Health and Human Services (HHS) Fiscal Year 2025 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

1) Agency for Healthcare Research and Quality (AHRQ)

AHRQ uses voluntary consensus standards in our national Medical Expenditure Panel Survey, in our Healthcare Costs and Utilization Project, and in our Quality Indicators. AHRQ supports the U.S. standards developing organizations (SDOs) through participation in relevant workgroups. By improving the uniformity, accuracy, validity, and digitization of health data used for research and decision making, AHRQ increases the robustness of its research findings and the usability of tools developed based on these findings.
AHRQ Quality Indicators - https://qualityindicators.ahrq.gov/
AHRQ Data Tools – MEPS and HCUP https://datatools.ahrq.gov/nhqdr/

2) Assistant Secretary for Technology Policy (ASTP)

Office of the National Coordinator for Health IT (ONC)

Standards are an integral component of ASTP/ONC's mission to support the development of a nationwide health information technology (health IT) infrastructure that allows for electronic use and exchange of information in a scalable manner, promotes the adoption of interoperable health IT in a cost-effective manner, and provides leadership in the development, recognition, and implementation of standards and certification of health IT products. The consistent use of health IT standards is a necessary requirement to achieve interoperability of health information, which is a central key to reducing health care costs.

One way in which ASTP/ONC encourages the consistent use of health IT standards is through ONC's Health IT Certification Program which is composed of functional requirements known as "certification criteria." Health IT standards are part of the certification criteria. Developers certify their Health IT Modules by demonstrating conformance to these certification criteria, using test procedures (that may have associated test tools and/or test data) approved by the National Coordinator. Additionally, ASTP provides clarifications to certification criteria through Certification Companion Guides (CCG) designed to assist with health IT product development.

One of the standards used in certification criteria is the United States Core Data for Interoperability (USCDI). The USCDI sets the foundation for the access, exchange, and use of electronic health information with the goal of enabling nationwide interoperable health information exchange. The USCDI standard is stewarded and adopted by ASTP/ONC on behalf of the U.S. Department of Health and Human Services (HHS). ASTP/ONC publishes new versions of the USCDI annually, with a draft version

released in January and a final version released in July. This publication schedule allows the USCDI to keep pace with clinical, technological, and policy changes that influence the use of clinical and related terminology. In 2020, ASTP/ONC published USCDI Version 1 and created an annual process for updating the USCDI based on public input. In 2025, ONC published USCDI Version 6 after going through the annual process and is now working on developing USCDI Version 7.

The USCDI's impact is not limited to health IT products certified under the ONC Health IT Certification Program. The ONC Cures Act Final Rule provisions related to "information blocking" also reference the USCDI as the initial scope of electronic health information (EHI) healthcare providers, health information networks and exchanges, and developers of certified health IT need to consider when it comes to the access, exchange, and use of EHI. Please see the USCDI v6 and the USCDI Fact Sheet for more information.

ASTP/ONC's **Standards Version Advancement Process** (SVAP) enables participants in the ONC Health IT Certification Program to voluntarily use newer versions of specific ASTP/ONC regulated standards and implementation specifications in their products, including newer USCDI versions. ASTP/ONC included USCDI v5 in the recently published **SVAP Approved Standards for 2025**, allowing health IT developers to upgrade their certified health IT products to that standard as of Aug. 29, 2025. ASTP/ONC also included USCDI v3.1 in the SVAP Approved Standards for 2025. Please see the SVAP Approved Standards on the ONC Certification Program SVAP webpage.

ONC provides some funding and works with the standards development organization, the Regenstrief Institute, in their development of Logical Observations Identifiers, Names and Codes (LOINC), a health IT standard for reporting and ordering laboratory tests, measurements, and other observations.

Another standard development organization that ONC works closely with and provides funding to is Health Level Seven (HL7) to support the development and ongoing maintenance of Fast Healthcare Interoperability Resources (FHIR) standard and related implementation guides along with their Consolidated Clinical Document Architecture (CCDA) standard. These standards are referenced in the ONC Certification Program and enables nationwide interoperability.

Additionally, ONC has worked with Integrating the Healthcare Enterprise (IHE) a non-profit organization that creates guidance, called "profiles," by combining a variety of standards and documents how they work together in order to support a specific use case. ONC's focus with IHE has largely been related to updating IHE profiles to use the HL7 FHIR standard.

Related Links:
https://healthit.gov/standards-and-technology/onc-standards-bulletin/ https://isp.healthit.gov/united-states-core-data-interoperability-uscdi
https://isp.healthit.gov/standards-version-advancement-process
https://healthit.gov/certification-health-it/certification-criteria/standards-version-advancement-process-svap/
https://healthit.gov/certification-health-it/

3) Centers for Disease Control and Prevention (CDC)

Office of Public Health Data Surveillance and Technology (OPHDST)

National Syndromic Surveillance Program (NSSP)

- HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 – US Realm, Standard for Trial Use (July 2019) *Current Document searchable at HL7.org: http://www.hl7.org/; **login or sign up required for download; Access Instructions: go to Standards and then Standards for Trial Use, scroll to or search Syndromic Surveillance guide (close date July 26, 2021).
- PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0 (April 2015): https://www.cdc.gov/nssp/documents/guides/syndrsurvmessagguide2_messagingguide_phn.pdf
- Erratum to the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings ADT Messages A01, A03, A04 and A08 Optional ORU^R01 Message Notation for Laboratory Data HL7 Version 2.5.1 (Version 2.3.1 Compatible) Release 2.0 (April 2015): https://www.cdc.gov/nssp/documents/guides/erratum-to-the-cdc-phin-2.0-implementation-guide-august-2015.pdf
- PHIN 2.0 Implementation Guide Meaningful Use Clarifying Document (PDF available on NIST Website): https://hl7v2-ss-r2-testing.nist.gov/ss-r2/api/documentation/doc?name=NIST-SS-Clarifications-and-Validation-Guidelines-V1-6.pdf

Electronic Case Reporting (eCR)

- HL7 CDA electronic initial case report implementation guide: HL7 CDA® R2 Implementation Guide: Public Health Case Report – the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1.1 – US Realm
- HL7 CDC reportable response implementation guide: HL7 CDA R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1 - US Realm
- HL7 FHIR eCR implementation guide: HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR) - 2.1.2 - STU 2

Data Policy and Standards Division (DPSD)

The Centers for Disease Control and Prevention's (CDC) Data Policy and Standards Division (DPSD) in the Office of Public Health Data Surveillance and Technology (OPHDST) is working collaboratively across the Agency, with federal partners, state, tribal, local, and territorial (STLT) partners, and healthcare to improve data sharing and interoperable data exchange. The focus of the work includes:

i. Ensuring core data sources are more complete and rapidly exchanged to support the collective ability to detect, monitor, investigate and respond to public health threats
ii. Ensure access, exchange and use of interoperable data across the healthcare and public health ecosystem

DPSD plays an active role in developing consensus-based definitions for the minimal data necessary (MDN) to support emergency response for six core areas of public health surveillance including: **case data; laboratory-based diagnostic testing data, syndromic surveillance/emergency department data; immunization/vaccine administration data; hospital capacity data; and death data/vital statistics**.

