

## U.S. Federal Register Update: September 28 – October 2, 2020

The U.S. Federal Register Update contains summaries of entries in the U.S. Federal Register that may be of particular interest to the standards and conformity assessment community. This update is provided on a weekly basis by ANSI as a service to its members as part of the Institute's e-newsletter, *What's New?*

### [MET Laboratories, Inc.: Grant of Expansion of Recognition](#)

**Published** 9/28/2020

**Reference** ANSI, UL

In this notice, OSHA announces the final decision to expand the scope of recognition for MET Laboratories, Inc., as a Nationally Recognized Testing Laboratory (NRTL). **The expansion of the scope of recognition becomes effective on September 28, 2020.**

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### [Importation of Prescription Drugs](#)

**Published** 10/1/2020

**Reference** ANSI, ASTM, ISO

The Secretary of Health and Human Services (Secretary) is issuing a final rule to implement a provision of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to allow importation of certain prescription drugs from Canada. Under this final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the Food and Drug Administration (FDA, the Agency, or we) for review and authorization. An importation program may be cosponsored by a State, Indian Tribe, pharmacist, or wholesaler. The final rule contains all requirements necessary for a sponsor to demonstrate that their importation program will pose no additional risk to the public's health and safety. In addition, the final rule requires that the sponsor explain how they will ensure their program will result in a significant reduction in the cost of covered products to the American consumer. **This final rule is effective November 30, 2020.**

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### [Reactor Vessel Material Surveillance Program](#)

**Published** 10/2/2020

**Reference** ASME, ASTM

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend the reactor vessel material surveillance program requirements for commercial light-water power reactors. This action would amend the requirements associated with the testing of specimens contained within surveillance capsules and reporting the surveillance test results. This action would also clarify the requirements for the design of surveillance programs and the capsule withdrawal schedules for surveillance capsules in reactor vessels purchased after 1982. These changes would reduce regulatory burden, with no effect on public health and safety. **Submit comments by November 2, 2020. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.**

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### [Reactor Vessel Material Surveillance Program](#)

**Published** 10/2/2020

**Reference** ASME, ASTM

The U.S. Nuclear Regulatory Commission (NRC) is amending the reactor vessel material surveillance program requirements for commercial light-water power reactors. This direct final rule revises the requirements associated with the testing of specimens contained within surveillance capsules and reporting the surveillance test results. This direct final rule also clarifies the requirements for the design of surveillance programs and the capsule withdrawal schedules for surveillance capsules in reactor vessels purchased after 1982. These changes reduce regulatory burden, with no effect on public health and safety. **This direct final rule is effective February 1, 2021, unless significant adverse comments are received by November 2, 2020. If this direct final rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the Federal Register. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Comments received on this direct final rule will also be considered to be comments on a companion proposed rule published in the Proposed Rules section of this issue of the Federal Register.**

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### [Notice of Scope Rulings](#)

**Published** 9/28/2020

#### Reference ASTM

The Department of Commerce (Commerce) hereby publishes a list of scope rulings and anti-circumvention determinations made during the period April 1, 2020 through June 30, 2020. We intend to publish future lists after the close of the next calendar quarter. **Applicable September 28, 2020.**

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#### [Prestressed Concrete Steel Wire Strand From Taiwan: Preliminary Affirmative Determination of Sales at Less Than Fair Value and Negative Preliminary Determination of Critical Circumstances](#)

**Published** 9/30/2020

#### Reference ASTM

The Department of Commerce (Commerce) preliminarily determines that prestressed concrete steel wire strand (PC strand) from Taiwan is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is April 1, 2019 through March 31, 2020. Interested parties are invited to comment on this preliminary determination.

**Applicable September 30, 2020.**

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#### [Prestressed Concrete Steel Wire Strand From Argentina, Colombia, Egypt, the Netherlands, Saudi Arabia, the Republic of Turkey, and the United Arab Emirates: Preliminary Affirmative Determinations of Sales at Less Than Fair Value and Preliminary Affirmative Critical Circumstances Determinations, in Part](#)

**Published** 9/30/2020

#### Reference ASTM

The Department of Commerce (Commerce) preliminarily determines that prestressed concrete steel wire strand (PC strand) from Argentina, Colombia, Egypt, the Netherlands, Saudi Arabia, the Republic of Turkey (Turkey), and the United Arab Emirates (UAE) is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is April 1, 2019 through March 31, 2020. The estimated margins of sales at LTFV are shown in the "Preliminary Determinations" section of this notice. Interested parties are invited to comment on these preliminary determinations.

