Certified Instrument Specialist (CIS) Exam Content Outline

Revised October 2024

HSPA

The CIS Exam Content Outline was created through the 2024 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 six 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 I: DECONTAMINATION PROCESSES (PERCENTAGE WEIGHT 12%)

A. MONITOR CLEANING QUALITY ASSURANCE

1. Planning and preparation for the cleaning process (e.g., supply, inventory, instrumentation prioritization)
2. Cleaning verification, quality control testing and documentation (e.g., equipment, instrumentation, process)
3. Potential gaps in the cleaning process

B. INTEGRATE CLEANING TOOLBOX SYSTEM

1. Water selection (e.g., pre rinse, final rinse)
2. Chemical compatability (e.g., detergent, adhesive remover, correct chemistry)
3. Personal Protective Equipment (PPE) (e.g., storage, donning, doffing)
4. Cleaning implements (e.g., brushes, borescopes, magnifying devices, automated mechanical and manual cleaning systems)

C. IDENTIFY PROCESSES FOR CLEANING, DECONTAMINATION AND HANDLING OF SPECIALIZED INSTRUMENTATION

1. Specialized cleaning processes for specialty specific instrumentation (e.g., ophthalmic instruments, robotics, specific washer decontaminator/disinfector cycles, flexible endoscopes, powered equipment)
2. Specialized handling processes (e.g., ebola, prions, chemo, TASS)

SECTION II: INSTRUMENTATION IDENTIFICATION (PERCENTAGE WEIGHT 32%)

A. DIFFERENTIATE BETWEEN SINGLE-USE, REPOSABLE AND REUSABLE INSTRUMENTATION

1. Design characteristics of surgical grade and floor grade instrumentation (e.g., symbols, finishes, country or origin)
2. Tracking procedures for reposables (e.g., breast sizers, monopolar/bipolar cords, robotic)

B. IDENTIFY SPECIALTY SURGICAL INSTRUMENTATION

1. Instrumentation for a specialty (e.g., orthopedic, neurosurgery)
2. Surgical terminology (e.g., procedures, anatomy)
3. Risk factors associated with specialty surgical instrumentation (e.g., cement for orthopedic and dental, magnetization of delicate instruments, viscoelastic in ophthalmic surgery)

C. IDENTIFY MANUFACTURING TYPES AND FINISHES

1. Impact of instrumentation composition on functionality and purpose (e.g., nickel, titanium, aluminum, tungsten carbide)

D. IDENTIFY PROCESSES FOR IMPLANTABLE DEVICES

1. Implantable devices by specialty, dimensions and orientation (e.g., orthopedic, neurosurgery)
2. Best practices for surgical implants (e.g., inventory, washer cycle selection, tray assembly, sterilization documentation, patient tracking)

E. APPLY INSTRUMENTATION IDENTIFICATION METHODS

1. Best practices for marking instrumentation (e.g., laser, etching, taping, dipping)
2. Maintenance, documentation and risk management (e.g., schedule, preventative maintenance [PM], policy, risk assessment)
3. Electronic and manual catalog use (e.g., identification, cross referencing)

SECTION III: INSTRUMENTATION INSPECTION, TESTING, INTEGRITY AND ASSEMBLY (PERCENTAGE WEIGHT 20%)

A. EVALUATE PROCESS COMPLIANCE

1. Purpose of instrumentation inspection, testing, integrity and assembly (e.g., identification of residual bioburden, cleaning efficacy)

B. SELECT AND UTILIZE INSPECTION TOOLS AND MATERIALS

1. Inspection tools and materials approved for use on medical instrumentation (e.g., inspection swabs, borescope, magnification)

C. SELECT AND UTILIZE TESTING TOOLS AND MATERIALS

1. Testing tools, materials and rejection criteria for use on medical instrumentation (e.g., index card, dowel rod, leather, rubber band)
2. Frequency of testing and functionality monitoring (e.g., insulated instrumentation, sharpness of scissors)

D. PERFORM VISUAL AND INTEGRITY INSPECTION

1. Integrity and functionality (e.g., intact instrumentation)
2. Defects (e.g., damage, staining, rust)
3. Cleanliness (e.g., free of contaminants and bioburden)