These established MDN data sets reduce the burden on STLT health departments at the beginning of an emergency response by establishing standardized data collection across CDC for the exchange of data on confirmed, probable, and suspected cases.

In addition to establishing standardized MDN requirements, OPHDST coordinates comments and feedback from across CDC to the Assistant Secretary for Technology Policy (ASTP) on United States Core Data for Interoperability (USCDI) and USCDI+ for public health specific use cases. USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. Inclusion of public health use cases in USCDI and USCDI+ make mission-critical data more consistent, compatible, and usable for interoperable public health and healthcare purposes.

The GUS is necessary for the following reasons:

i. Mission-Specific Requirements: The requirement includes technical and/or operational parameters unique to Federal mission execution that in some cases are not addressed by existing commercial or voluntary consensus standards. (In other cases, existing standards are being reinforced.)
ii. Interoperability with Existing Government Systems: The system must integrate with legacy Government infrastructure and platforms that are built to the referenced GUS. Adoption of a voluntary consensus standard would result in incompatibility, increased risk, and substantial cost impacts.
iii. Security/Public Health/Safety Considerations: The requirement includes safeguards and controls that exceed commercially available standards due to elevated risk tolerance associated with national security/public health/critical infrastructure/regulated environments.
iv. Lifecycle and Sustainment Efficiency: Maintaining consistency with the established GUS ensures continuity in maintenance, training, logistics, and configuration control, thereby minimizing total lifecycle cost and operational disruption.

Office of Laboratory Systems and Response (OLSR)

Division of Laboratory Systems (DLS)

- **Electronic Test Orders and Results**
    - DLS leads CDC's Public Health Laboratory Electronic Test Orders and Results (ETOR) Initiative. A key component of this work is implementing standard vocabulary, format, and transport mechanisms to ensure data interoperability between partners.
        - Standards include: Health Level 7 (HL7) Standards, Logical Observation Identifiers Names and Codes (LOINC), Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT), Unified Code for Units of Measure (UCUM)

- **Laboratory Response Network Data Exchange**
    - DLS supports the Laboratory Response Network (LRN) by providing comprehensive informatics and data exchange solutions to move data from LRN member laboratories to CDC.

    - Standards include: HL7 Standards, LOINC, SNOMED CT, UCUM

- **LOINC In Vitro Diagnostic Test Code Mapping**
    - DLS manages the LOINC In Vitro Diagnostic (LIVD) Test Code Mapping files used to identify and facilitate reporting of laboratory test results between laboratories and public health agencies.
        - Standards include: LOINC, SNOMED CT, UCUM
- **Forum on Adoption of Standards for Laboratory Data Exchange**
    - CDC hosts the Forum on Adoption of Standards for Laboratory Data Exchange and Interoperability to help address a CLIAC recommendation from November 2021. The goal of this forum is to provide a space for organizations to develop new relationships and discuss challenges and successes related to the adoption of laboratory standards. Participants include Federal partners, healthcare-related software vendors, and professional groups.
- **Blood Culture Contamination Quality Measure – continues in collaboration with CMS**
    - Quality measures to protect patients during the diagnostic process by monitoring adult blood culture contamination (BCC) rates.
    - Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals | CDC
- **Laboratory Quality Standards**
    - The Clinical Laboratory Improvement Amendments of 1988 (CLIA) has several requirements for establishing or verifying clinical test method performance. The Clinical & Laboratory Standards Institute (CLSI) creates voluntary guidelines for sensitivity, accuracy, precision, and linearity of test methods. In addition, CLIA uses a quality systems approach, and CLSI has a suite of relevant quality management system (QMS) documents that can be used to meet CLIA requirements. Several DLS personnel participate in document development committees that create and update evaluation protocols and QMS documents, and other documents that describe best practices for CLIA laboratories that are used by CDC and others.
        - **Committees/Workgroups**
            - Document Development Committee
                - DDC on Clinical Validation Workgroup
                - DDC on Respiratory Specimen Collection Workgroup (expecting completion in 2026)
                - DDC on Total Analytical Error
            - DDC on Verification of Comparability of Patient Results Within One Health Care System
            - U.S. TAG to ISO/TC212 Workgroup
            - Evaluation Protocols (EP) Glossary Workgroup
            - Consensus Council
            - Expert Panel on Point-of-Care Testing (POCT)
- **Next-Generation Sequencing Quality Initiative**

- The CDC/Association of Public Health Laboratories NGS QI (Next-Generation Sequencing Quality Initiative) utilizes the CLSI QMS standards to ensure the accuracy, reliability, and consistency of NGS testing processes. These standards are applied and built upon to ensure quality in all stages and steps of laboratory testing for public health and clinical applications.
- Standards for reporting and interoperability of metadata include those promulgated by the American College of Medical Genetics (ACMG) and Global Alliance for Genomics and Health (GA4GH). These standards help promote transparency, reproducibility, and interoperability in NGS research.

- **CMS to CDC Data Stream**
  - DLS is utilizing a design standard, representational state transfer (REST) for its application programming interface (API) as an architecture for data transfer from the Centers for Medicare & Medicaid Services to CDC.
    - CDC validated and currently maintains four API endpoints corresponding to four CMS datasets have been validated. DLS is currently regularly ingesting data from these endpoints using enterprise systems (EDAV).
  - For analysis of population-level data for public health trending and interventions, DLS/QSSB data analysis utilizes Observational Health Data Sciences and Informatics (OHDSI) and the OMOP Common Data Model.

4) Centers for Medicare & Medicaid Services (CMS)

The Centers for Medicare & Medicaid Services (CMS) works voluntarily with partners to develop, evaluate, and apply national and consensus-based standards. Below is a summary of significant standards used or adopted by CMS to increase the electronic exchange of health information for administrative, financial, quality reporting, and value-based purchasing programs. Organizations using these standards include HIPAA-covered entities (payers, healthcare clearinghouses, certain covered providers), payers regulated by CMS, Medicare providers covered under the Promoting Interoperability and Merit-Based Incentive programs, and entities engaged in Alternative Payment Models, among others.