**Applicable September 30, 2020.**

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#### [Energy Conservation Program: Test Procedures for Certain Commercial and Industrial Equipment; Early Assessment Review; Pumps](#)

**Published** 9/28/2020

#### Reference IEC

The U.S. Department of Energy ("DOE") is undertaking an early assessment review to determine whether to proceed with a rulemaking to amend the test procedure for commercial and industrial pumps. This request for information ("RFI"), DOE seeks data and information that could enable the agency to determine whether to amend its current test procedure as well as comment on the availability of consensus-based test procedures for measuring the energy use of commercial and industrial pumps that could be adopted with or without modification. DOE welcomes written comments from the public on any subject within the scope of this document (including topics not raised in this RFI), as well as the submission of data and other relevant information concerning this early assessment review. **Written comments and information will be accepted on or before December 14, 2020.**

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#### [Amendments Related to Marine Diesel Engine Emission Standards](#)

**Published** 10/2/2020

#### Reference ISO

The Environmental Protection Agency (EPA) is amending the national marine diesel engine program with relief provisions to address concerns associated with finding and installing certified Tier 4 marine diesel engines in certain high-speed commercial vessels. This relief is in the form of additional lead time for qualifying engines and vessels. **This final rule is effective on November 2, 2020.**

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#### [National Institute of Standards and Technology Performance Review Board Membership](#)

**Published** 9/28/2020

#### Reference NIST

This notice lists the membership of the National Institute of Standards and Technology Performance Review Board (NIST PRB) and supersedes the list published on October 2, 2019. **The changes to the NIST PRB membership list announced in this notice are effective September 28, 2020.**

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### [Establishment of the Civilian Innovation Advisory Board and Call for Nominations](#)

**Published** 10/2/2020

**Reference** NIST

The Secretary of Commerce (Secretary), announces the establishment of the Civilian Innovation Advisory Board (The Board) in accordance with the Federal Advisory Committee Act of 1972 (FACA), as amended, and the Secretary of Commerce (Secretary), a discretionary advisory committee. The Board shall provide independent advice and recommendations to the Secretary of Commerce and, upon request, to the Administrator of the General Services Administration (GSA) on issues relevant to the Federal Government's engagement and support of technological innovation, and the incorporation and adoption of emerging technologies and innovative means to address critical technological challenges facing the Federal Government in its provision of services to the public, within the framework of applicable national policies.

The National Institute of Standards and Technology (NIST or Institute) through the Department of Commerce (DoC) invites and requests nominations of individuals for appointment to the Board. NIST will consider nominations received in response to this notice for appointment to the Board, in addition to nominations already received. Registered Federal lobbyists may not serve on NIST Federal Advisory Committees in an individual capacity. **Nominations for the Board will be accepted on an ongoing basis and will be considered as and when vacancies arise effective October 1, 2020.**

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### [Guidance on Federal Conformity Assessment Activities](#)

**Published** 9/29/2020

**Reference** NIST

The National Institute of Standards and Technology (NIST) announces revisions to regulations updating guidance on Federal agency use of conformity assessment that reflects advancement in conformity assessment concepts, and the evolution in Federal agency strategies and coordination in using and relying on conformity assessment. The provisions are solely intended to be used as guidance for agencies in their use and reliance on conformity assessment to meet agency requirements and do not preempt the agency authority and responsibility to make decisions authorized by statute or required in establishing regulatory, procurement, or programmatic activities. **This rule is effective October 29, 2020.**

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### [Defense Federal Acquisition Regulation Supplement: Assessing Contractor Implementation of Cybersecurity Requirements \(DFARS Case 2019-D041\)](#)

**Published** 9/29/2020

**Reference** NIST

DoD is issuing an interim rule to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a DoD Assessment Methodology and Cybersecurity Maturity Model Certification framework in order to assess contractor implementation of cybersecurity requirements and enhance the protection of unclassified information within the DoD supply chain. **Effective November 30, 2020.**

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### [Promoting the Rule of Law Through Improved Agency Guidance Documents](#)

**Published** 9/28/2020

**Reference** NIST

The Department of Commerce (Department) issues regulations to implement the requirements of an Executive order entitled "Promoting the Rule of Law Through Improved Agency Guidance Documents" signed October 9, 2019. Consistent with the Executive order, these regulations require that the Department clearly state that guidance documents issued by the Department do not bind the public, except as authorized by law or as incorporated into a contract; establish procedures for the public to petition for withdrawal or modification of guidance documents; and provide, with certain exceptions, that for significant guidance documents, the Department will submit those documents for review by the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA) and provide for a period of public notice and comment of at least 30 days. **The interim final rule is effective October 28, 2020. Comments on the interim final rule must be received by October 28, 2020.**

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### [Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures](#)

**Published** 9/29/2020

**Reference** NIST

This final rule implements two new mandatory Medicare payment models under section 1115A of the Social Security Act — the Radiation Oncology Model (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model). The RO Model will promote quality and financial accountability for providers and suppliers of radiotherapy (RT). The RO

Model will be a mandatory payment model and will test whether making prospective episode payments to hospital outpatient departments (HOPD) and freestanding radiation therapy centers for RT episodes of care preserves or enhances the quality of care furnished to Medicare beneficiaries while reducing Medicare program spending through enhanced financial accountability for RO Model participants. The ETC Model will be a mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants, in order to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. The ETC Model adjusts Medicare payments on certain dialysis and dialysis-related claims for participating ESRD facilities and clinicians caring for beneficiaries with ESRD—or Managing Clinicians—based on their rates of home dialysis transplant waitlisting, and living donor transplants. We believe that these two models will test ways to further our goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries. **These regulations are effective on November 30, 2020.**

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