing how agencies can incorporate rule content by reference. Under OFR's regulations, what agencies must do to ensure that incorporated materials are "reasonably available" to the public has been deliberately left undefined. The regulations instead require that an agency "[s]ummarize, in the preamble of the final rule, the material it incorporates by reference" and explain "the ways that the materials it incorporates by reference are reasonably available to interested parties and how interested parties can obtain the materials."[42]

The organizations listed above belong to the first type of entities that establish a governing framework for standard-setting and governmental reliance on standards. As noted above, though, a second set of organizations—standard-setting organizations—actually develop voluntary codes and standards. These organizations of the second type typically follow accredited processes that accord with criteria established by ANSI. Some of these organizations are U.S.-based, while others are international. All are nongovernmental. Several examples of standard-setting organizations include:

- American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE)

  The American Society of Heating, Refrigerating and Air-Conditioning Engineers is a standard-setting organization focusing upon aspects of buildings such as heating, ventilation, and air conditioning systems and their energy efficiency.[43]

- ASTM International (ASTM)*

  ASTM International creates voluntary, consensus driven standards on many issues, including consumer products, aviation safety, and laboratory testing.[44] ASTM is one of

[39] 5 U.S.C. § 552(a)(1). The OFR also publishes a separate publication, the Code of Federal Regulations (CFR), which organizes agency rules into a code arranged by subject matter.
[40] The APA states that "a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published." 5 U.S.C. § 552(a)(1).
[41] *Id*. Further information about incorporation by reference is provided in Section Part IV.D.4 of this teaching guide as well as at the Penn Program on Regulation's voluntary codes and standards website, www.codes-and-standards.org.
[42] Incorporation by Reference, 1 C.F.R. § 51.5 (2014). For further discussion, see *infra* Part IV.E.4 (notes 115-134).
[43] *About ASHRAE*, AM. SOC'Y OF HEATING, REFRIGERATING, & AIR-CONDITIONING ENG'R, https://www.ashrae.org/about (last visited, July 13, 2021).
[44] *About Us,* ASTM INT'L, https://www.astm.org/ABOUT/overview.html (last visited, July 13, 2021).

the largest standard-setting organizations in the world, with more than 12,000 standards.[45] The organization works to form common standards on how products should perform and the testing methods for those products. In addition, ASTM provides training on testing procedures and performs interlaboratory study programs to help research labs in reproducing test methods.[46]

- International Code Council (ICC)*

  The International Code Council is a nonprofit organization that develops building safety standards addressing aspects of "product evaluation, accreditation, certification, codification and training."[47] The overarching goal of this standard-setting organization is to ensure safer buildings through the development of comprehensive international construction codes[48] which cover many facets of building and construction, such as fire protection, electrical systems, plumbing, HVAC, and even emergency exits for escape rooms.[49]

- Institute of Electrical and Electronics Engineers (IEEE)

  The Institute of Electrical and Electronics Engineers is a standard-setting organization focused on electrical, electronic, and computing products and technologies.[50]

- International Organization for Standardization (ISO)[51]

  The International Organization for Standardization is an international standardization organization with a membership of more than 165 national standards bodies.[52] The ISO allows only one member representative per country;[53]ANSI serves as the U.S. representative to ISO.[54] Based in Geneva, Switzerland, the ISO develops standards designed to ensure compatibility and interoperability across products, identify and manage safety risks in products and services, and facilitate information-sharing.[55] ISO has

[45] *Frequently Asked Questions*, ASTM INT'L, https://www.astm.org/ABOUT/faqs.html (last visited July 13, 2021).
[46] Penn Program on Regul., *Can You Describe the Process by Which ASTM Develops Standards*, YOUTUBE (June 12, 2018), https://www.youtube.com/watch?v=5iPuZOgzTfQ.
[47] *About the International Code Council*, INT'L CODE COUNCIL, https://www.iccsafe.org/about/who-we-are/ (last visited July 13, 2021).
[48] *Id.*
[49] *Int'l Bldg Code, About This Title,* INT'L CODE COUNCIL, https://codes.iccsafe.org/content/IBC2021P1/chapter-11-accessibility (last visited July 17, 2021).
[50] *History of IEEE*, INST. OF ELEC. & ELEC. ENG'R, https://www.ieee.org/about/ieee-history.html (last visited July 13, 2021).
[51] *ISO in Brief*, INT'L ORG. FOR STANDARDIZATION, https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100007.pdf.
[52] *About Us*, INT'L ORG. FOR STANDARDIZATION, https://www.iso.org/about-us.html (last visited July 13, 2021).
[53] *Members*, INT'L ORG. FOR STANDARDIZATION, https://www.iso.org/members.html (last visited July 13, 2021).
[54] *Id*.
[55] *ISO in Brief,* INT'L ORG. FOR STANDARDIZATION, https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100007.pdf.

adopted more than 23,000 standards[56] on products and processes as varied as playground safety and toothbrushes,[57] and refrigerators and nuclear power plants.[58]

- National Fire Protection Association (NFPA)

  The National Fire Protection Association is a nonprofit standard-setting organization which was established to reduce risks caused by fire and electrical hazards. It designs standards "establishing criteria for building, processing, design, service, and installation around the world."[59] In addition to publishing codes and standards guides, which are available for a fee, the NFPA also provides other services, including public education, training programs, and fire data analysis and research.

A brief discussion or introduction to one or more of these organizations in class, or as a background assignment preparatory to class, might be helpful for students to understand what standards are and where they come from. The range of issues addressed by these organizations can help communicate to students how voluntary codes and standards are important for various industries and different areas of legal practice. A listing of additional standard-setting organizations can be found in Appendix A to this teaching guide. Instructors may also find useful the videos associated with this module on the Penn Program on Regulation's voluntary codes and standards website (www.codes-and-standards.org), along with other materials located in "Reading Room" section of that website.

A final note about the above-mentioned standard-setting organizations (e.g., ASTM, NFPA, ISO, IEEE): they are all nongovernmental organizations. The government in the United States, through NIST and, on specific issues, other agencies, does follow what these organizations are developing. Government officials can and do get involved in the standard-setting process essentially as any other "stakeholder" would.[60] The staff of the U.S. Consumer Product Safety Commission (CPSC), for example, will attend and participate in ASTM meetings.

By contrast, in other countries, it is not uncommon for an even stronger and tighter nexus to exist between standard-setting organizations and government officials.[61] In fact, the standard-setting organizations in some countries are even constituted as governmental or quasi-governmental bodies. For example, South Korea's leading standard-setting organization, the Korean Agency for Technology and Standards (KATS), is a governmental body.[62]

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[56] *Standards Catalogue*, INT'L ORG. FOR STANDARDIZATION, https://www.iso.org/standards-catalogue/browse-by-ics.html (last visited July 13, 2021).
[57] *ICS 97*, INT'L ORG. FOR STANDARDIZATION, https://www.iso.org/ics/97/x/ (last visited July 13, 2021).
[58] *ICS 27*, INT'L ORG. FOR STANDARDIZATION, https://www.iso.org/ics/27/x/ last visited July 13, 2021).
[59] *NFPA Overview,* NAT'L FIRE PROT. ASS'N, https://www.nfpa.org/overview (last visited July 13, 2021).
[60] CONSUMER PROD. SAFETY COMM'N, *Voluntary Standards Activities Ann. Rep* at 10 (2020), https://www.cpsc.gov/s3fs-public/FY20-Annual-VSTAR-Report-FINAL_0.pdf?V9QY4qf9AqYhEHPDEqzzDZVq.7YeizcZ.
[61] *See* Emily S. Bremer, *American and European Perspectives on Private Standards in Public Law*, 91 TULANE L. REV. 325 (2016) (discussing how, "[i]n Europe, national governments established close relationships with private standards development organizations, resulting in a standardization system that, while nongovernmental, is coordinated, hierarchical, and directly regulated," and where the European Union even awards "funding to certain officially recognized European standards development organizations to develop new technical standards specifically designed to facilitate compliance with the essential requirements of specified EU legislation").
[62] NAT'L INST. FOR STANDARDS & TECH., NISTIR 7905, A PRIMER ON KOREA'S STANDARDS SYSTEM (2013), http://dx.doi.org/10.6028/NIST.IR.7905.

In the United States, although government agencies can and do send representatives to participate in standard-setting processes, they are not themselves standard-setting organizations even though, as noted above, administrative agencies can also issue non-binding normative statements called guidance. A few government agencies—such as the National Institute of Justice (NIJ) in the U.S. Department of Justice[63]—sometimes consider themselves to be akin to standard-setting bodies, as they create what they themselves consider to be "voluntary standards." Although these standards operate formally as a legal matter as agency guidance, when such guidance covers technical issues related to topics that are of the type usually covered by nongovernmental voluntary codes and standards (e.g., product standards), the agencies and other professionals interacting with them may at times consider these also to be similar to the kinds of technical standards adopted by standard-setting organizations.

The NIJ, for example, sees itself as an organization within the U.S. Department of Justice that, among other things, "identifies the need for new or improved standards"[64] and, when these standards cannot be developed adequately by nongovernmental organizations, "to develop new and update existing standards" itself.[65] By way of illustration, one such NIJ-created "voluntary standard" is NIJ Standard 0101.06 on Ballistic Resistance of Body Armor.[66] As this standard covers a topic and set of issues related to others that nongovernmental SSOs could also create—for example, ASTM has standards for the fit and measuring of body armor[67]—it is not difficult to see why the NIJ might consider itself to be in the business of setting "voluntary standards," especially since they are not binding. Nevertheless, for purposes of this teaching guide—and in almost all instances in practice—voluntary codes and standards in the United States will have been developed by nongovernmental standard-setting organizations.

