Certified Instrument Specialist (CIS) Exam Content Outline



Revised January 2019; Updated June 2022

The CIS Exam Content Outline was created through the 2018 job task analysis and outlines the specific areas of knowledge necessary to perform the duties of an Instrument Specialist. The Content Outline also details the percentage weight for each of the seven sections which comprise the CIS Exam. The higher the percentage weight, the more heavily the questions in that area will affect your overall test score.

SECTION 1: **INSTRUMENT IDENTIFICATION** (PERCENTAGE WEIGHT 30%)

I. SINGLE-USE VS REPOSABLES

- A. Symbols commonly used in medical device labeling internationally (e.g. single-use symbol)
- B. Tracking procedures for reposables (e.g. breast sizers, robotic)

II. SURGICAL SPECIALTY INSTRUMENTATION

- A. Instrument identification for a specialty (e.g. orthopedic, neurosurgery)
- B. Surgical terminology (e.g. procedures, anatomy)

III. IMPLANTABLE DEVICES

A. Implantable devices by specialty (e.g. orthopedic, neurosurgery)

IV. INSTRUMENTATION MARKING

- A. Methods for marking instrumentation (e.g. dipping, etching, bar coding, taping)
- B. Best practices for marking instrumentation

V. MANUFACTURING

A. Instrumentation composition (e.g. nickel, titanium, aluminum, stainless steel floor grade vs surgical grade)

SECTION 2: INSTRUMENT CLEANING & DECONTAMINATION PROCESSES (PERCENTAGE WEIGHT 16%)

I. WATER QUALITY

- A. Water types (e.g. municipal, tap, deionized, filtered)
- B. Water additives & contaminants (e.g. chlorine, lead, minerals)

II. INSTRUCTIONS FOR DECONTAMINATION

- A. Manual vs mechanical cleaning (e.g. precleaning processes)
- B. Disassembly of instrumentation
- C. Instrumentation composition & chemical compatibility

III. CLEANING, DECONTAMINATION & HANDLING OF SPECIALIZED PROCESSES

A. Specialized cleaning processes for speciality specific instrumentation (e.g. ophthalmic instruments, robotics, specific washer decontaminator/disinfector cycles)

IV. TROUBLESHOOTING EQUIPMENT

- A. Operation of equipment (e.g. follow troubleshooting procedure per manufacturer's Instructions for Use (IFUs))
- B. Escalation procedures (e.g. follow facility policies)
- C. Testing tools (e.g. cavitation, impingement, verification testing pre and post)

Certified Instrument Specialist (CIS) Exam Content Outline



Revised June 2022

SECTION 3: **PREPARATION & PACKAGING** (PERCENTAGE WEIGHT 10%)

I. PACKAGING SYSTEMS & ACCESSORIES

- A. Packaging standards (e.g. AAMI, AORN)
- B. Container systems (e.g. gaskets, weight limits, sterilization methods)
- C. Packaging systems (e.g. peel pouches, weight limits, sterilization methods)
- D. Tip protection (e.g. solid, perforated, paper)

SECTION 4: HUMAN FACTORS IMPACTING INSTRUMENT SYSTEMS (PERCENTAGE WEIGHT 16%)

I. TRAINING & EDUCATION

- A. Information resources (e.g. intranet, vendor websites)
- B. Cleaning tools (e.g. brushes, lumen size)
- C. Competency criteria (e.g. certification, facility documentation)
- D. Process improvement (e.g. SWOT, Lean, Six Sigma)

II. CUSTOMER RELATIONS

- A. Communication & collaboration (e.g. OR huddles)
- B. Internal & external teams (e.g. problem solving committees)

III. AUDITS & AUDITING DOCUMENTATION

- A. Quality assurance processes
- B. Common errors & omissions (e.g. cause & effect, Root Cause Analysis, Failure Mode Effect Analysis)
- C. Corrective action plan (e.g. additional training)

IV. TRACKING SYSTEMS

- A. Database management (e.g. manual & electronic systems)
- B. Loaner management process

SECTION 5: **INSTRUMENT INSPECTION, TESTING & ASSEMBLY** (PERCENTAGE WEIGHT 15%)

I. INSPECTION TOOLS

- A. Purpose & use of inspection tools (e.g. borescope, insulation tester, magnification device)
- B. How to appropriately test for sharpness (e.g. index card, dowel rod, osteotomes, scissor testing material

II. VISUAL INSPECTION

- A. Instrumentation functionality (e.g. intact instrumentation)
- B. Instrumentation defects (e.g. damage, staining, rust)
- C. Instrumentation cleanliness (e.g. free of contaminants & bioburden

III. PREVENTATIVE MAINTENANCE (PM)

A. Individual instrument sets for routine servicing per facility procedure (e.g. osteotomes, rongeurs)

Certified Instrument Specialist (CIS) Exam Content Outline



Revised June 2022

SECTION 6: **STERILIZATION & HIGH-LEVEL DISINFECTION (HLD)** (PERCENTAGE WEIGHT 13%)

- I. STERILIZATION & HIGH-LEVEL DISINFECTION (HLD) STANDARDS
 - A. Sterilization & HLD standards (e.g. AAMI, AORN)
 - B. Critical parameters (e.g. Minimum Effective Concentration (MEC), PSI, vacuum)
 - C. Material & modality compatibility (e.g. Instructions for Use (IFUs))
- II. STERILIZATION & HIGH-LEVEL DISINFECTION (HLD) TROUBLESHOOTING
 - A. Process failures & causes (e.g. wet packs, incorrect steam cycle, failure code)
 - B. Corrective action following sterilization & HLD failures