Every day around the globe, ASTM International standards make a vital contribution in the healthcare field. Proven ASTM standards advance human health by improving care delivery, supporting medical research and drug development, enhancing product manufacturing and much more. Developed by leading healthcare practitioners, engineering professionals and other technical experts, ASTM standards drive the science and innovation that bring about a healthier and safer way of life.
COMMITTEE F04: GLOBAL AGENDA FOR MEDICAL DEVICE STANDARDS

With its dynamic focus and a broad global membership of more than 950 professionals from 31 countries, ASTM International Committee F04 on Medical and Surgical Materials and Devices delivers over 280 standards that make an impact around the world. Since 1962, F04 has played an important role in the development of standards and test methods for medical/surgical instruments, orthopaedic devices, implant systems and more. Flagship F04 material standards, such as F899, Specification for Wrought Stainless Steels for Surgical Instruments, have assisted product manufacturers and supported quality patient care for decades.

As healthcare worldwide continues to change and advance, so do available therapies and technologies. Committee F04 has built on its earlier efforts in material and design standards to embrace a diverse agenda that has kept pace with the evolving discipline of medical technology. Today, F04’s 34 technical subcommittees address standards related to ceramics, metals and polymers as well as biocompatibility and magnetic resonance imaging; methods and practices for osteosynthesis, arthroplasty and spinal devices; medical and surgical devices used in cardiology, neurology, audiology, gastroenterology and plastic surgery; cell signaling, computer-assisted orthopaedic surgical systems, human clinical trials and tissue engineered medical products.

ADVANCING THE SCIENCE OF TEMPS

Tissue engineered medical products, commonly referred to as TEMPS, use biological components alone or in combination with synthetic components to restore human tissue through regeneration. To support continued progress in this field and its role in enhancing human health, F04 has subcommittees focused on TEMPS-related activities, including classification and terminology, biomaterials and biomolecules, cells and tissue engineered constructs, assessment, adventitious agent safety and cell signaling.

Among the F04 standards available in this area is F2900, Guide for Characterization of Hydrogels used in Regenerative Medicine. F2900 assists researchers and practitioners in determining the key attributes of hydrogels used in regenerative medicine, including biological properties, kinetics of formation, degradation and agent release, physical and chemical stability, and mass transport capabilities.


F2503: PROMOTING THE SAFE USE OF MRI

Magnetic resonance imaging technology has grown dramatically since its debut in the 1980s. MR scanners use magnetic signals to create images of the human body, helping physicians to study nerves, muscles, ligaments, bones and other tissues and to diagnose injuries and disease.

Within the MR environment, potential safety hazards pose concern for patients, MR technologists and other medical professionals. Implants such as pacemakers and metal joint replacements can interact with the MR scanner’s magnets and pulses resulting in device damage, malfunction and overheating that may lead to serious patient injury and death. There is also the risk of projectile accidents caused when other medical devices and metallic items are pulled into the bore of the MR system.

To mitigate technologist confusion and facilitate patient safety, F04 developed F2503, Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. Recognized in U.S. Food and Drug Administration guidance, F2503 provides a uniform marking system to indicate what MR conditions have been determined to be acceptable for a medical device or other item. It provides MR labeling terms and associated visual icons intended to reduce injuries when potentially hazardous items are brought into the MR environment.

ENSURING SAFETY IN PHARMACEUTICAL AND MEDICAL PRODUCT PACKAGING

Two of ASTM International’s most enduring committees, D10 on Packaging and F02 on Flexible Barrier Packaging, have long cooperated in developing standards that fulfill health and safety needs. D10 and F02 medical packaging standards respond to the needs of regulators and manufacturers both in the United States and internationally, and find broad use in primary packages, which maintain the sterility of the device, as well as their secondary shipping containers, which further protect the contents.

Committee D10, formed in 1914, has a portfolio of 135 standards, many geared toward critical medical applications. Highlighting these efforts is the work of Subcommittee D10.32 on Consumer, Pharmaceutical and Medical Packaging, which maintains standards such as D3475, Classification of Child-Resistant Packages, recently updated in 2011. D3475 defines the type of motions, skills or tools required for a particular type of child-resistant package and provides examples of current packaging within that type. Safety and reliability in drug labeling is the focus of another recently revised D10.32 standard, D4774, Specification for User Applied Drug Labels in Anesthesiology. D4774 covers the size, color and pattern, and type used on labels applied to unlabeled syringes filled by the users or their agents to better identify the drug content.

The efforts of Committee D10 are directly complemented by those of Committee F02, with the two groups often holding joint meetings and working sessions. F02 was established in 1957 and today is responsible for 54 standards, many of which are contained in the ASTM compilation, Consumer and Healthcare Packaging Standards, a valuable resource for packaging professionals, packaging engineers, pharmaceutical and healthcare companies, testing laboratories and FDA professionals.