Voluntary codes and standards thus differ from regulations not only in that they are not binding but also in that they are developed by these non-governmental institutions. Of course, as discussed further below, standards that begin as voluntary may become legally binding if they define a standard of care in tort law or become incorporated by reference into legislation or regulatory law.[68]

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[63] In a chapter in a leading NFPA publication, a general overview of voluntary codes and standards in building and construction lists the General Services Administration (GSA) and Department of Defense (DOD) as examples of standard-setting organizations. The GSA, for example, does provide standards for the construction of federal buildings, which cover topics similar to those contained in ICC or NFPA voluntary codes. Of course, for anyone contracting with the federal government to construct government buildings, the GSA "standards" will not be voluntary. Arthur E. Cote, and Casey C. Grant, *Codes and Standards for the Built Environment in* FIRE PROTECTION HANDBOOK 51-66, (20th ed. 2008), available at https://www.nfpa.org/~/media/files/forms%20 and%20premiums/fire%20protection%20handbook/codesfph.pdf.

[64] NAT'L INST. OF JUST., *Developing Technology Standards,* https://nij.ojp.gov/topics/articles/developing-technology-standards (last visited July 19, 2021).

[65] *Id.*

[66] NAT'L INST. OF JUST., NIJ STANDARD-0101.06: BALLISTIC RESISTANCE OF BODY ARMOR (2008), https://www.ojp.gov/pdffiles1/nij/223054.pdf.

[67] ASTM INT'L, ASTM E3003 – 20: STANDARD PRACTICE FOR BODY ARMOR WEARER MEASUREMENT AND FITTING OF ARMOR (2020), https://www.astm.org/Standards/E3003.htm.

[68] Further information about incorporation by reference is provided in Section Part IV.D.4 of this teaching guide as well as at the Penn Program on Regulation's voluntary codes and standards website, www.codes-and-standards.org.

Whether they are incorporated into law or not, voluntary codes and standards are sometimes said to constitute a form of private regulation or "soft law."[69] Instructors may thus wish to encourage their students to reflect on the role that private regulation plays in society's overall system of governance. Voluntary codes and standards may, for example, provide for important coordination and governance on many issues for which government agencies are unable to provide sufficient regulation of an activity or industry. They may provide predictability and clarity in areas where coordination is needed but where the law is silent. Voluntary codes and standards may also hold certain advantages over government regulations in that they are based on industry-specific expertise and may be more adaptable relative to government regulation. Standard-setting organizations' potential to act more quickly and nimbly than some government agencies may make them appropriate venues for governing new technology, such as artificial intelligence.[70] That said, to the extent that voluntary codes and standards are truly voluntary, they might also fail to provide sufficient behavioral motivation in some settings, and government regulation may be needed. These potential advantages and disadvantages of voluntary codes and standards are discussed in further detail below.

D. The Making of Voluntary Codes and Standards

Although different standard-setting organizations can use somewhat different processes to create voluntary codes and standards, the process of standard-setting is sufficiently similar that it can be described in general terms. Often the process involves extensive input from experts and other interested persons through procedures based on the consensus of committee members and other participants in the standard-setting process. The reliance largely on a consensus-based decision-making process is what leads some professionals to refer to voluntary codes and standards as *consensus standards*.

ANSI has established what it calls "essential requirements" for any organization's standard-setting process. The aim of these requirements is to provide "due process" in creating consensus standards by standard-setting organizations. ANSI has established the following essential requirements for a standard-setting process:

1) openness, such that all "materially interested" parties may participate (although a membership or participation fee may be charged);
2) "lack of dominance," to ensure consideration of multiple viewpoints;
3) a balance of interested parties;
4) coordination and efforts to resolve conflicts;
5) "notification of standards activity" to inform interested parties;
6) consideration to all written viewpoints submitted;
7) consensus votes;

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[69] *See, e.g.,* Lesley K. McAllister, *Harnessing Private Regulation*, 3 MICH. J. ENVTL. & ADMIN. L. 291-419 (2014).
[70] *See, e.g.*, Carlos Ignacio Gutierrez, Gary Marchant & Lucille Tournas, *Lessons for Artificial Intelligence from Historical Uses of Soft Law Governance*, 61 JURIMETRICS 133 (2020); GARY E. MARCHANT, KENNETH W. ABBOTT, BRADEN ALLENBY, EDS., INNOVATIVE GOVERNANCE MODELS FOR EMERGING TECHNOLOGIES (2013).

8) "realistic and readily available" appeals procedures; and
9) use of written and available procedures.[71]

These requirements are similar to those listed in OMB Circular A-119's definition of a standard-setting organization. According to OMB, standard-setting organizations are organizations that develop standards with:

1) openness, such that "interested parties" have "meaningful opportunities to participate";
2) balance, with "meaningful involvement from a broad range of parties" and no "dominance" in the process;
3) due process, including "adequate notice of meetings" and "sufficient time" to prepare responses;
4) an appeals process; and
5) consensus, meaning "general agreement, but not necessarily unanimity."[72]

Standard-setting is typically a committee-driven process. Committees are made up of representatives from relevant industries along with academic experts, government representatives, and other interested persons.

In this respect, the process followed by ASTM is illustrative of the process followed by many standard-setting organizations. ASTM's process comprises three levels of review and decision-making, organized in a hierarchy: task groups, subcommittees, and main committees.[73] Once an idea for a standard has reached ASTM, a task group within the assigned subject-matter committee begins the legwork of creating a draft standard and forwarding it up the hierarchy.[74] The standard must pass a vote on all levels to be adopted as an ASTM standard. Negative votes must be submitted with written statements explaining the technical reason that a draft standard should not be adopted or should be modified. In the face of one or more negative votes, a draft standard can be either modified to address the objections or the objections can be deemed to be unpersuasive.

As noted, representatives from government agencies frequently participate in the processes that lead to the creation of voluntary codes and standards. In fact, according to the National Technology Transfer Advancement Act of 1995, federal agencies are encouraged to "consult with voluntary, private sector, consensus standards bodies and shall, when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities, and budget resources, participate with such bodies in the development of technical standards."[75]

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[71] *ANSI Essential Requirements 2021*, AM. NAT'L STANDARDS INST., https://www.ansi.org/american-national-standards/ans-introduction/essential-requirements (last visited July 13, 2021).
[72] OMB Circular A-119, *supra* note 12.
[73] *Standards Development in ASTM*, ASTM INT'L, https://www.astm.org/studentmember/StandardsProcess.html (last visited July 13, 2021).
[74] Penn Program on Regul., *Can You Describe the Process by Which ASTM Develops Standards*, YOUTUBE (June 12, 2018), https://www.youtube.com/watch?v=5iPuZOgzTfQ.
[75] National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, 110 Stat. 775, 783 (1996).

E. The Interaction Between Voluntary Codes and Standards and the Law

If voluntary codes and standards are voluntary, some law students may well ask: "Why is it important for lawyers to know about them?" One purpose of this teaching guide is to offer instructors some answers to this reasonable question.

Voluntary codes and standards interact with the law in numerous ways across a wide range of substantive domains of the law and legal practice. Perhaps the best way to appreciate how voluntary codes and standards can affect the work that lawyers do is to provide examples of ways that private standards have intersect with litigation and other aspects of legal practice. In the sections below, six examples are elaborated below in the following domains: products liability; patent law; contracts; administrative law; international trade; and criminal law.

1. Products liability

Voluntary codes and standards can sometimes determine or help determine the standard of care in tort cases, especially in products liability cases. The prevailing "reasonable care" standard can often make it difficult for triers of fact to determine if a standard of care has been met in products liability cases, but voluntary codes and standards can provide helpful guideposts.

For lawyers, understanding relevant voluntary codes and standards, as well as understanding the process by which they are developed, can help them better analyze tort liability issues for their clients. In many products liability cases, the standard of care may be defined by reference to industry customs of the time of the design, manufacture, construction, or sale of the product. Failure to conform with voluntary codes and standards can function as a sword for the plaintiff in a products liability matter.

The Nevada Supreme Court in *M & R Investment Co. v. Anzalotti* upheld the trial court's instruction to the jury that both the manufacturer and the owner of an elevator must be presumed negligent if the elevator violated an industry safety code and the violation caused the injury.[76] This instruction to refer to the voluntary industry code added a bright line to what would have otherwise been a much murkier liability determination.

Some states have adopted legislation specifically providing for voluntary codes and standards to be used in tort cases. The Washington Products Liability Act, for example, explicitly allows triers of fact to consider whether a product conformed to a relevant voluntary code or standard related to its design, construction, performance, warnings, or instructions.[77] Kentucky has a similar statute, but goes further by creating a rebuttable presumption that a product is not defective if its design and manufacturing conform to the standard in place at the time of design and manufacturing.[78] Indiana, like Kentucky, creates a rebuttable presumption that a product is not defective if it conforms with the standards of the time in which it is "designed, manufactured, packaged, and labeled" or if it conforms with codes and standards created or adopted by the government.[79]

[76] M & R Inv. Co. v. Anzalotti, 773 P.2d 729, 730 (Nev. 1989) (per curiam).
[77] Wash. Rev. Code Ann. § 7.72.050 (1981).
[78] Ky. Rev. Stat. § 411.310 (1978).
[79] Ind. Code Ann. § 34-20-5-1 (1998).