Centers, Offices, and Groups within CMS engaged with standards development organizations include the Center for Clinical Standards and Quality (CCSQ), the Center for Medicare and Medicaid Innovation (CMMI), the Center for Consumer Information and Insurance Oversight (CCIIO), the Center for Medicare (CM), the Office of Healthcare Experience and Interoperability (OHEI) which includes the Health Informatics and Interoperability Group and National Standards Group, the Office of Enterprise Data and Analytics (OEDA), and the Office of Information Technology (OIT), which includes the claims payment group.

The National Standards Group (NSG) within the Office of Healthcare Experience & Interoperability at CMS is responsible for adopting and enforcing the use of national standards, code sets, identifiers, and operating rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification provisions to increase the electronic exchange of health information

between covered entities. HIPAA-covered entities include health plans, health care providers, and health care clearinghouses, as defined in HIPAA. Representatives from NSG participate with several national standards development organizations as they develop and/or update the standards and operating rules in preparation for the next version to be considered for adoption. NSG is committed to enforcing the adoption of electronic standards by all covered entities, including those organizations in the private and public sectors, as electronic transaction standards will increase healthcare efficiency.

The Center for Medicare uses the adopted HIPAA standard for its eligibility system and transactions. The Center for Consumer Information and Insurance Oversight uses a modified version of the enrollment transaction for the employers participating in its program. It is not the HIPAA standard but a modified version that meets the needs of CCIIO. The staff in CCIIO are active participants in the X12 enrollment workgroup to develop a version of the transaction that meets federal requirements. The Center for Medicare also collaborates with ASTP/ONC to adopt a standard for pharmacy prior authorization under the Part D program, specifically the NCPDP SCRIPT standard, and coordinates with NCPDP on its development, use, updates, and education for payers and PBMs.

The standards development organizations in which CMS employees are engaged and which develop and maintain many of the HIPAA standards, including those for enrollment, eligibility, claims, claim status, electronic funds transfer, remittance advice, prior authorization, and attachments, are listed below. CMS staff, including those from OHEI, participate in workgroups of the standards-setting organizations:

- Health Level 7 (HL7): (www.HL7.org) – Fast Healthcare Interoperability Resources (FHIR) standards and Implementation Guides
- National Council for Prescription Drug Programs (NCPDP): (www.ncpdp.org) – Pharmacy standards
- Accredited Standards Organization, Insurance (X12N): (www.x12.org) – EDI administrative standards

Organizations responsible for code sets:

- American Dental Association: (www.ada.org) – The ADA manages the dental code set adopted under HIPAA.
- American Medical Association (www.ama-assn.org) chairs the National Uniform Claim Committee (NUCC), which is responsible for designing and maintaining the standardized health insurance claim form. The AMA also manages the CPT code set for billing, which has been adopted under HIPAA.
- National Uniform Billing Committee is chaired by the American Hospital Association. The NUBC maintains the UB-04 data set for institutional healthcare providers. It is the standard billing form and data set for institutional providers and data sets.
- NSG also consults with other stakeholder groups, such as the National Uniform Claim Committee (NUCC), Workgroup for Data Interchange (WEDI), and regularly engages with the National Committee on Vital and Health Statistics (NCVHS), advisory body to the Secretary.

Organizations responsible for Operating Rules:

- Council for Affordable Quality Healthcare (CAQH) Committee for Operating Rules for Information Exchange (CORE) CAQHCORE: (www.caqh.org)
- NACHA (the Electronic Payments Association): (https://www.nacha.org/)

The CMS Quality Measurement and Value-Based Incentives Group (QMVIG) in the Center for Clinical Standards and Quality (CCSQ) selects performance measures within its various quality initiatives, including healthcare provider public reporting and value-based purchasing programs.

CMS prefers selecting performance measures (https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualitymeasures) that have been reviewed through a consensus process and can be considered consensus-based standards. Battelle Memorial Institute (Battelle), a not-for-profit, nonpartisan organization offering free membership to participate in consensus-based entity (CBE) activities, meets the NTTAA definition of a consensus-based organization. CMS currently contracts Battelle to execute a public and transparent consensus development process to endorse and maintain performance measures.

Battelle's Endorsement & Maintenance (E&M) process (https://p4qm.org/EM) includes an open call for candidate consensus standards (i.e., performance measures), multi-stakeholder review of scientific and statistical evidence against the established endorsement criteria, discussion and evaluation of measures by multi-stakeholder experts including patients and caregivers; and opportunities for stakeholder feedback and public comments throughout the process. The E&M process also allows stakeholders and the public to appeal a decision on measures after they receive consensus-based endorsement. These processes are consistent with the NTTAA and OMB Circular A-119.

- CMS Quality Measures: https://mmshub.cms.gov/
- Partnership for Quality Measurement: https://p4qm.org

The Health Informatics and Interoperability Group at CMS requires CMS-regulated payers to use HL7 FHIR standards to implement application programming interfaces (APIs) under the 2020 Interoperability and Patient Access and 2024 Interoperability and Prior Authorization final rules to create a more efficient method to exchange clinical information between patients, providers, and payers. HL7 is the standards development organization that developed and maintains the FHIR standard and implementation guides. The required standards have also been adopted by ASTP/ONC. A list of the standards and implementation guides is available from https://www.cms.gov/priorities/burden-reduction/overview/interoperability/implementation-guides-and-standards/application-programming-interfaces-apis-and-relevant-standards-and-implementation-guides-igs.

5) Food and Drug Administration (FDA)

FDA is responsible for protecting public health by helping to bring safe and effective medical products and foods to the U.S. public; and advancing public health by ensuring the public has the most accurate, science-based information they need to use medicines and foods to improve and maintain their health. Standards help to ensure data and process consistency and enable use of advanced technology and analytics in FDA's performance of its mission. Where feasible, FDA participates in the development and uses voluntary consensus standards to help facilitate consistent and predictable product manufacturing and assessment, regulatory testing, clinical trial data exchange, and product labeling, just to name a few examples. Information exchange with our stakeholders promotes efficiency and awareness in the standards setting processes. The Agency looks for the appropriate time, process, and forum by which we can engage with standard development organizations. By doing so, FDA can facilitate standard setting activities and not hinder or duplicate efforts that are already underway in complementary

bilateral or multilateral discussions. The use of voluntary consensus standards can increase predictability, streamline premarket review, and facilitate market entry for safe and effective products, including products of emerging technologies, under FDA regulatory authority.

