Use of Standards in Regulation

OMB Circular A-119 directs all federal agencies to incorporate "in whole, in part, or by reference" privately developed standards for regulatory and other activities "whenever practicable and appropriate." For this policy to succeed, private authors must have an incentive to create works useful to the government. OMB thus requires agencies to "observe and protect the rights of the copyright holder and any other similar obligations." Recent case law, however, is trending towards limiting copyright protection in IBR'd standards.

If SDOs cannot fund standards development as a result of loss of copyright in IBR'd standards, standards may not be updated as frequently, or for some industries not at all. Federal, state, and local agencies may not be able to continue to rely on private sector standards for IBR purposes and these agencies will need to develop alternative ways to regulate.

To the extent an agency wishes to use privately developed standards, several non-exhaustive examples are provided below of alternatives to IBR currently in use at the federal level. Examples are also provided of agency programs that make use of private entities to manage compliance and definition of applicable standards (see p. 6-7). Individual federal agencies are responsible for determining the practices that best meet their needs, operating within the parameters of their authorities, the Administrative Procedure Act and other federal laws and policies.

	Alternate to IBR	**Sample Regulatory Text**	**Current Use**	**Link**
1	Use of an excerpt or portion of a standard with attribution and permission	N/a	Agency obtains permission from SDO to reproduce a small portion of the standard in a regulation Regulation should also include proper attribution and copyright notice to the SDO/copyright holder	
2	Agency prepares and maintains lists of recognized and acceptable standards.	___ recognized consensus standard identified by the [AGENCY], including [SPECIFIC INFORMATION REQUIRED BY X STANDARD].	**FDA, with respect to various standards:** This guidance refers to voluntary consensus standards recognized by FDA in the Federal Register in accordance with section 514(c) of the FD&C Act as "FDA-recognized consensus standards." A list of consensus standards that FDA has	Recognized Consensus Standards: Medical Devices (fda.gov) Appropriate Use of Voluntary Consensus

		This example could appear as a footnote of a document referencing an agency-recognized consensus standard.	recognized or decided to recognize is available on the FDA Recognized Consensus Standards Database Web site.	Standards in Premarket Submissions for Medical Devices – Guidance for Industry and Food and Drug Administration Staff
3	Require compliance with a "nationally recognized standard" without necessarily specifying one.	Each [PRODUCT] must be properly designed and constructed in accordance with a code of practice developed by a nationally recognized association or independent testing laboratory as specified below: [further guidance here] Note to paragraph (a)(1). The following codes of practice may be used to comply with paragraph (a)(1) of this section: [SDO AND TITLE OF STANDARD USED] 40 CFR § 280.20 (12.26.2024)	**EPA General Guidance for Using EPA's Standard Test Procedures for Evaluating Release Detection Methods:** Nationally recognized association refers to a Standard Developing Organizations in the United States, such as the American Society for Testing and Materials (ASTM International). This practice specifies compliance with national recognized standards, and then can provide non-exhaustive examples.	40 CFR § 280.20 Performance standards for new UST systems.
4	Agency describes the criteria that a standard needs to meet (either process or performance-based criteria) rather than incorporating a	[Entity] must [description of action] that complies with ___ commonly accepted standards identified by the [AGENCY], including, [description of qualitative contents of what the standard will prescribe].	**HR 3565, with respect to NG911 Relevant Standards** "The term 'commonly accepted standards' means the technical standards followed by the industry developed and approved by a standards development organization that is accredited by an American standards body (such as the American National Standards Institute) or an equivalent international standards body in a process— (I) that is open to	FCC Takes Action to Expedite the Transition to Next Generation 911 | Federal Communications Commission FCC 24-78

	standard by reference into the regulation.	47 CFR § 9.29(b)(1)	the public, including open for participation by any person; and (II) provides for a conflict resolution process; (ii) subject to an open comment and input process before being finalized by the standards development organization; (iii) consensus-based; and (iv) made publicly available once approved." **EPA Use of Lead Free Pipes, Fittings Fixtures, Solder and Flux for Drinking Water** "This action involves technical standards. EPA is establishing a requirement that can be satisfied…either by self certifying compliance with the SDWA lead prohibition or by achieving a voluntary standard that mirrors the SDWA requirements, such as the NSF/ ANSI 372 standard. While EPA is not specifying a technical standard under this final rule, EPA is establishing the use of several technical standards that meet the new definition of lead free as a means of demonstrating compliance with this rule."	40 CFR §§ 141, 143
5	Provide alternate means of compliance	You may take credit for [action] required by [CFR citation] if, before [the effective date of the rule], you complied with [standards]. [Agency] has deemed that using [standards] satisfies the requirements of [CFR citation/this section].	**FAA Airworthiness Directive provides express permission to use AMOC:** (1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (o) of this AD and email to: *AMOC@faa.gov*. Before using any approved AMOC, notify	FAA Order 8110.103B - Alternative Methods of Compliance (AMOC) Sample FAA Airworthiness Directive 2024-19.02, Docket No. FAA-2024-1482