E. FACILITATE PREVENTATIVE MAINTENANCE (PM) AND REPAIRS

1. Individual instrumentation sets for routine servicing per facility procedure (e.g., osteotomes, rongeurs, needle holders)
2. Preventative maintenance (PM) of inspection tools and equipment (e.g., borescope, continuity tester, insulation tester)
3. Cleaning and inspection of instrumentation pre and post preventative maintenance (PM)/repair

SECTION IV: PREPARATION AND PACKAGING (PERCENTAGE WEIGHT 10%)

A. EVALUATE AND SELECT PACKAGING SYSTEMS AND ACCESSORIES

1. Purpose of sterilization packaging (e.g., packaging standards, sterile barrier)
2. Types of sterilization packaging (e.g., disposable, woven, paper-plastic, anodized aluminum)
3. Factors impacting the selection of packaging (e.g., technique, gaskets, weight limits)
4. Material compatibility with sterilization methods
5. Routine maintenance and quality testing (e.g., heat sealers, rigid containers)

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SECTION V: DISINFECTION AND STERILIZATION PROCESSES (PERCENTAGE WEIGHT 6%)

A. APPLY STERILIZATION AND DISINFECTION STANDARDS

1. Sterilization and disinfection standards (e.g., AORN, AAMI)
2. Critical parameters and chemical compatibility for high-level disinfection (HLD) (e.g., Minimum Effective Concentration [MEC], time, temperature)
3 Sterilization parameters and material compatibility (e.g., Tyvek used for low-temperature sterilization)

B. TROUBLESHOOT STERILIZATION AND DISINFECTION FAILURES

1. Process failures and causes (e.g., packaging methods, sterilizer maintenance, failure code, loading technique, wet packs, failed biologicals)
2. Corrective action following sterilization and disinfection failures (e.g., load recall, reprocess instrumentation)

SECTION VI: QUALITY AND INFORMATION SYSTEMS (PERCENTAGE WEIGHT 20%)

A. PROMOTE AND MAINTAIN TRAINING AND EDUCATION

1. Internal and external resources (e.g., access and interpret manuals, policies and procedures, regulations, standards, guidelines)
2. Competency and continuing education (e.g., in-service, certification, facility documentation, frequency)
3. Periodic review of documentation (e.g., standards, Instructions for Use [IFU], Safety Data Sheet [SDS])

B. FOSTER CUSTOMER RELATIONS AND PROCESS IMPROVEMENT

1. Communication and collaboration (e.g., Sterile Processing Department [SPD] and Operating Room [OR] huddles, instrumentation conflict resolution)
2. Internal and external teams (e.g., problem solving committees, multidisciplinary team)
3. Process improvement (e.g., SWOT, Lean, Six Sigma, key performance indicators [KPIs], action plan)
4. Reduction in instrumentation turnover and immediate use steam sterilization (IUSS) (e.g., schedule review with OR, prioritization, tags for turnover trays, increasing inventory)

C. CONDUCT AUDITS AND MAINTAIN DOCUMENTATION

1. Quality assurance processes (e.g., random sampling, rounding, customer survey, instrumentation storage)
2. Common errors and omissions (e.g., cause and effect, Root Cause Analysis [RCA], Failure Mode Effect Analysis [FMEA])

D. OVERSEE INSTRUMENTATION MANAGEMENT SYSTEMS

1. Advances in database management (e.g., manual and electronic system updates, unique device identification [UDI])
2. Features and challenges of instrumentation tracking systems (e.g., count sheet maintenance, software updates, communication, data management)

E. COORDINATE LOANED INSTRUMENTATION PROCESS

1. Planning and implementation of loaned instrumentation process (e.g., receipt, implants, preparation, sterilization, storage)
2. Processing challenges (e.g., vendor and OR communication, delivery delay, tracking, labelling, availability of Instructions for Use [IFU])
3. Post operative process (e.g., point of use treatment, restock, decontamination, pick up)

F. MONITOR WATER QUALITY

1. Categories (e.g., utility, critical, steam)
2. Parameters and other considerations (e.g., pH, alkalinity, conductivity, endotoxins)
3. Testing frequency at point-of-water-use (e.g., daily visual, monthly endotoxin)
4. Requirements for process stages and equipment (e.g., final rinse, reverse osmosis [RO], deionized water)
5. Impacts of water quality on instrumentation processes (e.g., pitting, staining, rusting)