Reference Source	Document Title	Subject Matter
FDA	Guidance for Industry – Sterile Drug Products Produced by Aseptic Processing	Aseptic Operations
FDA	All Guidance documents	Covers all areas of Interest
EU Annex 1	GMP for Medicinal Products for Human and Veterinary Use – Manufacture of Sterile Medicinal Products	Aseptic Operations
ISO 14644	Cleanrooms and Associated Controlled Environments Parts 1-9 (Part 6 – definitions)	Standards on classification, testing, metrology, operations, Separative devices,
ISO 14698-1,2	Biocontamination Control	General Principles
AS 2252.1	Biological Safety Cabinets (Class1)	Australian Std
AS 2252.2	Biological Safety Cabinets (Class 2)	"
AS 2647	Biological safety cabinets – Installation and use	"
ASTM F-51	Sizing and Counting Particulate Contamination in and on Cleanroom Garments	Testing of garments (Original manual method)
ASTM F-24	Measuring and Counting Particulate Contamination on Surfaces	Manual method
ASTM F-25	Sizing and Counting Airborne Particulate Contamination in Cleanrooms and Other Dust Controlled Areas Designed for Electronic and Similar Applications	Manual method
ISO 11137	Sterilization of Healthcare Products	Dosimetric aspects for Radiation sterilization
ISO 11138	Sterilization of Healthcare Products	Biological Indicators
ISO 11140	Sterilization of Healthcare Products	Chemical Indicators (Note: Part 3 – Bowie Dick type indicator)
ISO 11607	Packaging for Terminally Sterilized Medical Devices	Bag testing procedures
ISO 11737	Sterilization of Healthcare Products	Sterility
ISO 13408	Aseptic Processing of Healthcare Products	Aseptic Operations
ISO 13409	Sterilization of Healthcare Products	Methods A and B – validation for purchased sterile products
ISO 13485	Medical Devices – Quality Management Systems	Regulatory requirements
ISO 14872	Sterilization of Healthcare Products	Chemical and Biological indicator test equipment
ISO 14937	Sterilization of Healthcare Products	Characterization of a sterilizing agent and development, validation and routine control of a sterilization process
ISO 14971-1	Medical Devices	Risk Management
ISO 15223	Medical Devices	Symbols for labels
ISO 15882	Sterilization of Healthcare Products	Chemical indicators
prEN 13098	Guidelines for measurement of airborne micro-organisms and endotoxin	EU Standard
prEN	Sterilization of medical devices – validation and	EU Standard (this is the EU version of ISO

13824	routine control of an aseptic process	13408)
IEST RP-CC-001	Recommended Practice for HEPA and ULPA Filters	Basic provisions for URS
IEST RP-CC-002	Recommended Practice for Laminar Flow Clean Air Devices	Basic provisions for URS
IEST RP-CC-003	Recommended Practice for Garment System Considerations	Cleanroom garments and test methods (includes HELMKE DRUM)
IEST RP-CC-004	Recommended Practice for Evaluating Wiping Materials	Cleanroom wipes - specifications
IEST RP-CC-005	Recommended Practice for Gloves and Finger Cots	Cleanroom glove - specifications
IEST RP-CC-006	Recommended Practice for Testing Cleanrooms	Performance testing of cleanrooms
IEST RP-CC-007	Recommended Practice for Testing ULPA Filters	Certification for ULPA filters
IEST RP-CC-012	Recommended Practice for Considerations in Cleanroom Design	Factors to consider
IEST RP-CC-013	Recommended Practice for Procedures for the Calibration or Validation of Equipment	Instruments used in testing cleanrooms
IEST RP-CC-014	Recommended Practice for Calibrating Particle Counters	Calibration
IEST RP-CC-018	Recommended Practice for Cleanroom Housekeeping	This is the basis of the SOP I sent you for cleaning and sanitization
IEST RP-CC-021	Recommended Practice for Testing HEPA and ULPA Filter Media	Physical and Filtration properties
IEST RP-CC-026	Recommended Practice for Cleanroom Operations	Test methods for equipment particle generation
IEST RP-CC-027	Recommended Practice for Personnel in Cleanrooms	Overview document
IEST RP-CC-034	Recommended Practice for HEPA and ULPA Filter Leak Test	Certification document
T.O. 00-25-203	Contamination Control of Aerospace Facilities, US Air Force	Best basic cc document
EOS/ESD Std. number 2	Standard for Protection of Electrostatic Discharge Susceptible Items: Personnel Garments	Test method for ESD on cleanroom garments --- your current garments should follow this method
SEMI E14-90	Measurement of Particle Contamination Contributed to the Product from the Process or Support Tool	URS specification for equipment
PDA	All Technical reports and Supplements	All subjects