			your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office. **Substantial Equivalence & Predicate Devices in FDA Safe Medical Devices Act (HR 3095) & the Food, Drug and Cosmetic Act** : Medical devices are regulated based on the risk posed to the consumer. All devices are subject to general controls (e.g., registration and listing), which are intended to ensure that the devices are safe and effective once marketed. Certain devices, because of the risk they pose to consumers, must undergo FDA premarket review to determine whether they provide reasonable assurance of safety and effectiveness prior to marketing. To prove that a new medical device is roughly equivalent in safety and effectiveness to devices already approved by the FDA, you need to demonstrate "substantial equivalence" by submitting a 510(k) premarket notification, which essentially compares your new device to a legally marketed "predicate device" and shows that they are very similar in terms of intended use, design, materials, performance, and safety features, thus establishing that your device is not significantly different in terms of risk and benefit profile. A claim of substantial equivalence does not mean the new and predicate devices needs to be identical. FDA first establishes that the new and predicate devices have the same intended use and any differences in technological characteristics do not raise different questions of safety and effectiveness.	

			EPA, in Clean Water Act: The Clean Water Act Alternate Test Procedure (ATP) program is described at 40 CFR 136.4 and 136.5. This program provides a mechanism for submission and review of an application for nationwide use or limited use of an ATP for measurement of a pollutant as an alternative to the methods approved at 40 CFR Part 136. An ATP may fall into one of two categories: 1. A method using a determinative technique (e.g., a pollutant detector) different from that in an existing Part 136 method (for method validation and evaluation purposes this type of method is referred to as a **new method**), or 2. A modification to a Part 136 method that falls outside the scope of the modification flexibility described in the Part 136 method, or at 40 CFR 136.6 (for validation and evaluation purposes this type of method is referred to as an **ATP**).	

Coordination with Private Entity via Regulatory Schema

As compared to IBR, the following agency programs make use of private entities to manage compliance and definition of applicable standards. The private entities report to the creating agency and are subject to the rules and parameters set forth by the regulation that creates it.

Name of Program	Description	Use of Standards	Link
OSHA Nationally Recognized Testing Laboratory (NRTL) Program	OSHA's Nationally Recognized Testing Laboratory (NRTL) is a private-sector organization that OSHA has recognized as meeting the legal requirements in 29 CFR 1910.7 to perform testing and certification of products using consensus-based test standards. Each NRTL has a scope of test standards that they are recognized for, and each NRTL uses its own unique registered certification mark(s) to designate product conformance to the applicable product safety test standards.	Each NRTL requests specific safety standards to be allowed to certify products as expansion of program scope. OSHA undergoes notice and comment to evaluate the request and posts a notice if the standard is acceptable. If approved, OSHA posts a notice and the standard is listed as part of acceptable scope for NRTLs on OSHA website, but there is no specific IBR. "Properly certified" generally means: 1) the product is labeled or marked with the registered certification mark of the NRTL; 2) the NRTL issues the certification for a product covered within the scope of a test standard for which OSHA has recognized it; and 3) the NRTL issues the certification from one of its sites (i.e., locations) that OSHA has recognized. OSHA's recognition of an NRTL is not an endorsement of the equipment certified by the NRTL.	OSHA's Nationally Recognized Testing Laboratory (NRTL) Program | Occupational Safety and Health Administration List of Appropriate Standards
FCC Equipment Authorizations	47 CFR part 2 requires authorization for Radio Frequency (RF) devices. The Office of Engineering and Technology (OET) administers the authorization program under authority delegated to it by FCC. The authorizations follow procedures enumerated in the regulation, which	Compliance testing must be done at a qualified testing laboratory. For SDoC, the testing laboratory does not have to be FCC recognized, provided that it keeps a record of measurement facilities and a record of measurements. SDoC requires the party responsible to ensure equipment complies with **appropriate technical standards**.	Accredited Testing Laboratories Equipment Authorization

Name of Program	Description	Use of Standards	Link
	depend on type: either Supplier's Declaration of Conformity (SDoC) or Certification.	For certification, it must be done at an FCC-recognized accredited testing laboratory. There is a section of the regulation (Section 2.910) called "Incorporation by Reference," which lists 12 standards specifically.	
DoD Cybersecurity Maturity Model Certification (CMMC) Program	The DoD defines the Cyber AB as the official private entity responsible for authorizing and accrediting independent Third Party Assessment Organizations (C3PAO) that conduct CMMC assessments of companies. From there, C3PAOs go on to assess companies to ensure they meet the CMMC standards, which are set by the DoD.	Relies upon security requirements from NIST SP 800-171, NIST SP 800-172 The Program sets out various status Levels that require compliance with certain standards defined by the CMMC. Section 170.2 of the final rule addresses the standards and guidelines that are incorporated by reference. The Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51 approves any materials that are incorporated by reference (as detailed in the Office of the Federal Register's Incorporation By Reference (IBR) Handbook, June 2023). Materials that are incorporated by reference in this rule are reasonably available.	About CMMC Cyber AB Cybersecurity Maturity Model Certification Program Final Rule Published > U.S. Department of Defense > Release Federal Register: Cybersecurity Maturity Model Certification (CMMC) Program