

# UPDATES TO ASTM F2847-17

In 2017, a new version of ASTM F2847 was released (Standard Practice for Reporting and Assessment of Residues on Single-Use Implants and Single-Use Sterile Instruments), updating how reference and guidance documents can be used. For many medical device manufacturers, this changes the types of methods that can be used, and the way that results are reported.

ASTM Standard Changes	
+	E29 - Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications
ISO Standard Changes	
+	ISO 17294-1 - Water Quality_Application of Inductively Coupled Plasma Mass Spectrometry (ICP-MS) - Part 1: General Guidelines
+	ISO 17294-2 - Water Quality_Application of Inductively Coupled Plasma Mass Spectrometry (ICP-MS) - Part 2: Determination of Selected Elements Including Uranium Isotopes
United States Pharmacopeia (USP) Changes	
+	USP <161> Transfusion and Infusion Assemblies and Similar Medical Devices
+	USP <232> Elemental Impurities - Limits
+	USP <233> Elemental Impurities - Procedures
+	USP <631> Chromatography
+	USP <643> Total Organic Carbon
+	USP <730> Plasma Spectrochemistry
+	USP <731> Loss on Drying
+	USP <851> Spectrophotometry and Light Scattering
European Pharmacopoeia (PhEUR) Changes	
-	2.2.55 - Peptide Mapping
Other Reference Changes	
+	FDA Guidance for Industry Pyrogen and Endotoxins Testing: Q&A, June 2012
-	FDA Guideline on Validation of the Limulus Amebocyte and Animal Parenteral Drugs, Biological Products, and Medical Device. 1987
-	200.7 - EPA Methodologies for ICP

## DOCUMENTATION UPDATES TO ASTM F2847

ASTM F2847-17 contains many updates related to new reference documentation and standards, providing additional guidance related to quantification limits and precision, extraction methods, and total carbon determination. The recent revision also suggests a variety of analytical test methods that should be used for the identification and specification of critical compounds, residues, and residue requirements.

## MAJOR CHANGES TO ASTM F2847-17

The table to the left shows a list of significant changes included in ASTM F2847-17, as well as updates to supporting or reference documentation. Additions to the specification are marked with a +, and deletions are marked with a -.