Conformity with voluntary codes and standards may thus sometimes serve as a manufacturer's shield in defending against claims that a manufacturer did not satisfy its duty of care. For example, in *McKinnon v. Skil Corp.*, a consumer sued a power saw manufacturer in federal court following injuries that occurred when using the saw.[80] One point of contention on appeal centered on the district court's decisions to admit into evidence a voluntary industry standard developed by Underwriter's Laboratory (UL) but not a federal Occupational Safety and Health Administration (OSHA) regulation.[81] The U.S. Court of Appeals upheld the district court's decisions with respect to both the OSHA regulation and the UL standard.[82] The appellate court reasoned that the OSHA regulation was not sufficiently relevant to defining an industry standard of care because OSHA "may impose a standard of conduct upon employers greater than that which would be considered reasonable in the industry."[83] By contrast, the UL standard was reasonably related to industry custom and practice and thereby provided, in a case involving a consumer product, "some evidence of the defendant's due care regarding the design and manufacture of the saw."[84]

Moreover, the *McKinnon* court noted that the admission of the UL standard enabled the defendant to undermine the testimony of the plaintiff's expert witness.[85] The product design engineer for the defendant manufacturer had testified to his familiarity with the UL standard and to the product's conformity with that voluntary standard. But the plaintiff's expert witness, by contrast, admitted on cross-examination to noticing the UL seal of approval on the plaintiff's saw but not to knowing anything about the UL standard for power saws. As a result, the evidence of the UL standard served to "cast doubt upon the thoroughness of [plaintiff expert's] investigation of the saw and upon the extent of his general knowledge of the design and manufacture of portable circular saws."[86] (For this reason, this case provides an additional lesson for attorneys: select experts who have knowledge of relevant voluntary codes and standards!)

In another case altogether, the California Supreme Court held in *Kim v. Toyota Motor Corp.* that voluntary codes and standards may be admissible under a risk-benefit test used in strict liability cases involving claims of defective products, and in so doing the court upheld the denial of the plaintiffs' motion to exclude such evidence.[87] The risk-benefit test allows a manufacturer to escape liability in a products liability case if the benefit of the product's design outweighs the risks of the design.[88] Under *Kim*, voluntary codes and standards may be admitted because they may help a jury determine if the manufacturer's risk-benefit analysis in designing the product reflects the industry's standard of risk and benefit in that product.[89]

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[80] 638 F.2d 270 (1st Cir. 1981).
[81] About, UL STANDARDS, https://ulstandards.ul.com/about/ (last visited May 27,2022).
[82] 638 F.2d 276-277.
[83] *Id* at 275.
[84] *Id*. at 276-77.
[85] *Id* at 277.
[86] *Id*.
[87] Kim v. Toyota Motor Corp., 424 P.3d 290 (Cal. 2018).
[88] Judicial Council of California Civil Jury Instructions No. 1204 (2020), available at https://www.justia.com/trials-litigation/docs/caci/1200/1204/.
[89] *Kim*, 424 P.3d 290.

Of course, voluntary codes and standards will not always be allowed as evidence in products liability litigation. In Pennsylvania, for example, the state supreme court upheld a trial court's decision to exclude evidence of an American Society of Mechanical Engineers standard related to electric hoists in a strict liability case.[90] Although the manufacturer of the allegedly defective electric hoist had hoped to introduce the standard to show its conformity with industry norms, the trial court ruled that such conformity was irrelevant in a strict products liability case because negligence was not an issue.[91]

2. Patent law

When a standard requires that a manufacturer or other business use a specific patented technology, that technology is referred to as a standard-essential patent, or "SEP."[92] Under ANSI's Patent Policy, the patent owner must then license the patent on fair, reasonable, and non-discriminatory terms—or "FRAND" terms.[93] Non-discriminatory here refers to having similar rates for different parties.[94]

FRAND terms help prevent collusion in the standards industry.[95] Patent owners are usually involved with the standards process and are members of standard-setting organizations. They have an interest to see that the only way to meet a standard would be to use a product for which they own the patent. In the absence of a FRAND requirement, the owner of a patent that is essential to a standard's conformity could hold out and demand supra-competitive payments to obtain a license to use its patented product or technique.

When a patent becomes an essential part of a standard, complications can arise surrounding what exactly are the FRAND terms for licensing that patent.[96] Standard-setting organizations do not themselves decide FRAND licensing rates because of the competition concerns raised by companies joining together to set pricing.[97] Consequently, the patent owner and the prospective

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[90] Lewis v. Coffing Hoist Div., Duff-Norton Co., 528 A.2d 590 (Pa. 1987).
[91] *Id*.
[92] Further information about standard-essential patents can be found at the Penn Program on Regulation's voluntary codes and standards website, www.codes-and-standards.org. The website includes a module with a case study based on the *Microsoft v. Motorola* dispute discussed below as well as a teaching guide prepared by Professor Cynthia Dahl on standard-essential patents. These materials can be accessed at: https://www.law.upenn.edu/institutes/ppr/codes-standards/standard-essential-patents.php.
[93] Cynthia Laury Dahl, *When Standards Collide with Intellectual Property: A Teaching Guide to Standard Setting Organizations, Technology, and the Cautionary Tale of* Microsoft v. Motorola*,* PENN PROGRAM ON REGULATION: VOLUNTARY CODES AND STANDARDS, 1–2, available at https://www.law.upenn.edu/live/files/7767-dahl-sep-case-study.
[94] University of Pennsylvania Carey Law School, *What Does It Mean to Set a FRAND Licensing Rate*, YOUTUBE (May 22, 2018), https://www.youtube.com/watch?v=q8YviI5KMoo.
[95] *Id.* A patented technology belonging to a nonmember can also be placed into a standard. The non-member patent owner, however, will not be bound to license on FRAND terms because the FRAND requirement is a contractual one that accompanies membership in the standard-setting organization. For further discussion, see the next section below discussing how voluntary codes and standards can interact with contract law. That said, in part because of competition concerns, FRAND terms are often ill-defined in these member agreements and in some cases may not even be written into any signed document.
[96] Dahl, *supra* note 93, at 3–4.
[97] *Id.* at 4.

licensee must attempt to agree on FRAND terms. (Incidentally, FRAND may also sometimes be called RAND—for "reasonable and nondiscriminatory.")[98]

In *Georgia-Pacific Corp. v. United States Plywood Corp.*, the federal court in the Southern District of New York came up with what is now a widely used method for determining FRAND rates when assessing royalty damages.[99] The *Georgia-Pacific* framework involves imagining a hypothetical negotiation between a licensor and a licensee and considering fifteen factors to determine the rate.[100]

In the *Microsoft v. Motorola* case, Microsoft sued Motorola in federal court for breach of contract after Motorola offered to license certain standard-essential patents to Microsoft at rate that Microsoft considered unreasonably high.[101] Motorola then countersued for patent infringement, as the patents at issue were being used in Microsoft products. The federal court in the Western District of Washington determined the FRAND licensing terms for Motorola's standard-essential patents. The court set the rate much lower than that which Motorola had offered to Microsoft. To determine the rate, the district court judge used a modified version of the *Georgia-Pacific* framework.[102]

FRAND terms now play an integral role in the licensing of standard-essential patents, and, after *Georgia-Pacific* and *Microsoft v. Motorola*, it is clear that disputes over FRAND terms can be the fodder for litigation.[103] Law students intending to practice intellectual property law should therefore have some understanding of voluntary codes and standards and the frameworks for determining FRAND terms for licensing standard-essential patents.

3. Contracts

Voluntary codes and standards appear in contract law. *Microsoft v. Motorola*, as just discussed, arose out of a contractual dispute.[104] The obligation of a patent owner to license a standard-essential patent on FRAND terms arises out of private agreements between member patent holders and the standard-setting organizations to which they belong (such as, in the *Microsoft v. Motorola*

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[98] *Id.* at 4, n. 12 ("SSOs and courts alternately refer to this requirement as either 'FRAND' or 'RAND,' although the two terms refer to the same concept. More typically, professionals in the United States use the term 'RAND,' but in an age of international standards and international companies, the terminological distinction is not a strong one.").
[99] 318 F. Supp. 1116 (S.D.N.Y. 1970).
[100] *Methodologies for Determining Reasonable Royalty Damages*, FISH & RICHARDSON, https://www.fr.com/reasonableroyalty/.
[101] Microsoft Corp. v. Motorola, Inc., 2013 WL 2111217 (W.D. Wash. April 25, 2013).
[102] David Long, *Ninth Circuit Affirms Judge Robart's Rand Decision (Microsoft v. Motorola)*, ESSENTIAL PATENT BLOG (July 31, 2015), https://www.essentialpatentblog.com/2015/07/ninth-circuit-affirms-judge-robarts-rand-decision-microsoft-v-motorola/.
[103] Since *Microsoft v. Motorola*, there have been a few other notable decisions related to SEPS. For example, in *Godo Kaisha IP Bridge 1 v. TCL Communication Technology*, 967 F.3d 1380 (Fed. Cir. 2020) the Federal Circuit held that SEP holders were entitled to back damages from a jury award. *See* MICHAEL RENAUD, JAMES WODARSKI, & DANIEL WEINGER, THE BIG SEP VICTORIES OF PATENT OWNERS IN 2020, LAW 360 (Dec. 21, 2020), available at https://www.mintz.com/sites/default/files/media/documents/2021-01-05/The%20Big%20SEP%20Victories%20Of%20Patent%20Owners%20In%202020.pdf. Another notable case in the SEP landscape was *Federal Trade Commission v. Qualcomm*, 969 F. 3d 974 (9th Cir. 2020). In *Qualcomm*, "the Ninth Circuit effectively foreclosed antitrust law as an avenue to seek relief for breach of a standard-setting organization commitment." *Id.*
[104] A case study based on the *Microsoft v. Motorola* dispute can be found at the Penn Program on Regulation's voluntary codes and standards website, www.codes-and-standards.org.

case, the International Telecommunications Union, or ITU).[105] *Microsoft v. Motorola* involved both patent infringement claims and breach of contract claims.