In addition, FDA participates actively in the standard setting process of the Codex Alimentarius, which for over 50 years has provided governments with a venue for adoption of food standards to facilitate safety and fair-trade practices. Codex is a joint body of the Food and Agricultural Organization of the United Nations and of the World Health Organization, and the standards developed through this body are recognized by the World Trade Organization. FDA supports Codex through the participation of experts and delegates representing the United States and through hosting meetings, along with the U.S. Department of Agriculture's (USDA) USDA Food Safety and Inspection Service. While FDA is not obligated to adopt the standards, Codex provides greater assurances of the safety of food imports, as many countries that export to the United States will adopt Codex standards.

Standards developed through interactions with various standard development bodies, including VCS organizations and/ or industry consortia, can provide benefit to both the Agency and our stakeholders in multiple ways such as:

- Standards can assist regulatory reviewers with assessment of products and product applications;
- Standards can assist industry with methodologies they can adopt for the assessment of their products;
- Standards often result in better utilization of limited internal resources;
- International standards can be used by multiple regulatory regions that can facilitate global harmonization, to the extent feasible;
- Direct participation by a broad group of stakeholders in development of standards can result in consensus among users, practitioners, manufacturers, and government regulators on safety and effective use of regulated products;
- Reduction in the costs and in transcription errors resulting from manual data entry such as for registrations and listing and adverse event reporting; and
- Reduction in the cost for incorporating new electronic processes such as electronic food and device labeling by leveraging existing exchange standards, business processes and information technology (IT) systems.

FDA policy is to help develop and use voluntary consensus standards wherever possible in the management of products FDA regulates. FDA supports the letter and spirit of the National Technology Transfer and Advancement Act (NTTAA) and the Office of Management and Budget (OMB) Directive. For more information about FDA's policies and procedures related to standards management, please see our Staff Manual Guide 9100.1 at: https://www.fda.gov/media/79684/download

For more information about FDA data standards and the FDA Data Standards Advisory Board, please see: http://www.fda.gov/ForIndustry/DataStandards/default.htm

Center for Devices and Radiological Health (CDRH)

CDRH gained additional authority under the 21st Century Cures Act to enhance its Standards Recognition Program. A final guidance titled Recognition and Withdrawal of Voluntary Consensus Standards

published on September 15, 2020 notes that FDA will publish its rationales about recognition decisions, respond to recognition requests within 60 days and establish transition times to revised recognized standards (when appropriate). Finally, the guidance reflects FDA's commitment to periodically update the Recognized Standards Database with pending recognitions. This means that once FDA conveys its intention to recognize a standard it will appear in the standards recognition database. Manufacturers may cite it in premarket submissions and will no longer need to wait for the publication of a *Federal Register* notice.

During FY2025, in accordance with section 514(c), 21 U.S.C. 360d(c), FDA/CDRH published the following notices to the Federal Register to announce the addition, withdrawal, correction, and/or revision of certain consensus standards the Agency will recognize for use towards a declaration of conformity in premarket submissions and other requirements for medical devices:

Publications in the Federal Register related to Modifications to the List of Recognized Standards is available at
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm

Standards recognitions published during FY 2025:

Date	Federal Register Notice
June 26, 2025	FR Notice (List #64) [Docket No. FDA-2004-N-0451]

Federal Register Volume 90, Number 121 (Thursday, June 26, 2025)

https://www.govinfo.gov/content/pkg/FR-2025-06-26/html/2025-11792.htm

March 20, 2025	FR Notice (List #63) [Docket No. FDA-2004-N-0451]

Federal Register Volume 90, Number 53 (Thursday, March 20, 2025)

https://www.govinfo.gov/content/pkg/FR-2025-03-20/html/2025-04711.htm

Access to the current FDA List of Recognized Consensus Standards, as published and updated in the Federal Register, can be found at
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Conformity Assessment

In general, conformity assessment activities for FDA-regulated products are conducted under applicable regulations and guidance that are informed by our standards development efforts described above. Standards may become part of conformance activities as they may provide an acceptable approach to ensure compliance with applicable laws and regulations.

Effective September 19, 2023, the U.S. Food and Drug Administration's Accreditation Scheme for Conformity Assessment (ASCA) Program was converted from a pilot to a permanent program as

authorized by Medical Device User Fee Amendments of 2022 (MDUFA V). Conceptualized to promote a least burdensome approach to medical device review, ASCA was developed in conjunction with the device manufacturing industry, standards development organizations and conformity assessment entities. The ASCA Program relies upon international consensus standards (ISO/IEC 17011 and ISO/IEC 17025) augmented by additional ASCA specifications and is designed to increase FDA's confidence in testing methods and results from ASCA-accredited testing laboratories. The ASCA Program makes device review more efficient, ensuring patients have access to safe and effective medical devices without unnecessary delay. The ASCA Program continues to be implemented through guidances outlining program specifications that can be found on the ASCA web page and listed below:

- **ASCA program guidance:** *The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Final Guidance*
- **Basic Safety and Essential Performance standards-specific guidance:** *Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*
- **Biocompatibility standards-specific guidance:** *Biocompatibility Testing of Medical Devices- Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*

These guidances are under docket FDA-2019-D-3805 published on September 25, 2020. Draft updates to these guidance documents were published on September 23, 2024 under the same docket.

CDRH reports annually on the progress of the ASCA Program and works with stakeholders for further input on programmatic improvements and/or considerations for expansion.

Human Foods Program (HFP) and Center for Veterinary Medicine (CVM)

As of October 1, 2024, the unified Human Foods Program (HFP), a new model for field operations and other modernization efforts is now in effect. The reorganization establishes the HFP by realigning the functions of the Center for Food Safety and Applied Nutrition, the Office of Food Policy and Response, as well as key functions from the Office of Regulatory Affairs (ORA) under one program. [1] [2]

The FDA Food Safety Modernization Act (FSMA) gives the Agency explicit authority to establish a program for accreditation of conformity assessment bodies (identified in the statute as third-party auditors) to conduct food safety audits and issue certifications of foreign food facilities for FDA-regulated food, which includes human food, and animal food. In 2015, FDA issued regulations (21 CFR Part 1 subpart M) establishing the Accredited Third-Party Certification Program. The regulations describe the framework, procedures, and requirements for accreditation bodies seeking recognition by the FDA, as well as requirements for third-party certification bodies seeking accreditation, under the program. Accreditation bodies and third-party certification bodies may use documentation of their

[1] https://www.fda.gov/news-events/press-announcements/fdas-unified-human-foods-program-new-model-field-operations-and-other-modernization-efforts-go

[2] https://www.fda.gov/news-events/press-announcements/fdas-reorganization-approved-establishing-unified-human-foods-program-new-model-field-operations-and

conformance with ISO/IEC 17011:2004, ISO/IEC 17021:2011, and ISO/IEC 17065:2012 in meeting the requirements of the regulations, supplemented as necessary (e.g., to meet the conflict of interest, reporting, and notification standards in section 808 of the FD&C Act). FDA recommendations on third-party certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under the voluntary third-party certification program are contained in a guidance document entitled, "Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards: Guidance for Industry and FDA Staff."