Notable F02 standards that support medical packaging integrity include F88, Test Method for Seal Strength of Flexible Barrier Materials, which covers techniques to measure seal strength and thus provide process validation, control and capability. Similar utility can be found in F1140, Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages, which covers how to determine the ability of packages to withstand internal pressurization, and F1929, Test Method...
for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration, a procedure that locates leaks in a package seal.

E31: IMPROVING ACCURACY AND TIMELINESS OF PATIENT INFORMATION

As the nation’s healthcare system continues to transform itself to improve quality of care, providers are increasingly embracing electronic health records to enable more reliable patient information exchange. EHRs are a critical component in the continued progress of healthcare that can strengthen the relationship between patients and their doctors. By improving the accuracy and availability of medical records, EHRs can reduce errors, speed treatment and care delivery, and keep patients better informed.

A major focus of ASTM International Committee E31 on Healthcare Informatics is the development of standards that help doctors and healthcare practitioners preserve and transfer patient information using EHR technologies. E31 has been collaborating on consensus standards since its organization in 1970. With representation from 17 countries in its membership, the committee develops standards for the architecture, content, storage and communication of information used within healthcare, including patient-specific information and medical knowledge as well as integrity and confidentiality.

Flagship E31 standards include E2369, Specification for Continuity of Care Record (CCR). The CCR defines a core set of information to be sent to the next healthcare provider whenever a patient is referred, transferred or uses different medical facilities or providers. For both doctors and patients, the CCR facilitates better coordination and improved medical care. E2369 has been adopted in countries around the world and has been incorporated in leading EHR platforms such as Microsoft HealthVault. In the United States, the Office of the National Coordinator for Health Information Technology, part of the U.S. Department of Health and Human Services, has included the use of E2369 in its formal certification criteria for EHR technologies.

Two other benchmark E31 documents also provide utility in the EHR area. These standards are: E1384, Practice for Content and Structure of the Electronic Health Record (EHR), a comprehensive structure for data collected in patient care records that draws on specialty disciplines and particularly integrates clinical laboratory data with other patient information, and E1633, Specification for Coded Values Used in the Electronic Health Record, which details value sets for explicit data attributes in E1384.

ASTM STANDARDS AND UNIVERSAL PATIENT IDENTIFICATION

Another emphasis of E31’s standards development activities is the dynamic and evolving area of universal patient identification. Issues related to UPI have been the focus of much discussion since the signing of the Health Insurance Portability and Accountability Act of 1996. Incorrectly identifying a patient continues to be a major area of concern in the healthcare environment and has serious unwanted consequences, including adverse drug events, unnecessary and duplicate testing, clinical complications, prolonged hospital stays and patient dissatisfaction. A UPI approach would help reduce errors, improve patient safety and enhance the interoperability and efficiency of health information networks.

Two E31 standards are supporting the implementation of a voluntary universal patient identification system. These include E2553, Guide for Implementation of a Voluntary Universal Healthcare Identification System, which describes the principles needed to create such a system, addressing issues of privacy, security and cost-effectiveness. Similar utility is found in E1714, Guide for Properties of a Universal Healthcare Identifier (UHID), outlining the requirements to create a UHID system.

E56 NANOTECH STANDARDS SUPPORT CANCER RESEARCH

The battle against cancer is getting a boost from several breakthrough test methods under the jurisdiction of ASTM Committee E56 on Nanotechnology. E56, organized in 2005, is supporting cutting-edge research efforts that could pave the way for commercially available nanoscale cancer drugs. The standards have been developed within Subcommittee E56.02 on Characterization: Physical, Chemical and Toxicological Properties, and include the following:

- E2524, Test Method for Analysis of Hemolytic Properties of Nanoparticles, is a protocol for examining the destruction of red blood cells (hemolysis) that can lead to anemia, jaundice and other issues.
- E2525, Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies, describes a method for evaluating nanoparticle stimulation or inhibition of the maturation of certain bone marrow cells (macrophages). A common side effect of anti-cancer drugs is inhibition of this process, and bone marrow cells may be particularly sensitive to nanoscale material.
- E2526, Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials on Porcine Kidney Cells and Human Hepatocarcinoma Cells, enables the nanomaterial toxicity evaluation by examining effects on kidney and cancerous liver cells. Because studies have indicated that many nanoparticles are cleared from the body through the kidney or liver, these organs are good choices for target organ toxicity evaluation.

Users of E56 test methods include nanotech drug developers, scientists in the pharmaceutical, cancer research and nanotechnology fields, regulatory agencies and agencies evaluating the environmental health and safety risks associated with nanoparticles.