The first contract issue was whether Microsoft, a third-party to Motorola's FRAND agreements, could bring a breach of contract claim at all. Because both parties were members of FRAND policy-setting entities, such as the ITU, the court held that Microsoft had pled a valid breach of contract claim even though Motorola's FRAND agreements were with the ITU rather than directly with Microsoft. The court then reached the second contract issue, which involved determining what would constitute "fair, reasonable, and non-discriminatory terms."[106] Because both parties contracted to license under FRAND terms, the court in *Microsoft v. Motorola* determined the appropriate rate that it found would conform with FRAND under a modified *Georgia-Pacific* framework.[107]

Beyond contractual disputes over patent licensing and FRAND terms, voluntary codes and standards can interact with contract law in other ways as well. In many instances, voluntary codes and standards are used to define terms in a contract.[108] For example, products may be required to be tested according to ASTM standards, as was case in the contract at issue in *Cities Service Company v. Derby & Company.*[109] The parties had contracted to trade crude oil and agreed that an independent inspector would use tests outlined in certain voluntary standards, such as ASTM's and the American Petroleum Institute's joint "Standard Method of Sampling Petroleum and Petroleum Products," to determine the quantity and quality of the crude oil at the discharge location.[110] The independent inspector, however, did not act in conformity with the standards, resulting in the defendant, Derby & Co., receiving more crude oil than it paid for.[111] A federal district court held for the plaintiff, explaining that when a contract includes a term for an independent third party to determine value according to established standards, "the failure of such independent third party to follow the standards or procedures prescribed in the contract will invalidate any certification or determination so made even if the contract makes such certification or determination conclusive and binding."[112]

Contracts can reference voluntary codes and standards while simultaneously specifying terms even more stringent than industry standards. In *M. Maropakis Carpentry v. United States*, the parties incorporated into their contract by reference standards adopted by the American Architectural Manufacturers Association.[113] Other provisions, however, specified the parties' own terms, some

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[105] Dahl, *supra* note 93, at 3.
[106] *Id*. at 8–9.
[107] In addition to FRAND terms, ANSI's Patent Policy calls for patent owners to disclose potentially relevant patents. Roger G. Brooks & Damien Geradin, *Interpreting and Enforcing the Voluntary FRAND Commitment*, CRAVATH, SWAINE & MOORE, https://www.cravath.com/a/web/536/3234075_1.pdf. The disclosure requirement is an additional source of contract law issues, as under-disclosing may be a breach of contract or of good faith and fair dealing. Long, *supra* note 102, at 6.
[108] *See e.g.*, City of Stoughton v. Thomasson Lumber Co., 675 N.W. 2d 487 (Wis. Ct. App. 2003) (discussing a contract that called for treatment of wooden poles in conformity with ANSI and American Wood Preservers Association in a lumber contract).
[109] 654 F. Supp. 492 (S.D.N.Y. 1987).
[110] *Id*. at 497–98.
[111] *Id*. at 498.
[112] *Id*. at 501.
[113] 2008 WL 4489276 (Fed. Cl. Oct. 3, 2008).

of which were more stringent than the incorporated industry standards. The contract called for the application of industry standards as well as the contract's own stipulations, "whichever are more stringent."[114] In resolving a dispute over the contract, the court held that it was within the contracting parties' rights to demand higher standards than industry standards.[115] It seems clear that, to be able to counsel clients effectively on contractual matters, it can sometimes be important for lawyers to understand the relationship between industry standards referenced in a draft contract and any other specific terms that a draft contract may contain.

4. Administrative law

Voluntary codes and standards can become mandatory when they are given legal effect by legislative or administrative bodies.[116] The building codes developed by the International Code Council and the fire codes developed by the National Fire Protection Association (NFPA), for example, are often adopted by state legislatures, city councils, and building commissions and become part of mandatory codes.

When voluntary codes and standards are incorporated *by reference* into law, the binding law does not have to contain any details of what exactly the incorporated code or standard requires; the law may simply refer to the voluntary code or standard by its name or other identifying number. For example, the building code for Baltimore County, Maryland contains the following provision:

> All generators shall comply with this code as well as the latest editions of NFPA 37 Standard for the Installation and Use of Stationary Combustion Engines and Gas Turbines, and NFPA 110 Standard for Emergency and Standby Power Systems.[117]

Just as voluntary codes and standards can be adopted at the state and local level through incorporation by reference, federal agencies can also make voluntary codes and standards mandatory through incorporation by reference. OMB Circular A-119, which outlines federal policies governing voluntary standards, provides "factors for agencies to consider when evaluating whether to use a standard."[118] Furthermore, the National Technology Transfer and Advancement Act of 1995 (NTTAA) calls on federal agencies to "use technical standards that are developed or adopted by voluntary consensus standards bodies," provided that doing so would not conflict with applicable law or be "otherwise impractical."[119]

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[114] *Id*. at 5.
[115] *Id*. at 18.
[116] Further information about incorporation by reference is provided at the Penn Program on Regulation's voluntary codes and standards website. In particular, an extensive teaching module on incorporation by reference includes a teaching guide and presentation materials prepared by Professor Emily Bremer along with a suite of instructional videos. This module can be accessed at https://www.law.upenn.edu/institutes/ppr/codes-standards/incorporation-by-reference.php.
[117] BALT. CNTY. BLDG. CODE § 128.12 (2015), available at https://resources.baltimorecountymd.gov/Documents/Permits/Building_Plans_Review/2015buildingcode.pdf.
[118] OMB Circular A-119, *supra* note 12.
[119] National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, 110 Stat. 775, https://www.nist.gov/standardsgov/national-technology-transfer-and-advancement-act-1995.

In addition to these general policies, sometimes specific substantive statutes can call upon agencies to adopt voluntary codes and standards. For example, when the Occupational Safety and Health Act was adopted in 1970, it specifically called for the Occupational Safety and Health Administration to "promulgate as an occupational safety or health standard any national consensus standard" unless doing so would not improve safety or health.[120] More recently, Congress included a provision in section 106(a) of the Consumer Product Safety Improvement Act of 2008 mandating that the Consumer Product Safety Commission incorporate specific ASTM standards related to toy safety into mandatory consumer product safety standards.[121]

The incorporation by reference of voluntary codes and standards has raised notable legal questions. Typically, private standard-setting organizations copyright the standards they create and fund their standard-setting processes from the sale of those standards.[122] When legislatures or administrative agencies adopt a voluntary code or standard through incorporation by reference, they do not eliminate the copyright protection given to the code or standard. Instead, to read the incorporated content that the law requires, it is usually necessary for individuals to purchase a copy—at times at significant expense—of the code or standard that has been incorporated by reference.

As a general rule, of course, the law itself is not copyrightable because of public due process concerns. In 2020, for example, the U.S. Supreme Court held that annotations of the Georgia state code, written by a private party hired by a legislative commission, were subject to the government edicts doctrine and could not be copyrighted.[123] However, the U.S. Supreme Court has never directly ruled on whether the incorporation by reference of a private copyrighted code or standard means that the code or standard no longer retains its copyrighted status.[124] There appear to be somewhat inconsistent decisions on this legal question from the federal courts, with the Second[125] and Ninth Circuits[126] holding that private entities are permitted to retain such copyrights to material incorporated by reference, while the Fifth Circuit[127] has suggested that in some circumstances standard-setting organizations may no longer be allowed to retain their copyright to incorporated materials.[128]

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[120] Occupational Safety and Health Act of 1970, § 655(a) 29 U.S.C. §§ 651-678 (1994).
[121] Consumer Product Safety Improvement Act of 2oo8, Pub. L. No. 110-314, § 106a available at http://www.cpsc.gov/cpsia.pdf.
[122] Emily Bremer, *Technical Standards Meet Administrative Law: A Teaching Guide on Incorporation by Reference*, 71 ADMIN. L. REV. 315 (2019).
[123] Ga. v. Public.Resource.Org, Inc., 140 S. Ct. 1498 (2020).
[124] Katie M. Colendich, *Who Owns "the Law"? The Effect on Copyrights When Privately Authored Works are Adopted or Enacted by Reference into Law*, 78 WASH. L. REV. 589 (2003).
[125] CCC Info. Services v. Maclean Hunter Market Reports, Inc., 44 F.3d 61 (2nd Cir.1994).
[126] Practice Management Info. Corp. v. American Medical Ass'n, 121 F.3d 516 (9th Cir.1997).
[127] Veeck v Southern Building Code International, Inc 293 F.3d 791 (5th Cir. 2002), cert. denied 539 U.S. 969 (2003). The Fifth Circuit held that model codes adopted into law cannot be protected by copyright, although the original model code is still technically protected. The Court distinguished model codes written to be adopted wholesale into law from individual voluntary standards, and it reasoned that when a governmental body decides to adopt a model code, the body becomes the author of that law.
[128] In addition, litigation still in progress in the D.C. Circuit has raised these issues. Am. Soc'y for Testing & Materials v. Public.Resource.Org, Inc., 896 F.3d 437 (D.C. Cir. 2018); Am. Soc'y for Testing & Materials v. Public.Resource.Org, Inc., 2022 U.S. Dist. LEXIS 60922 (D.D.C. 2022).

Copyright restrictions placed on incorporated standards, and the corresponding need to pay for such material, has created what legal scholars have argued is a serious obstacle to governmental transparency.[129] As legal scholar Emily Bremer has noted, some scholars argue that incorporation by reference "can erect a barrier impeding access to the law."[130] This is so despite the fact that material incorporated by reference by an federal agency into regulatory must be made available in a public reading room at the agency's offices. In addition, some standard-setting organizations have started to make it possible for members of the public to view at least some incorporated material the organizations' websites without a fee.