As part of these recommendations, FDA cited ISO/IEC 17021:2011 and ISO/IEC 17065:2012, which are voluntary consensus standards on accreditation that are widely used in determining the qualifications of third-party conformity assessment bodies that audit and certify the food industry. As of the end of FY25, the FDA has recognized 4 accreditation bodies which have 8 accredited certification bodies. FDA maintains an online registry of accreditation bodies recognized, and certification bodies accredited, under this program.

FSMA also gives us express authority to establish a laboratory accreditation program for the analyses of human and animal foods. FDA issued a final rule in December 2021 establishing the Laboratory Accreditation for Analyses of Foods (LAAF) program. The final rule specifies the oversight, uniformity, and standards necessary to help ensure that the results of certain food testing of importance to public health are reliable and accurate. Under the LAAF program, FDA recognizes accreditation bodies that accredit laboratories to the standards established in the final rule ("LAAF accredit"); only LAAF-accredited laboratories may conduct the food testing covered by the final rule. The final rule incorporates by reference two voluntary consensus standards: ISO/IEC 17011:2017 forms the foundational requirement for accreditation bodies, and ISO/IEC 17025:2017 forms the foundational requirement for food testing laboratories. As of the end of FY25, FDA has recognized 8 accreditation bodies that have accredited 47 testing laboratories. FDA maintains an online registry of accreditation bodies recognized, and laboratories accredited, under this program.

FDA's Moffett Proficiency Testing Laboratory (Moffett PT), located within CFSAN's Office of Food Safety, Division of Food Processing Science and Technology and part of the Institute for Food Safety and Health (IFSH), has been an ISO/IEC 17043 accredited proficiency testing laboratory since February 2017 but has been in operation within FDA in varying capacities since the 1950s. This PT program's scope of work is expansive as it is the official PT provider for FDA's inter-/intra-agency programs (CVM Veterinary Laboratory Investigation and Response Network, Office of Regulatory Affairs (ORA) Office of Regulatory Science (ORS) Quality Assurance programs/dietary supplement adulteration, FDA/USDA Food Emergency Response Network) as well as regulatory and food safety programs for milk, shellfish, vitamins, and food microbiology. FDA's Moffett PT incorporates both food microbiological and chemical analytes and matrices based on the historical, current, and emerging food safety and defense requirements of the FDA. Microbiological PT schemes, for example, include bioterror agents such as B. anthracis (attenuated), Y. pestis (attenuated) or F. tularensis (attenuated strains) and food pathogens such as Listeria, Salmonella, Vibrio and others in a variety of food products. Chemical PT schemes include glyphosate, tetramine, thallium, aflatoxin B1, carbamates, ricin and other toxins in a variety of food products. In addition, FDA's Moffett PT schemes include detection for fraudulent weight loss and erectile dysfunction drugs in dietary supplements. Moffett PT's expansive ISO/IEC 17043 accredited scope of work has greatly contributed to the groundwork built by FSMA for model laboratory standards, accreditation, and capability building of the nation's food laboratory networks.

Regarding pharmacovigilance, CVM personnel actively participate in the VICH pharmacovigilance expert working group. The full title of VICH is the "International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products. VICH is a trilateral (EU-Japan-USA) program that encourages participation from other global regions. The efforts of the working group members have culminated in the development of an internationally harmonized adverse event message, associated data standards, and 5 international PV VICH guidelines that has successfully been implemented in multiple regions and has facilitated exchange of safety information globally. One established data standard by VICH is Veterinary Dictionary of Drug Regulatory Activities (VeDDRA). VeDDRA is a list of clinical terms used for reporting suspected adverse events (AEs) in animals and humans to veterinary medicinal products and the list is updated annually. AE reporting using VEDDRA terminology ensures different regions and industry are all using the same terminology when reporting AEs. In addition, VICH working groups have established additional standards and maintenance procedures for VICH GL30 vocabulary lists which are harmonized lists of terms used as data elements in AE reporting.

Regarding animal food ingredients, CVM personnel actively participate in the International Cooperation for Convergence of Technical Requirements for the Assessment of Feed Ingredients (ICCF). ICCF work aims to develop and establish common guidance that covers technical requirements for the assessment of feed ingredients, including new uses of existing feed ingredients. ICCF full members represent feed ingredient industry and regulatory jurisdictions in Canada, the European Union, the United States of America, and the global feed industry through The International Feed Industry Federation (IFIF). The efforts of expert working group members have culminated in 9 ICCF technical guidance documents. In addition, the ICCF publishes a glossary of terms for use in guidance documents and the expert working groups for improved consistency.

Office of Chief Scientist (OCS)

Through self-coordinated or collaborative method development & research to support regulatory analysis at the OCS Regulatory Lab Testing Enterprise: Office of Analytical and Regulatory Laboratories (OARL) and Office of Specialty Laboratories & Enforcement Support (OSLES), supported by Office of Science and Laboratory Advancement (OSLA) and Informatics and Business Operations Staff (IBOS), actively contributes to the repertoire of consensus analytical methods that are published in the AOAC's compendium of the Official Methods of Analysis. According to 21CFR2.19, the Official Methods of Analysis of the AOAC INTERNATIONAL are specified to be used in cases where a method of analysis is not prescribed in the regulation.

OCS/OARL laboratories conduct analytical work aimed at updating official methods of analysis which are published in USP pharmaceutical analysis monographs.

All OCS regulatory testing labs are accredited to ISO/IEC 17025:2017 standards. The FDA's National Forensic Chemistry Center (NFCC), the OCS forensics specialized laboratory, is accredited to the standards of ANSI-ASQ National Accreditation Board (ANAB) in the field of Forensic Testing. OCS laboratories also conform to well established method validation and verification criteria such as ICH,

USP, AOAC standards when qualifying their analytical methods. Each laboratory in the OCS Regulatory Lab Testing Enterprise is audited by an ISO/IEC 17025:2017 accreditor.

Each laboratory conforms to the core requirements of a Quality Management System which includes the design and maintenance of a proficiency testing and exercise schedule. This proficiency testing program of OCS regulatory laboratories is called the National Check Sample Program and aims to provide an assessment of laboratory proficiency in performance of analytical methods in the accreditation scope. Some proficiency tests utilized in the National Check Sample Program are internally generated sample panels prepared with third party vendor standard materials while other proficiency tests are obtained commercially.