BUILDING A NEW ROAD MAP FOR PHARMACEUTICAL MANUFACTURING

When it comes to pharmaceutical manufacturing, a global industry whose products can literally mean the difference between life and death, quality and efficiency are major concerns. ASTM International Committee E55 on Manufacture of Pharmaceutical Products is working to improve on the current level of quality and efficiency through the development of standards for the pharmaceutical manufacturing industry.
With a global participation of representatives from industry, academia, trade associations, financial organizations and the FDA, E55 has developed several watershed standards. The committee was born from an expansion of the Process Analytical Technology initiative, a program developed by the FDA to overhaul pharmaceutical manufacturing processes to ensure good, safe and reliable products for consumers.

E55’s first standards were focused on furthering the goals of the PAT framework throughout the pharmaceutical industry. These include E2363, Terminology Relating to Process Analytical Technology in the Pharmaceutical Industry, and E2474, Practice for Pharmaceutical Process Design Utilizing Process Analytical Technology. The most recent addition to E55’s PAT standards is E2476, Guide for Risk Assessment and Risk Control as it Impacts the Design, Development and Operation of PAT Processes for Pharmaceutical Manufacture. E2476 is intended to identify and eliminate risk at the earliest point of the manufacturing process, during its initial design. The committee is developing several other PAT-related standards that will provide guidance in such areas as process sampling, validation and continuous processing.

The newest standards in E55’s growing portfolio have been released by Subcommittee E55.03 on General Pharmaceutical Standards. To facilitate purity testing of pharmaceutical water, the most common component or ingredient used in pharmaceutical and biopharmaceutical manufacturing, the committee developed E2656, Practice for Real-Time Release Testing of Pharmaceutical Water for the Total Organic Carbon Attribute. In 2011, E55.03 also released E2810, Practice for Demonstrating Capability to Comply with the Test for Uniformity of Dosage Units, for use in drug content uniformity and dissolution testing.

Most recently added to the committee is Subcommittee E55.04 on General Biopharmaceutical Standards, which will develop standards for manufacturing biopharmaceutical products. In addition to assuming responsibility for existing standards on the topic, E55.04 is developing WK36552, Practice for Process for Inactivation of Retrovirus by pH.

**MAKING AN IMPACT ON HEALTHCARE PRODUCTS AND SERVICES**

Several other ASTM International technical committees are involved in standards development activities that serve to enhance healthcare products and services for people around the world.

These committees include the following.

ASTM Committee F30 on Emergency Medical Services, organized in 1984. F30 has a membership of about 100 stakeholders who serve on four technical subcommittees focusing on topics that include EMS equipment such as immobilization devices and air ambulances; training of emergency medical technicians and first responders; EMS system structure; and medical dispatch management and communications. Notable among the committee’s portfolio of more than 50 standards is F2020, Practice for Design, Construction and Procurement of Emergency Medical Services Systems (EMSS) Ambulances, and F2428, Guide for Selection and Use for Pelvic Ring Circumferential Compression Stabilization Devices (PRCCSD), most recently updated in 2011.

Subcommittee D11.40 on Consumer Rubber Products, which is part of Committee D11 on Rubber, has an extensive array of standards that impact the quality, performance and safety of healthcare products such as medical gloves, condoms and drainage tubes. Among its widely used standards are D3577, Specification for Rubber Surgical Gloves, and D7427, Test Method for Immunological Measurement of Four Principal Allergenic Proteins (Hev b 1, 3, 5 and 6.02) in Natural Rubber and Its Products Derived from Latex. D11.40 also has several new standards under development. These include a specification for antimicrobial medical gloves, which aims at determining antimicrobial efficacy on the surface of gloves to reduce the number of microorganisms reaching the wearer.

With a membership of almost 100 professionals, ASTM Committee F29 on Anesthetic and Respiratory Equipment develops standards for medical systems such as gas monitors, ventilators and other systems. The committee has a significant international focus, formulating the U.S. technical advisory group’s position for ISO/Technical Committee 121 on Anesthetic and Respiratory Equipment. Notable F29 standards include F2726, Specification for Fixation Devices for Tracheal Tubes and Other Airway Devices, and its newest standard, F2761, Medical Devices and Medical Systems — Essential Safety Requirements for Equipment Comprising the Patient-Centric Integrated Clinical Environment (ICE) — Part 1: General Requirements and Conceptual Model, which addresses the interconnectivity of medical devices in the clinical environment.

As healthcare needs evolve and expand around the globe, ASTM standards will continue to drive the scientific and medical advancements that support healthier and longer lives.

**ASTM INTERNATIONAL TECHNICAL COMMITTEES FOR THE HEALTHCARE AND MEDICAL SECTOR:**

The ASTM technical committees highlighted in this piece include:

- D10 on Packaging
- D11 on Rubber
- E31 on Healthcare Informatics
- E55 on Manufacture of Pharmaceutical Products
- E56 on Nanotechnology
- F02 on Flexible Barrier Packaging
- F04 on Medical and Surgical Materials and Devices
- F29 on Anesthetic and Respiratory Equipment
- F30 on Emergency Medical Services