As previously noted, the Administrative Procedure Act allows agencies to incorporate voluntary standards into federal regulations provided these materials are "reasonably available" to the public.[131] In 2012, several law professors petitioned the Office of the Federal Register (OFR) to issue a rule that defined reasonable availability to mean that material has been published online and is available to the public for free.[132] OFR rejected the law professors' suggestion, reasoning that such an approach would exceed the OFR's statutory authority.[133] Moreover, OFR cautioned that conditioning incorporation by reference on free online availability of incorporated private standards "could place OFR in the middle of a contentious fight over copyright limitations."[134] Ultimately, OFR declined to define "reasonably available" and opted instead to give agencies flexibility in how they could make incorporated standards available to the public. In a rule it issued in 2014, OFR required agencies to pursue transparency of incorporated material in ways that would be compatible with the copyrights owned by standard-setting organizations.[135] Under the rule, agencies seeking to incorporate voluntary standards by reference must simply explain how they are making the standards available to the public and publish a short summary of the standards in the *Federal Register*.[136]

5. International trade

Both government regulations and voluntary standards play prominent roles in international trade. Although regulations must be complied with, conformity with standards is not mandatory.[137]

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[129] Emily Bremer, *On the Cost of Private Standards in Public Law*, 63 KAN. L. REV. 279 (2015).
[130] Emily Bremer, *Incorporation by Reference in an Open-Government Age*, 36 HARV. J.L. & PUB. POL'Y 131, 136 (2013); *see also* Brief of Administrative Law Professors Cynthia Farina, Michael Herz, et al. as Amici Curiae Supporting Neither Party in Milice v. Consumer Prod. Safety Comm'n, 2021 U.S. App. LEXIS 19764 (D.C. Cir. July 2, 2021) (No. 21-1071) (arguing that the Freedom of Information Act requires that the CSPC be ordered to publish a standard incorporated by reference); Nina A. Mendelson, *Private Control over Access to Public Law: The Perplexing Federal Regulatory Use of Private Standards,* 112 MICH. L. REV. 737-807 (2014) (assessing the growth of incorporation by reference and arguing that incorporation by reference does not allow adequate public access to the law).
[131] *See infra* note 35 and accompanying text.
[132] Office of the Federal Register, Announcement of a Petition for Rulemaking and Request for Comments.77 Fed. Reg. 11,414 (Feb. 27, 2012).
[133] Office of Federal Register, Partial Grant of Petition, Notice of Proposed Rulemaking, 78 Fed. Reg. 60,784 (Oct. 2, 2013); Office of Federal Register, Final Rule, 79 Fed. Reg. 66,267 (Nov. 7, 2014).
[134] 78 Fed. Reg. at 60,790.
[135] 79 Fed. Reg. at 66,278.
[136] *Id*.
[137] WTO Agreement: Agreement on Technical Barriers to Trade (TBT), Jan. 1, 1995, Annex 1, 1868 U.N.T.S. 120. *See generally* Mario De Rosa, *The International Technical Standards and their Legal Effects in the Light of the TBT*

Notwithstanding standards' non-mandatory nature, product conformity with universal standards can facilitate more efficient international trade. The World Trade Organization's Agreement on Technical Barriers to Trade (TBT), for example, emphasizes this point and delineates how member states should prepare, adopt, and apply both regulations and standards to promote productive international trade.[138]

International trade law, in principle and as articulated in the TBT Agreement, limits the ability of countries to impose distinctive regulations that would act as barriers to international trade. For example, the TBT Agreement states that "[m]embers shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade."[139] In addition to limiting members' ability to impose regulations that are restrictive of international trade, the TBT Agreement also includes various provisions that encourage countries to rely on international standards more than their own regulations. For example, member states are directed to use international standards as "a basis for their technical regulations."[140]

Similar provisions favoring the reliance on international standards over domestic regulations were contained in drafts of the Transatlantic Trade Investment Partnership between the European Union and the United States.[141] Similarly, the Trans-Pacific Partnership Agreement, proposed by Obama Administration to facilitate trade and investment in the Asia Pacific, envisioned similar provisions.[142]

Because the TBT Agreement encourages reliance on international standards, the agreement also encourages every member state to contribute to developing international standards.[143] The U.S. plays an active role in setting international standards, such as those adopted by the ISO.[144] Although ANSI is the U.S. representative to ISO, the National Technology Transfer and Advancement Act of 1995 calls for NIST to ensure U.S. interests are adequately reflected in international standards.[145] NIST is housed within the Department of Commerce, and "serves as the U.S. 'inquiry' point for information on proposed regulations that might affect trade."[146]

Agreement, 9 (LUISS Acad. Research Paper No. 2/2013-2014, 2015), https://luissuniversitypress.it/wp-content/uploads/2020/09/Working20Paper20De20Rosa20def-1.pdf.

[138] *See generally* WTO TBT Agreement, *supra* note 137, at art. 1.

[139] *Id.* at art. 2.2.

[140] *Id.* at art. 2.4. Other parts of the TBT point to a need for members to implement standards-related conformity assessments. *Id.* at art. 6.1.1 (calling for "adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting Member").

[141] European Union, T-TIP Textual Proposal for Chapter: Regulatory Cooperation (March 21, 2016), available at https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf (describing the purpose of the chapter as "to further the development and implementation of internationally agreed regulatory documents in order to achieve consistent regulatory outcomes with each other and third countries.").

[142] United States Trade Representative, *Summary of the Trans-Pacific Partnership Agreement*, USTR ARCHIVES (Oct. 2015), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/summary-trans-pacific-partnership.

[143] *See, e.g.*, WTO Agreement, *supra* note 137, at art. 2.6, 5.5.

[144] NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY, NISTIR 8007, A REVIEW OF U.S.A. PARTICIPATION IN ISO AND IEC 6 (2014).

[145] *Id.*

[146] *Id.*

In addition, the Office of the United States Trade Representative (USTR) with its work related to international standards. A member of the National Economic Council (NEC), the USTR is responsible for "developing and coordinating the implementation of U.S. international trade policy."[147] The NEC and the USTR are part of an interagency group called the Trade Policy Staff Committee, which includes a Subcommittee on Standards chaired by the USTR. The Subcommittee on Standards "manages policy coordination and forms U.S. government positions in standards."[148]

6. Criminal law

Standards play an important role related to the criminal law system's goal of ensuring accurate convictions. Some research indicates that up to fifty-two percent of wrongful convictions have resulted from misapplied forensic science.[149] But the practices undertaken within forensic laboratories are generally not regulated by law,[150] but instead operate under voluntary standards.[151] Those laboratories that can show that their equipment, techniques, and operations conform to the applicable voluntary standards for can become accredited.[152]

The most comprehensive set of voluntary standards related to forensic science have been issued by ASTM International, a nongovernmental standard-setting organization.[153] ASTM's forensic science committee—Committee E30—comprises over 700 members from private and public laboratories. Since its establishment in 1970, Committee E30 has adopted over 50 standards, such as those related to storing, testing, and analyzing evidence.[154]

One key challenge that criminal courts confront when considering evidence from forensic laboratories is that science is always evolving.[155] As a result, courts will sometimes use conformity with ASTM standards to determine whether expert testimony on forensic evidence is admissible. For example, in *United States v. Weiss*, a federal district court determined that the government's expert from the U.S. Postal Inspector Service Crime Laboratory conformed to ASTM's standards

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[147] *Id.* at 122.
[148] *Id.*
[149] *Overturning Wrongful Convictions Involving Misapplied Forensics*, THE INNOCENCE PROJECT, available at https://innocenceproject.org/overturning-wrongful-convictions-involving-flawed-forensics/.
[150] Simon A. Cole, *Who Will Regulate American Forensic Science?*, 48 SETON HALL L. REV. 563, 571 (Apr. 28, 2018).
[151] NIST provides general oversight and engagement with respect to "strengthening forensic practice through research and improved standards." NIST, *Forensic Science: Overview*, https://www.nist.gov/forensic-science.
[152] *What Sets ANAB Apart for Forensic Accreditation*, ANAB, available at https://anab.ansi.org/en/forensic-accreditation. *See also* QUATTRONE CENTER FOR THE FAIR ADMINISTRATION OF JUSTICE, THE AUSTIN POLICE DEPARTMENT DNA LABORATORY, 2010–2015: LOOKING BACK TO LOOK FORWARD 6 (Sept. 2020), available at http://www.austintexas.gov/edims/pio/document.cfm?id=347884.
[153] ASTM, *Forensic Science Standards*, https://www.astm.org/Standards/forensic-science-standards.html. *See also* Brad Kelechava, *Standard Practice for Examining and Preparing Evidence in Criminal or Civil Litigation*, ANSI (Oct. 26, 2017), https://blog.ansi.org/2017/10/standard-practice-evidence-litigation-astm/#gref.
[154] *Id*.
[155] QUATTRONE CENTER FOR THE FAIR ADMINISTRATION OF JUSTICE, *supra* note 152, at 16 ("The analysis of forensic DNA samples, like all science, is a continuously evolving field.").

for analysis of handwritten and typewritten documents.[156] Based in part on the expert's conformity with ASTM standards, the court held that the expert testimony was admissible.[157]

When it comes to DNA analysis, the Supreme Court of Minnesota in *State v. Schwartz* similarly held that the admissibility of laboratory results in a criminal case "hinges on the laboratory's compliance with appropriate standards and controls."[158] The DNA evidence the state sought to admit in that case had been analyzed by a laboratory using procedures that failed to satisfy the FBI's non-binding guidelines for "validation protocols."[159] The court held that the DNA evidence was inadmissible.[160]

Standards related to specific scientific disciplines can also sometimes play a role in criminal law. In *Howard v. State*, the Supreme Court of Mississippi overturned a conviction based on outdated forensic science.[161] The defendant was convicted for murder after a forensic odontologist matched molds of his teeth to bite marks on the victim's body.[162] At the time the odontologist testified at trial, his conclusions were consistent with the standards established by the American Board of Forensic Odontology (ABFO).[163] By time the case reached the Supreme Court of Mississippi on appeal, however, ABFO's standards had been revised in a manner that no longer supported the expert's testimony at trial.[164]

Given the important role that forensic evidence plays in the criminal law system, the standards related to this evidence are also of obvious important. Law students would be well-served to understand how voluntary standards apply to forensic laboratories and how they can affect the ways that courts will evaluate forensic evidence at trial.