OCS Laboratories are also active members of the Integrated Consortium of Laboratory Networks (ICLN) and CODEX International; and adopt consensus standards developed by these organizations that pertain to specialized testing areas such as veterinary drug residue testing, radiation testing, and pesticide testing.

Center for Biologics Evaluation and Research (CBER)

The Center for Biologics Evaluation and Research's (CBER) Division of Biological Standards and Quality Control (DBSQC), in the Office of Compliance and Biologics Quality, was scheduled to be audited for ISO 17025:2017: "General requirements for the Competence of Testing and Calibration Laboratories" for the biological and chemical testing for product lot release, and ISO 17034:2016: "General Requirements for the Competence of Reference Material Producers" in September/October 2025. Due to the government shutdown, the audit was postponed until January 2026. During FY 2025, reference materials were produced and calibrated by DBSQC including influenza antigens and sheep antisera for influenza vaccine potency testing, as well as tetanus and diphtheria antitoxin for flocculation tests. Reagents for egg-propagated, cell-propagated and recombinant A(H1N1), A(H3N2) and B/Victoria-lineage seasonal influenza vaccine components, as well as A(H2N3), A(H5N6), A(H5N8), A(H7N9) and A(H9N2) pandemic reagents, were prepared and calibrated by CBER; DBSQC also collaborated with the WHO Essential Regulatory Laboratories at MHRA, UK; TGA, Australia; and NIID, Japan to calibrate influenza reagents produced to support influenza vaccine manufacturing world-wide.

CBER's Laboratory of Immunobiochemistry (LIB), in the Division of Bacterial, Parasitic and Allergenic Products, Office of Vaccines Research and Review, was internally audited for ISO 17025: 2017: "Regulatory Equipment Performance and Calibration" in December 2025. No deficiencies were identified. The scope of accreditation for the LIB covers the "ELISA Competition Assay for Quantitative Determination of Relative Potency of Allergenic Extracts." Additionally, LIB has reviewed over 341 protocols for lot release in conjunction with ELISA potency tests and shipped over 3,124 references to manufacturers of allergenic products during FY 2025. Finally, LIB replaced reference E12-Df during FY 2025 as part of the Reference Replacement Maintenance Program.

CBER coordinates with CDER to implement data standards related to the following:

- Real-World Data and Real-World Evidence (RWD/E)
- ISO Identification of Medicinal Products (IDMP) via Global Working Group (GIDWG)
- CDISC standards for clinical and nonclinical study data (e.g., SDTM, ADaM, SEND) and

terminologies (e.g., MedDRA, MED-RT, SNOMED CT, WHO Drug Global, NCIt/EVS)
- Study data standard validation project
- FDA data standard guidance development (e.g., FDA technical conformance guidance, FDA data standard catalog)
- Study data standard review tool training (e.g., JMP, SAS, MedDRA, MAED)
- ICH M11, the Clinical Electronic Structured Harmonized Protocol (CeSHarp)
- HL7 v3 and FHIR for exchange of data for numerous use cases including labeling, drug registration and listing, and other use cases
- HL7 ICSR for individual adverse event report data
- ICH M8 electronic Common Technical Document (eCTD) v4.0 for standardization of the format of regulatory submissions
- ICH M4Q(R2) to standardize the content of Quality information submitted within eCTD modules 2 and 3
- ICH M16, Structured Product Quality Submissions (SPQS) further standardized quality submissions from a document-centric approach (e.g., PDFs) to add a data-centric one (e.g., standardized data elements) that support automated and real-time data analysis
- Bioresearch Monitoring Data Standards (BIMO)
- BioCompute Objects for High-throughput Sequencing Data
- For more information, see Study Data for Submission to CDER and CBER, FDA Data Standards Advisory Board, FDA Data Standards Catalog, and FDA CBER-CDER Data Standards Program Joint Action Plan 2025

The 21st Century Cures Act was signed into law in December 2016. Section 3036 directs the FDA to collaborate with the National Institute of Standards and Technology (NIST) and FDA stakeholders to coordinate and prioritize standards development for regenerative medicine and regenerative medicine advanced therapies.

To encourage the use of standards for regenerative medicine products, CBER published the final guidance Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies on October 19, 2023. This guidance describes a standards recognition program for regenerative medicine therapies (SRP-RMT) designed to identify and recognize Voluntary Consensus Standards (VCS) to facilitate the development and assessment of regenerative medicine therapy (RMT) products regulated by CBER when such standards are appropriate. CBER encourages the use of appropriate standards in the development of CBER-regulated products. The use of recognized VCS can assist stakeholders in more efficiently meeting regulatory requirements and increasing regulatory predictability for RMT products. This program is modeled after the formal standards and conformity assessment program, or S-CAP, for medical devices. CBER posts a list of recognized standards on Standards Development for Regenerative Medicine Therapies, the regenerative medicine therapies portion of the FDA website. Since implementation of the SRP-RMT, CBER has reviewed and recognized 43 standards.

To further collaborations between FDA, NIST, and FDA stakeholders, a workshop on AI and Flow Cytometry took place on June 9 – 10, 2025. The aim of this workshop was to advance AI/ML applications in flow cytometry. This effort focused on emerging applications in disease diagnosis, therapeutic development, manufacturing, clinical trials, and patient dosing and monitoring. For example, standardization of high-quality data sets for flow cytometry to enable reproducibility in clinical data. A report on the workshop was published in the Journal of Immunology, AI and Flow Cytometry: https://doi.org/10.1093/jimmun/vkaf292.

Revision of ICH guidelines to include regenerative medicine therapies (aka Advanced Therapy Medicinal Products, ATMPs) is a new focus for ICH. CBER staff are participating in revising ICH Q1/Q5C Guidance on stability and an annex to ICH Q5E on comparability.

Center for Drug Evaluation (CDER)

CDER recognized the following pharmaceutical quality standards through the Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality:

- ASTM E2503-13 (Reapproved 2020) Standard Practice for Qualification of Basket and Paddle Dissolution Apparatus
- ASTM E3042-16 (Reapproved 2024) Standard Practice for Process Step to Inactivate Rodent Retrovirus with Triton X-100 Treatment. (updated to new version of the standard.)
- ISO TS 4958:2024 Nanotechnologies – Vocabulary – Liposomes.

Additional information can be found on the program's webpage, CDER Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality (CDER Quality Standards Program).

Center for Tobacco Products (CTP)

Catalyzed by NTTAA and OMB circular A-119 and to encourage the appropriate use of voluntary consensus standard, CTP has established an ongoing working group to draft a guidance for industry. An outline has been developed for this guidance document. Additionally, CTP has established a working group and initiated an active standards recognition program to enhance application review efficiency. The program currently focuses on testing methods but may expand the scope in the future to include other types of standards such as software or human factors testing standards. The program is developing comprehensive strategies and criteria for recognition, qualification, and evaluation using unified approaches across FDA centers.