F. The Advantages and Disadvantages of Voluntary Codes and Standards

From the standpoint of governing, voluntary codes and standards can have advantages as well as disadvantages. In terms of advantages, voluntary codes and standards can be potentially more flexible and adaptable.[165] Because they are voluntary and developed by private organizations, they can be developed without going through the process that governments must follow in creating new

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[156] United States v. Weiss, 2007 WL 9677017, (D. Colo. April 23, 2007).
[157] *Id*. Other courts have similarly used conformity with ASTM standards to determine admissibility, especially in the context of testimony identifying the writer of handwritten documents. *See, e.g*., United States v. Yagman, 2007 WL 4409618 (C.D. Cal. May 22, 2007) (denying defendant's motion to exclude evidence in part because the expert who testified about the evidence in question analyzed it in accordance with ASTM standards); Pettus v. United States, 37 A.3d 213 (D.C. 2012) (holding that testimony on handwritten documents was admissible in part because the analyzing laboratory followed ASTM standards).
[158] 447 N.W. 2d 422, 428 (Minn. S. Ct. 1989).
[159] *Id*. at 426–27.
[160] *Id*. at 428. Not all jurisdictions, however, have held that DNA evidence will be inadmissible when laboratories lack accreditation. In *J.H.H. v. State*, for example, the Court of Criminal Appeals in Alabama held that the trial court had not abused its discretion in admitting DNA evidence analyzed by a laboratory that was not accredited at the time the DNA was tested. 897 So. 2d 419 (Ala. Crim. App. 2004).
[161] 300 So.3d 1011 (Miss. 2020).
[162] *Id*. at 1017.
[163] *Howard*, 300 So.3d at 1017–18.
[164] *Id*. at 1020.
[165] INTERNATIONAL INSTITUTE FOR SUSTAINABLE DEVELOPMENT, GLOBAL GREEN STANDARDS 17–18 (1996), available at https://www.iisd.org/system/files/publications/globlgrn.pdf.

regulations. Voluntary codes and standards may thus be potentially easier to change more quickly as technology changes.[166]

Although voluntary standards are not legally binding, they nevertheless can have a meaningful impact on the business practices and individual behavior across a range of sectors. Market forces may reinforce them; sometimes large purchasers customers require conformity with standards by their suppliers. Moreover, the very consensus-based nature of their development, with direct involvement by experts within the relevant industries, means that they should be both well-informed and well-accepted by those to whom they apply.[167] Because members of the industry subject to the voluntary standards were involved in creating these standards, they might feel a greater sense of buy-in to follow those private standards than to follow regulations adopted by a government agency.[168]

Despite potential advantages, voluntary codes and standards may sometimes suffer from some of the drawbacks of consensus-based decision-making.[169] It is possible that "articulate and forceful participants can have tremendous influence over a committee" that develops standards.[170] Furthermore, if an issue is met with a stalemate within the group over the best standard to adopt, a consensus-based approach might result in an outcome set at the lowest common denominator of the group.[171]

The very voluntary nature of codes and standards may prove problematic. Although it is true that market pressures might reinforce the need for firms to conform to voluntary codes and standards, those pressures may affect different firms to different degrees—and overall, there may be an absence of adequate incentives needed to change behavior, especially if the needed behavioral change is costly to firms.

In the end, a voluntary approach—sometimes described as "soft law"—may turn out to have at most "a modest impact on the overarching problems it seeks to solve because it is, well, soft."[172] Whether voluntary standards can provide behavioral change will depend on the existence of "other external or internal motivations, rather than providing much of an incentive on its own" and ultimately "the scope of participation in a voluntary regime might thus be quite limited and the actual achievements of those businesses that participate might be limited as well."[173]

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[166] ARCADIS, THE FEASIBILITY OF INTRODUCING A CERTIFICATION SCHEME/STANDARD FOR RECYCLING TREATMENT FACILITIES v (Oct. 2012), available at https://rpaltd.co.uk/uploads/report_files/j772-1.pdf. *See generally* Gregory Tassey, *The Roles and Impacts of Technical Standards on Economic Growth and Implications for Innovation Policy*, 1 ANNALS SCI. & TECH. POL'Y 215 (2017).
[167] *Id*.
[168] McAllister, *supra* note 69, at 316.
[169] From the standpoint of public policy, a consensus decision rule can introduce a number of problems. Cary Coglianese, "Is Satisfaction Success? Evaluating Public Participation in Regulatory Policy Making," in ROSEMARY O'LEARY AND LISA BINGHAM, EDS., THE PROMISE AND PERFORMANCE OF ENVIRONMENTAL CONFLICT RESOLUTION 69-86 (2003), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=331420.
[170] *Id*.
[171] *Id*.
[172] Cary Coglianese, *Environmental Soft Law as a Governance Strategy*, 61 JURIMETRICS 19, 32 (2020).
[173] *Id*.

There also can be advantages and disadvantages to incorporation by reference. Incorporating codes and standards by reference into law relieves the government of the burden to research and develop its own regulations, potentially saving the government time, money, and resources.[174] Because the government lacks the necessary industry knowledge, private standards that are simply incorporated by reference into law can be more administratively efficient. Incorporation by reference can also ensure that government regulations do not conflict with privately developed voluntary codes and standards.[175]

If the standards being incorporated are not adequate to solving the problems that regulators seek to solve, of course, then merely making these suboptimal or ineffectual standards mandatory will hardly be ideal. Moreover, incorporation by reference also can diminish the transparency of what the law requires.[176] They are incorporated merely by reference, which means that what they actually demand of regulated entities will not be immediately known from reading the regulations. The details will be contained in what are often copyrighted material, available only for purchase from a private standard-setting organization.[177] Although some individual standards are available in read-only format online at no cost, sometimes consulting a standard can be expensive. According to one estimate, for example, it would cost almost $10,000 to purchase all the standards incorporated into law by the Pipeline and Hazardous Materials Administration.[178]

Given the role voluntary codes and standards can play in multiple domains of law and governance, it is important for students to understand both their potential benefits and potential drawbacks. The same is true with respect to the incorporation by reference of voluntary codes and standards into law.

V. Discussion Questions

The following section includes a list of suggested questions to accompany class discussion. Additional questions can be drawn from the Learning Objectives section of the teaching guide as well. Instructors might consider providing their students with this list of questions ahead of class for background preparation.

A. Voluntary Codes and Standards

Question 1: What do documents such as Circular A-119 and the NTTAA indicate about the relationship between standard-setting organizations and government agencies?

Question 2: Many standard-setting organizations emphasize values such as openness, consensus, and due process. Are there other values that should guide the drafting and development of voluntary codes and standards?

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[174] Cary Coglianese & Gabriel Scheffler, *Private Standards and the Benzene Case: A Teaching Guide*, 71 ADMIN. L. REV 355, 379 (2019).
[175] *Id*.
[176] *Id*. at 380.
[177] Penn Program on Regulation, *What are the Advantages and Disadvantages of Incorporation by Reference?*, YOUTUBE (Sept. 24, 2020), available at https://www.youtube.com/watch?v=E1c1uARGOzE.
[178] *See* Emily S. Bremer, *On the Cost of Private Standards in Public Law*, 63 U. KAN . L. REV . 279, 313-317 (2015).

Question 3: How should organizations that set safety standards assess acceptable levels of risk associated with certain products and procedures? How should these organizations consider tradeoffs between costs and health or safety?

Question 4: Should standard-setting organizations' work be limited in scope to purely "technical" issues such as interoperability of products or systems? Or do they have an important role to play in promoting responsible social and environmental practices too?

a) What would be the benefit to society for leaving the latter role to industry representatives alone to determine these standards? What might be the dangers?

Question 5: What are the consequences to businesses from their non-conformity with voluntary standards? Do voluntary codes and standards provide enough incentives for firms to invest in costly measures to address safety or environmental risks?

a) What other incentives or prohibitions might exist or be created to encourage businesses to conform their products and practices to voluntary codes and standards?

B. Public versus Private Regulation

Question 6: What position does the NTTAA and OMB Circular A-119 take with respect to the virtues of privately created voluntary codes and standards? What might be some of larger policy implications of that stance?

Question 7: Are nongovernmental standard-setting strategies a viable alternative to traditional government regulation? Or is a market-based voluntary standards approach inherently incompatible with the kind of regulation needed to solve market failures?

a) What benefits and consequences are there to this form of "outsourcing" of governance?
b) What checks exist to ensure the quality and efficacy of voluntary codes and standards?

Question 8: Might laws and policies such as the NTTAA and OMB Circular A-119, which encourage government agencies to rely on the work of private standard-setting organizations actually hinder the functioning of governmental agencies?

Question 9: What are some administrative law safeguards either currently in place or which might be enacted to ensure that industry cannot exert undue influence over standard-setting?

C. Incorporation by Reference

Question 10: What are the benefits and drawbacks of incorporation by reference? Can you think of any alternative routes that would avoid or lessen the severity of the drawbacks?

Question 11: Currently, standard-setting organizations fund themselves through proceeds on their copyrighted model codes. Could or should their business model be

reorganized or perhaps federally subsidized in cases where their standards are incorporated into law?

Question 12: What copyright protections exist to prevent the government from publishing legal standards developed by the organizations?

a) Is there an alternative system through which the Office of the Federal Register might be able to make public the standards incorporated by reference?
b) What action could Congress take to address the accessibility concerns presented by incorporation by reference?

Question 13: Why might it be desirable for standard-setting organizations to be able to copyright their work products?

Question 14: Could the fair use doctrine, which permits limited uses of copyrighted materials without payment, help resolve copyright issues presented by incorporation by reference?

VI. Model Lesson Plans

This module can be adapted for the desired coverage of the instructor. To cover the entire breadth of the module, instructors might consider combining each of the following smaller lesson plans. These plans can also be used as smaller section of a larger lesson for instructors with limited time but who would nevertheless like to introduce students to these topics.

The guidelines below offer suggestions for materials in this module that might be most suitable for each topic. The materials include a mix of legislative material, academic articles, videos, and sample governmental agency materials. Instructors may also choose to assign excerpts of the suggested reading materials rather than the entire passages. The material for all the suggested reading assignments can be found on the webpage for this module at www.codes-and-standards.org.

For the instructor's convenience, the suggested Discussion Questions, which appear in the section above, are reprinted below and organized by topic.

A. Voluntary Codes and Standards

Goal: For students to learn the basics of what voluntary codes and standards are and how they can be distinguished from legally binding regulations. Students should also understand their scope and the basic framework of how they are developed and implemented by standard-setting organizations.

Class Time: 10-30 minutes

Reading Assignment:

- For an overview discussing the importance and scope of voluntary codes and standards, assign one or more of the following:
    - Cary Coglianese & Caroline Raschbaum, *Teaching Voluntary Codes and Standards to Law Students*, 72 ADMIN. L. REV. 307 (2019) (available online)

- Gordon Gillerman, Video Interview, *What are voluntary codes and standards?*, https://www.youtube.com/watch?v=1jUKTa9Pm2s
- Primer on Voluntary Codes and Standards (available online)

Guiding the Classroom Discussion: Students should come prepared with an understanding of what voluntary codes and standards are and how they differ from legally enforceable regulations. The short video listed above (and additional interviews with organization leaders included on the website) would provide a good starting point for class discussion. Instructors also might choose to select several legal areas not traditionally associated with government regulation (such as criminal law) to communicate to students the wide breadth of relevance of voluntary codes and standards. The discussion in Part IV.E of this teaching guide can offer suggestions.

Discussion Questions:

- *For discussions of law and government policy related to voluntary codes and standards, see Question 1:*

  Question 1: What do documents such as Circular A-119 and the NTTAA indicate about the relationship between standard-setting organizations and government agencies?

- *For discussing the procedures by which standard-setting organizations make voluntary codes and standards, see Questions 2-4:*

  Question 2: Many standard-setting organizations emphasize values such as openness, consensus, and due process. Are there other values that should guide the drafting and development of voluntary codes and standards?

  Question 3: How should organizations that set safety standards assess acceptable levels of risk associated with certain products and procedures? How should these organizations consider tradeoffs between costs and health or safety?

  Question 4: Should standard-setting organizations' work be limited in scope to purely "technical" issues such as interoperability of products or systems? Or do they have an important role to play in promoting responsible social and environmental practices too?
  a) What would be the benefit to society for leaving the latter role to industry representatives alone to determine these standards? What might be the dangers?

- *For discussing the overall value of voluntary codes and standards, see Question 5:*

  Question 5: What are the consequences to businesses from their non-conformity with voluntary standards? Do voluntary codes and standards provide enough

incentives for firms to invest in costly measures to address safety or environmental risks?

a) What other incentives or prohibitions might exist or be created to encourage businesses to conform their products and practices to voluntary codes and standards?

B. Public versus Private Regulation

Goal: To introduce students to the idea of private standard-setting and have them engage in a discussion about its impact on governmental agencies, companies, and consumers. The instructor ideally will have students consider why private regulation is helpful and necessary, whether or how it can substitute for or augment a system of public regulation, and what potential negative effects might arise from having nongovernmental organizations engage in setting standards that affect the public.

Class Time: 10-30 minutes

Reading Assignment:

- For an introduction to the relevant, guiding policies, assign:
  - OMB Circular A-119:
    - OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, at: https://www.nist.gov/system/files/revised_circular_a-119_as_of_01-22-2016.pdf.
  - ANSI February 2016 Webinar Slides highlighting the significance of the 2016 revision to A-119. (Available to view online or download at: ANSI Webinar: OMB A-119 Revision)
- For a general introduction to the interaction between private and public regulation, assign the following article. Instructors may wish to narrow student's attention to just the first section ("Private Regulation and its Harnessing"), or to an excerpt of this section, as it addresses nicely the relative virtues of private regulations.
  - Lesley K. McAllister, *Harnessing Private Regulation*, 3 MICHIGAN J. ENVTL. & ADMIN. L. 291-419 (2014).
- For case studies illustrating the process of outsourcing public regulation to private organizations in specific policy domains, the instructor could assign one of the following articles:
  - Dara O'Rourke, *Outsourcing Regulation: Analyzing Nongovernmental Systems of Labor Standards and Monitoring*, 31 POL'Y STUD. J. 1 (2003).
  - Cary Coglianese, *Environmental Soft Law as a Governance Strategy*, 61 JURIMETRICS 19 (2020) (especially pages 29-33 on "Commonalities, Advantages, and Challenges")

Guiding the Classroom Discussion: Ideally, students will arrive with an understanding of the major differences between private and public regulation and will understand how the posture that the NTTAA and OMB A-119 take to the role of voluntary standard-setting organizations. Some class time might be spent in reviewing A-119, as it is one of the foundational documents. The ANSI Webinar slides listed above would provide a helpful guide to organize such a discussion.

Discussion Questions: The most suitable Discussion Questions will depend on the length and depth of the desire classroom discussion.

- *For a discussion of current government policy vis-à-vis private regulation, see Questions 6 and 7:*

  Question 6: What position does the NTTAA and OMB Circular A-119 take with respect to the virtues of privately created voluntary codes and standards? What might be some of larger policy implications of that stance?

  Question 7: Are nongovernmental standard-setting strategies a viable alternative to traditional government regulation? Or is a market-based voluntary standards approach inherently incompatible with the kind of regulation needed to solve market failures?

  a) What benefits and consequences are there to this form of "outsourcing" of governance?

  b) What checks exist to ensure the quality and efficacy of voluntary codes and standards?

- *For a discussion of the policy implications of outsourcing governance functions to private organizations, see Questions 8 and 9:*

  Question 8: Might laws and policies such as the NTTAA and OMB Circular A-119, which encourage government agencies to rely on the work of private standard-setting organizations actually hinder the functioning of governmental agencies?

  Question 9: What are some administrative law safeguards either currently in place or which might be enacted to ensure that industry cannot exert undue influence over standard-setting?

C. Incorporation by Reference

Goal: To introduce students to the subject of incorporation by reference, including its legal origins and basis. Instructors may choose to focus more attention on the copyright law aspects of incorporation by reference depending on the subject matter of their course. Another goal of this lesson plan would be for students to consider the policy implications of incorporation by reference and possible solutions to the challenges it poses for making law publicly accessible.

Class Time: 10-30 minutes

Reading Assignment: In preparation for class, have students review the short video clips available at the links below or online at www.codes-and-standards.org, and read through the background materials below. Students need only skim the *Incorporation by Reference Handbook* or the *Regulatory Group Document Drafting Handbook* to get a basic understanding of the process.

- For a very general overview about what incorporation by reference is and why it is relevant, assign the following:
    - Emily S. Bremer Video Interview, *What is incorporation by reference and why is it important?,* https://www.youtube.com/watch?v=tFkXlqi_79U
    - Nina Mendelson Video Interview, *What is incorporation by reference and why does it matter?,* https://www.youtube.com/watch?v=LIMX62S2SJg
    - Miriam Vincent, Office of the Federal Register, Incorporation by Reference, (slides), https://www.archives.gov/files/federal-register/write/conference/ibr.pdf
    - Incorporation by Reference Handbook, Office of the Federal Register (Oct. 2017), https://www.archives.gov/files/federal-register/write/handbook/ibrh.pdf
    - The Regulatory Group, Inc., Federal Register Document Drafting Handbook, Chapter 6: What is Incorporation by Reference, and How Do I Do It?, https://www.regulationwriters.com/downloads/DDH-chapter-6.pdf
      (This helpful source was written for federal agency personnel seeking to incorporate a private standard).

- For a flavor of the debate over the policy and legal implications of incorporation by reference, assign:
    - Nina A. Mendelson, Public *Access to the Law Must Be Taken More Seriously*, THE REGUL. REV. (2015), https://www.theregreview.org/2015/01/28/mendelson-public-access/.
    - Emily S. Bremer, *New Rules on Incorporated Standards Encourage Necessary Public-Private Collaboration*, THE REGUL. REV. (2015), https://www.theregreview. org/2015/01/27/bremer-public-private-collab/
- If further background material is desired, one or both of the following articles is recommended:
    - Emily Bremer, *Incorporation by Reference in an Open-Government Age*, 36 HARV. J. L. PUB. POL'Y 131-210 (2012).
    - Emily Bremer, *On the Cost of Private Standards in Public Law*, 63 KANSAS L. REV. 279-333 (2015).