In partnership with Clinical Data Interchange Standards Consortium (CDISC), CTP developed data standards to facilitate tobacco product research and scientific review. On June 10, 2024, CDISC released Tobacco Implementation Guide v1.0, a foundational data standard that can help optimize scientific accuracy and review efficiency. The guide was developed by a multidisciplinary team from CTP, tobacco industry stakeholders, and CDISC, and included public/community review. This initial version of the Guide implements several data models, including Clinical Data Acquisition Standards Harmonization, Study Data Tabulation Model, and Analysis Data Model.

In FY25 (Oct. 2024 – Sept. 2025), CDISC and FDA continued Phase 2 collaborative project with two primary goals: 1) broader TIG education and 2) development of mock submission content following TIG standards. Goal 1 - TIG Education: The Education Workstream maintained weekly meetings, completed fundamental standards training, and provided ongoing feedback. New and revised educational resources are currently in development for release by project completion. Goal 2 - Mock Submission Content: CDISC and FDA completed scoping for industry mock submission content. Industry team member volunteers created standardized datasets and provided feedback with CDISC support. CDISC

additionally prepared over 300 conformance rules for electronic dataset validation. Planning is underway for a white paper that will describe project findings and establish a long-term framework for collaboration and standards management."

6) Indian Health Service (IHS)

The primary mission of the Indian Health Service (IHS) is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level. Standards and conformity assessment activities are an integral part of the effective operations of the IHS in achieving its mission. There are health-related standards that are used for numerous purposes in the health industry. The IHS has used them for privacy/security, interoperability, compliance/accreditation, and certification.

Privacy and security standards are used throughout IHS and comply with Department of Homeland Security (DHS) requirements. Privacy and security standards are used for other purposes beyond those related to patient and employee data. The IHS also uses privacy and security standards to address communication of biomedical diagnostic and therapeutic information for digital imaging, telemedicine, national drug codes, energy-efficient and environmentally friendly construction, and for reporting medical services and procedures.

Interoperability is achieved within IHS through following standards from various development organizations, e.g. the use of Health Level Seven (HL7) schemas and International Classification of Disease, Tenth Edition (ICD-10) codes. The HL7 standard allows interoperability among health information systems both within and beyond the IHS healthcare environment, such as immunization data exchange to various state and federal partners. ICD-10 is a clinical cataloging system used by IHS and its providers, coders, information technology professionals in addition to insurance carriers, government agencies and others use to properly note diseases on health records, track epidemiological trends, and assist in medical reimbursement decisions. It brings interoperability among disparate systems for information sharing.

Accreditation is a process of review in which healthcare organizations participate to demonstrate the ability to meet predetermined criteria and standards of accreditation established by a professional accrediting agency. DirectTrust Agent accreditation recognizes excellence in health data processing and transactions. It ensures compliance with industry-established standards, HIPAA regulations and the Direct Project. Accreditation granted by the DirectTrust Agent Accreditation Program for Health Information Service Providers from the Electronic Healthcare Network Accreditation Commission (EHNAC) and DirectTrust is valid for a two-year period; thereafter, a re-accreditation process take place.

Certification is a process by which an accreditation body assesses and verifies the attributes of a product in accordance with established requirements or standards. Over the past decade, the IHS successfully achieved certification of its Electronic Health Record for both ambulatory and inpatient settings against the 2011, 2014, 2015 Edition, and 2015 Edition Cures Update standards published by the Office of the National Coordinator for Health Information Technology (ONC). This has allowed IHS, Tribal, and Urban Indian health care organization hospitals and providers to qualify for various Centers for Medicare and Medicaid Services (CMS) Meaningful Use incentives authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act and to participate in CMS Quality Payment Programs. The IHS has certified to the requirements that were due in 2025 for the ONC HTI-1 Update per ONC's

timeline in the Federal Register. The IHS is continuing work to comply with the requirements due in 2026 as well. The IHS has utilized and incorporated numerous information technology standards promulgated by development organizations and specified in the various ONC Final Rules in order to meet the rigorous certification requirements.

The IHS Office of Information Technology maintains a website that references a number of the standards and policies in use by the agency that can be found at: https://www.ihs.gov/oit/standardspolicy/

7) National Institutes of Health (NIH)

National Library of Medicine (NLM)

The National Library of Medicine (NLM) is a leader in biomedical informatics and computational health data science research and the world's largest biomedical library. With a mission to acquire, collect, preserve, and disseminate materials relevant to research, medicine, and public health, NLM makes the world's biomedical data and information discoverable and accessible to all: scientists, clinicians, students, educators, librarians, and the public. NLM's biomedical information services enable data-driven scientific discovery, health care, and public health. In addition, NLM's innovative research programs develop and apply novel computational approaches to accelerate biomedical discovery and advance health.

As the central coordinating body within the U.S. Department of Health and Human Services for clinical terminology standards for health data interoperability, NLM plays a critical role in promoting health data interoperability through the development, maintenance, and dissemination of health data standards. In this role, NLM works across the National Institutes of Health and federal government to advance the interoperable exchange of health data for care and quality reporting in support of federal health information technology (IT) interoperability requirements and of research.

In FY 2025, NLM continued to support improvements in health data standards, services for standards-based information sharing, and use of standards in its literature services.

NLM continued to support the improvement of three standards used to assure the precise and current representation of terms and codes needed for clinical care and research:

1) SNOMED CT® (Systematized Nomenclature of Medicine Clinical Terms): Supported expansion by adding nearly 8,000 concepts and the addition of more than 450 concepts to enable users to capture information specific to the U.S. health care system.

2) LOINC® (Logical Observation Identifiers, Names and Codes): Added over 600 new terms to support the provision of high-quality interoperable laboratory information.

3) RxNorm: Added more than 300 new terms to facilitate sharing of over-the-counter and prescription drug-related information in support of care management and payment activities in health care.

NLM also continued to support services that facilitate standards-based information sharing for health care and public health:

1) MedlinePlus Connect: Provides patients and clinicians with direct, tailored access to MedlinePlus resources automatically through EHR systems, patient portals, and other health information technology (IT) systems at the point of care. In FY 2025, MedlinePlus Connect responded to nearly 300 million electronic requests from health IT systems.

2) Value Set Authority Center: A repository and authoring tool for value sets, or lists of codes and corresponding terms, from NLM-hosted standard clinical vocabularies (such as SNOMED CT®, LOINC®, and RxNorm), that define clinical concepts to support effective and interoperable health information exchange. In FY 2025, in collaboration with the Centers for Medicare & Medicaid Services and the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, NLM published value set specifications for the 2026 electronic clinical quality measures (eCQMs).

Lastly, NLM continued to employ use of and provide support for the Journal Article Tag Suite (JATS), an application of NISO Z39.96-2021, which defines a set of XML elements and attributes for tagging journal articles and describes three article models. NLM supported the NISO JATS Standing Committee by acting as a vital resource in the FY 2025 release of JATS version 1.4.

National Cancer Institute (NCI)/Nanotechnology Characterization Laboratory (NCL)

The Nanotechnology Characterization Laboratory (NCL) (https://www.cancer.gov/nano/research/ncl) is part of the Frederick National Laboratory for Cancer Research operated by Leidos Biomedical Research Inc. (contractor) for the National Cancer Institute (NCI). The NCL is guided by the NCI's Alliance for Nanotechnology in Cancer, Cancer Imaging Program, the Division of Cancer Treatment and Diagnosis. The laboratory is dedicated to supporting the extramural research community.

The mission of the NCL is to advance the science of nanoparticle characterization. As part of these efforts, the NCL has developed 82 assays and 5 characterization guides for nanomaterial characterization, termed NCL's Assay Cascade. All NCL assays are published on the NCL website and are free to download: https://www.cancer.gov/nano/research/ncl/protocols-capabilities

Over 550 nanomaterials of varied platform types have passed through the NCL Assay Cascade. The laboratory updates existing assays on a regular basis and develops and validates new assays to meet the needs of the nanotechnology research community. This year, one new protocol was added to our catalogue:

- NCL Method ITA-38: Analysis of Nanoparticle Effects on IgE-Dependent Mast Cell Degranulation

In addition to these assays, the NCL commonly applies the following voluntary standards and guides:

- ISO/TR 10993-22:2017: Biological evaluation of medical devices — Part 22: Guidance on nanomaterials
- ISO 10993-4:2017 Biological Evaluation of Medical Devices — Part 4: Selection of Tests For Interactions With Blood
- USP Bacterial Endotoxins Test, December 2012

NCL team members are active participants of the standards organizations ASTM International and ISO, which develop voluntary consensus standards. Several of the NCL's protocols have been adapted as ASTM standards:

- ASTM E2524-22: Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles
- ASTM E2525-22: Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies
- ASTM E2526-22: Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells
- ASTM E3351-22: Standard Test Method for Detection of Nitric Oxide Production In Vitro

NCL staff also serve as subject matter experts in various nanotech-related working groups within these organizations. In addition to working to promote NCL's assay to standards, the NCL also contributed to the development of several other standards:

- ISO 29701:2010 Nanotechnologies—Endotoxin test on nanomaterial samples for in vitro systems — Limulus amebocyte lysate (LAL) test
- ISO TS 21362: Nanotechnologies — Analysis of nano-objects using asymmetrical-flow and centrifugal field-flow fractionation.
- ASTM E3297-21: Standard Test Method for Lipid Quantitation in Liposomal Formulations Using High Performance Liquid Chromatography (HPLC) with a Charged Aerosol Detector (CAD)
- ASTM E3324-22: Standard Test Method for Lipid Quantitation in Liposomal Formulations Using Ultra-High-Performance Liquid Chromatography (UHPLC) with Triple Quadrupole Mass Spectrometry (TQMS)

NCL contributed to the revision of another ASTM document undergoing review for adaptation as a standard:

- ASTM 60553 ballot:Standard Method for Analysis of Nanoparticle Effects on Phagocytosis

Staff are also working with ASTM International and ISO on the preparation and adoption of new standards:

- ISO TC 229 WG2: ISO working item Nanotechnologies – Total, encapsulated, and free drug quantitation in doxorubicin hydrochloride liposomal formulation.
- ASTM E56.02: Asymmetrical-Flow Field-Flow Fractionation methodology for mRNA-lipid nanoparticles.
- ASTM WK75607: Standard Guide for Characterization of Encapsulation, Extraction, and Analysis of RNA in Lipid Nanoparticle Formulations for Drug Delivery
- ASTM WK67980: Standard Test method for Poly(ethylene glycol) Coating Quantitation on Gold Nanomaterials Using High Performance Liquid Chromatography and Evaporative Light Scattering Detector (HPLC/ELSD)

8) Substance Abuse and Mental Health Services Administration (SAMHSA)

SAMHSA supports the National Technology Transfer and Advancement Act (NTTAA) and OMB Circular A-119 by participating in the development, use, and maintenance of voluntary consensus standards (VCS) related to behavioral health quality measurement, health information technology, and data standards.

SAMHSA collaborates with the Centers for Medicare & Medicaid Services (CMS) through interagency coordination and participation in CMS-convened federal workgroups supporting quality measurement

used in federal health programs. In FY 2025, SAMHSA participated in standards-related activities primarily through CMS Core Set federal workgroup discussions, including stakeholder input, measure maintenance considerations, and technical specification discussions.

SAMHSA contributed subject-matter expertise to consensus-based quality measurement activities administered by CMS, operating under nationally recognized consensus processes. These activities included participation in measure updates and technical alignment supporting Medicaid and Medicare reporting programs, including Adult, Child, and Health Home Core Sets, which rely on voluntary consensus standards where practicable.

SAMHSA also participated in CMS electronic clinical quality measures (eCQM) governance structures, including the eCQM Governance Group, which provides a forum for collaboration and communication with federal partners on eCQM updates. Through this participation, SAMHSA engaged in discussions related to measure specification, interoperability, and reporting that were informed by voluntary, consensus-based standards. These activities aligned with Circular A-119 principles by promoting interagency coordination, reducing duplicative federal standards development, and supporting harmonization across federal health programs.

Information on SAMHSA's quality measurement and standards-related activities is available at: https://www.samhsa.gov; and

https://www.samhsa.gov/communities/certified-community-behavioral-health-clinics/guidance-and-webinars#:~:text=The%20quality%20measures%20for%20Behavioral%20Health%20Clinics,using%20the%20Section%20223%20Demonstration%20Years%20(DY)

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2025. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Current total GUS = 1

Table 1: Current Government Unique Standards FY2025

(1) Government Unique Standard

FDA Guidelines on Aseptic Processing (2004) [Incorporated: 2004]

Voluntary Standard

ISO 13408-1 Aseptic Processing of Health Care Products, Part 1, General Requirements

Rationale

FDA is not using the ISO standard because the applicability of these requirements is limited to only portions of aseptically manufactured biologics and does not include filtration, freeze-drying, sterilization in place, cleaning in place, or barrier-isolator technology. There are also significant issues related to aseptically produced bulk drug substance that are not included in the document.