Guiding the Classroom Discussion: Students should ideally come to class with a basic understanding of what incorporation by reference is. Instructors may choose to ask students to come prepared with a list of advantages and disadvantages of this form of private regulation. Instructors may start the lesson by reviewing the structure of incorporation by reference and open the floor for students to share their thoughts on the possible legal and public policy issues driven by this process. Depending on the concentration of the class and amount of time allotted, the instructor may also choose to narrow the discussion to one or more of the themes raised by incorporation by reference, including those related to regulatory capture or to copyright law and public access to the law.

Discussion Questions:

Question 10: What are the benefits and drawbacks of incorporation by reference? Can you think of any alternative routes that would avoid or lessen the severity of the drawbacks?

Question 11: Currently, standard-setting organizations fund themselves through proceeds on their copyrighted model codes. Could or should their business model be reorganized or perhaps federally subsidized in cases where their standards are incorporated into law?

Question 12: What copyright protections exist to prevent the government from publishing legal standards developed by the organizations?

a) Is there an alternative system through which the Office of the Federal Register might be able to make public the standards incorporated by reference?

b) What action could Congress take to address the accessibility concerns presented by incorporation by reference?

Question 13: Why might it be desirable for standard-setting organizations to be able to copyright their work products?

Question 14: Could the fair use doctrine, which permits the limited use of copyrighted materials without payment, be used to resolve copyright issues presented by incorporation by reference?

VII. Additional Reading Materials

JEREMY BAGOTT, DISPATCHES FROM THE COSMIC COBRA BREEDING FARM (2019).

Emily Bremer, *Incorporation by Reference in an Open-Government Age*, 36 HARV. J.L. & PUB. POL'Y 131 (2013).

Emily Bremer, *On the Cost of Private Standards in Public Law*, 63 KAN. L. REV. 279 (2015).

Emily S. Bremer, *Technical Standards Meet Administrative Law: A Teaching Guide on Incorporation by Reference*, 72 Admin. L. Rev. 315-352 (2019).

NILS BRUNSSON AND BENGT JACOBSSON, A WORLD OF STANDARDS (Revised ed. 2002).

TIM BÜTHE & WALTER MATTLI, THE NEW GLOBAL RULES: THE PRIVATIZATION OF REGULATION IN THE WORLD ECONOMY (2011).

Tim Büthe & Walter Mattli, *International Standards and Standard-Setting Bodies in* THE OXFORD HANDBOOK OF BUSINESS AND GOVERNMENT 440-471 (David Coen, Graham Wilson, and Wyn Grant eds., 2010).

ROSS E. CHEIT, SETTING SAFETY STANDARDS: REGULATION IN THE PUBLIC AND PRIVATE SECTORS (1990).

Katie M. Colendich, *Who Owns "the Law"? The Effect on Copyrights When Privately Authored Works are Adopted or Enacted by Reference into Law*, 78 WASH. L. REV. 589 (2003).

Cary Coglianese, *Environmental Soft Law as a Governance Strategy*, 61 JURIMETRICS 19 (2020).

Cary Coglianese, *Private Standards and Public Governance*, REG. REV. (Nov. 4, 2019), https://www.theregreview.org/2019/11/04/coglianese-private-standards-public-governance/.

Cary Coglianese & Jennifer Nash, *Compliance Management Systems: Do They Make a Difference? in* CAMBRIDGE HANDBOOK OF COMPLIANCE, (D. Daniel Sokol & Benjamin van Rooji eds., 2021).

Cary Coglianese & Caroline Raschbaum, *Teaching Voluntary Codes and Standards to Law Students*, 72 ADMIN. L. REV. 307 (2019).

Cary Coglianese & Gabriel Scheffler, *Private Standards and the Benzene Case: A Teaching Guide*, 72 ADMIN. L. REV. 353-390 (2019).

JORGE CONTRERAS, ED., ABA COMM ON TECH. STANDARDIZATION, STANDARDS DEVELOPMENT PATENT POLICY MANUAL (2007).

JORGE CONTRERAS, ED., THE CAMBRIDGE HANDBOOK OF TECHNICAL STANDARDIZATION LAW: VOL. 2 – FURTHER INTERSECTIONS OF PUBLIC AND PRIVATE LAW (2019).

Jorge L. Contreras, *From Private Ordering to Public Law: The Legal Framework Governing Standards-Essential Patents*, 30 HARV. J.L. & TECH. 211-231 (2017).

DIETER ERNST, AMERICA'S VOLUNTARY STANDARDS SYSTEM: A 'BEST PRACTICE' MODEL FOR ASIAN INNOVATION POLICIES? (2013).

Robert W. Hamilton, *The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety or Health*, 56 TEX. L. REV. 1329 (1978).

VIRGINIA HAUFLER, A PUBLIC ROLE FOR THE PRIVATE SECTOR: INDUSTRY SELF-REGULATION IN A GLOBAL ECONOMY (2001).

SAMUEL KRISLOV, HOW NATIONS CHOOSE PRODUCT STANDARDS AND STANDARDS CHANGE NATIONS (1997).

Lesley K. McAllister, *Harnessing Private Regulation*, 3 MICH. J. ENVTL. & ADMIN. L. 291-419 (2014).

Nina A. Mendelson*, Private Control over Access to Public Law: The Perplexing Federal Regulatory Use of Private Standards*, 112 MICH. L. REV. 737 (2014).

CRAIG N. MURPHY AND JOANNE YATES, THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO): GLOBAL GOVERNANCE THROUGH VOLUNTARY CONSENSUS (2009).

NATIONAL RESEARCH COUNCIL, STANDARDS, CONFORMITY ASSESSMENT, AND TRADE: INTO THE 21ST CENTURY (1995).

National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, 110 Stat. 775.

OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities (notice of availability published at 81 Fed. Reg. 4673 (Jan. 27, 2016)).

STEPHEN M. SPIVAK, AND F. CECIL BRENNER, STANDARDIZATION ESSENTIALS: PRINCIPLES AND PRACTICE (2018)

G.M. Peter Swann, *International Standards and Trade: A Review of the Empirical Literature*, OECD Trade Policy Papers, No. 97, OECD Publishing, Paris, (2010), https://www.oecd-ilibrary.org/trade/international-standards-and-trade_5kmdbg9xktwg-en

Gregory Tassey, *The Roles and Impacts of Technical Standards on Economic Growth and Implications for Innovation Policy*, 1 ANNALS SCI. & TECH. POL'Y 215 (2017).

JOANNE YATES & CRAIG N. MURPHY, ENGINEERING RULES: GLOBAL STANDARD SETTING SINCE 1880 (2019).

* * *

In addition to the above sources, several symposia have featured extensive discussion of issues and exchange of ideas related to voluntary codes and standards, including:

- S*ymposium on Joanne Yates and Craig N. Murphy's "Engineering Rules,"* NOTICE & COMMENT (2019), https://www.yalejreg.com/topic/symposium-on-joanne-yates-and-craig-n-murphys-engineering-rules/.

- *Incorporating Private Standards into Public Regulations*, REG. REV. (2015), https://www.theregreview.org/2015/01/26/series-incorporation-by-reference/.

- *The Continuing Debate Over Regulatory Incorporation*, REG. REV. (2013), https://www.theregreview.org/2013/10/14/continuing-debate-over-regulatory-incorporation/.

- *Regulating by Reference*, REG. REV. (2013), https://www.theregreview.org/2013/07/02/regulating-by-reference/.

Appendix A: Examples of Standard-Setting Organizations

American Petroleum Institute (API) https://www.api.org/	Oil extraction and refining
ASTM International https://www.astm.org/	Wide variety of industries
Institute of Electrical and Electronics Engineers (IEEE) https://www.ieee.org/	Electrical, electronic, and computing
International Code Council (ICC) https://www.iccsafe.org/	Building safety
International Electrotechnical Commission (IEC) https://www.iec.ch/homepage	International trade and infrastructure of electronic goods
International Organization for Standardization (ISO) https://www.iso.org/home.html	Wide variety of industries
National Fire Protection Association (NFPA) https://www.nfpa.org/	Building construction and fire safety
National Pork Producers Council (NPPC) https://nppc.org/	Pork industry
Nuclear Information and Records Management Association (NIRMA) https://nirma.org/	Nuclear industry records and information management
Underwriter's Laboratories (UL) https://www.ul.com/	Consumer products
U.S. Green Building Council (USGBC) https://www.usgbc.org/	Construction
Alliance For Telecommunications Industry Solutions (ATIS) https://www.atis.org/	Mobile telecommunications

Appendix B: Glossary

ANSI	American National Standards Institute
API	American Petroleum Institute
ASTM	ASTM International
CSPC	Consumer Product Safety Commission
CSPIA	Consumer Product Safety Improvement Act
FRAND	Fair, reasonable, and non-discriminatory terms
IEEE	Institute of Electrical and Electronics Engineers
IBR	Incorporation by reference
ICC	International Code Council
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
NFPA	National Fire Protection Association
NIJ	National Institute of Justice
NIST	National Institute of Standards and Technology
NPPC	National Pork Producers Council
NIRMA	Nuclear Information and Records Management Association
NTTAA	National Technology Transfer and Advancement Act of 1995
UL	Underwriter's Laboratories
OMB	Office of Management and Budget
RAND	Reasonable and non-discriminatory terms
SSO	Standard-setting organization
SEP	Standard-essential patent