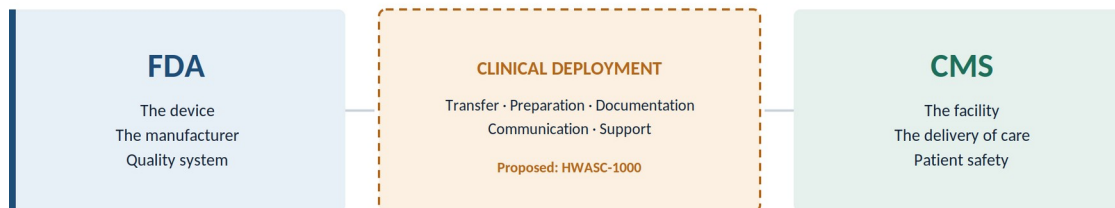


Bridging FDA Medical Device Regulation and CMS Patient Safety Through Clinical Deployment Standards

A Proposal for a Voluntary Consensus Standard for the Clinical Deployment of Manufacturer-Supplied Loaner Medical Devices and Implants



A White Paper and Call for Participation

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About this document. This white paper is a discussion document and a call for participation. It does not establish requirements, does not represent the position of any regulatory agency, and does not constitute legal or regulatory advice. It is intended to describe an operational interface in healthcare delivery, explain why that interface may benefit from voluntary consensus standardization, and invite interested parties to join an open and balanced standards development effort.

About HWASC. HWASC is a standards developing organization accredited by the American National Standards Institute (ANSI). HWASC develops voluntary consensus standards through processes intended to satisfy the ANSI Essential Requirements, including openness, balance of interest, lack of dominance by any single interest category, due process, consideration of views and objections, and the right of appeal. Nothing in this document implies endorsement by FDA, CMS, ANSI, or any accrediting organization.

Executive Summary

Every day, manufacturers ship thousands of loaner instrument systems, implant sets, capital equipment, and single-use devices into hospitals and ambulatory surgery centers across the United States. These sets frequently arrive shortly before a scheduled procedure, are received by facility staff, are inspected and reprocessed by sterile processing departments, are delivered to operating rooms, and are ultimately used in the care of a patient — often within a span of hours.

This flow of devices crosses a boundary between two well-developed regulatory systems:

- **The U.S. Food and Drug Administration (FDA)** regulates the medical device and the manufacturer, through premarket review, quality management system requirements, labeling and instructions for use, unique device identification, risk management expectations, and postmarket surveillance and reporting.
- **The Centers for Medicare & Medicaid Services (CMS)** regulates the healthcare facility and the delivery of care, through Conditions of Participation and Conditions for Coverage addressing governance, contracted services, quality assessment and performance improvement, infection prevention and control, the physical environment, surgical services, and the medical record.

Each framework is mature within its own domain. Between them lies an operational space — the **clinical deployment** of a device from the manufacturer's quality system into the facility's patient safety system.

Activities in this space are governed today by a combination of manufacturer procedures, facility policies, contractual terms, accreditation program requirements, supplier credentialing programs, and professional practice guidelines from organizations such as AAMI, AORN, and HSPA. Notable work already exists: ANSI/NEMA SC 1-2020, *American National Standard for Supplier Credentialing in Healthcare*, standardizes the credentials a supplier representative must present to enter a healthcare facility, and ASTM F565-21, *Standard Practice for Care and Handling of Orthopedic Implants and Instruments*, is an FDA-recognized consensus standard addressing handling within the facility. That combination provides meaningful oversight. It is not, however, organized into a single widely recognized consensus framework addressed specifically to the deployment interface itself. As a result, practices differ from manufacturer to manufacturer, facility to facility, and service line to service line — including in areas such as delivery lead time, set completeness verification, transfer of the current version of processing instructions, documentation of custody, and closure of the loop when a problem is identified.

HWASC proposes the development of **Clinical Deployment Standards**: voluntary consensus standards that define good practice for the safe transfer, preparation, documentation, communication, and support of manufacturer-supplied medical devices before, during, and after patient use.

The first proposed document in this family is:

HWASC-1000 — Clinical Deployment Standard for Manufacturer-Supplied Loaner Medical Devices and Implants

HWASC is not publishing a finished standard. HWASC is publishing a problem statement and an invitation. Manufacturers, distributors, logistics providers, hospitals and ambulatory surgery centers, sterile processing and perioperative professionals, surgeons and anesthesia professionals, regulators, accrediting organizations, standards experts, insurers, and patient representatives are invited to participate in developing this standard through an open, balanced consensus process.

Section 1 — The Regulatory Gap

1.1 The deployment lifecycle

A loaner instrument set or consigned implant system typically moves through a sequence of custody and control transitions:

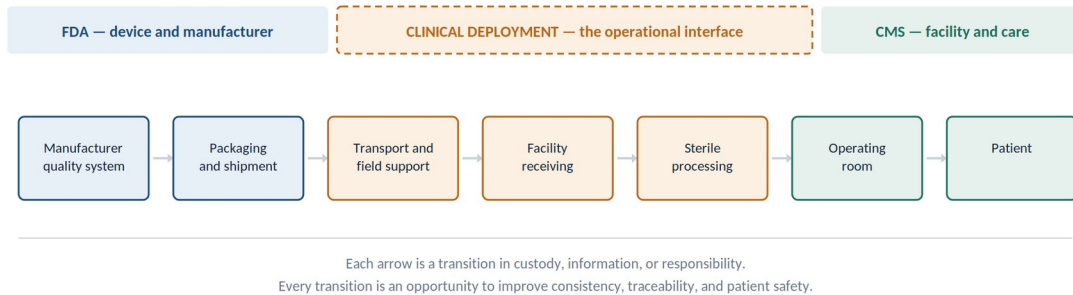


Figure 1. *The clinical deployment lifecycle. Two mature regulatory frameworks meet at an operational interface that neither was written to govern.*

Every transition in this sequence represents an opportunity to improve consistency, communication, traceability, and patient safety.

1.2 What “the gap” means — and what it does not

It would be inaccurate to describe clinical deployment as unregulated or unsupervised. Oversight exists, and it comes from multiple sources simultaneously:

- FDA requirements applicable to the manufacturer, the device, and its labeling.
- CMS Conditions of Participation and Conditions for Coverage applicable to the facility.
- Standards of accrediting organizations operating under CMS-approved deeming authority.
- State licensure requirements and state health department survey activity.
- Voluntary consensus standards and technical information reports, including ANSI/AAMI ST79, ANSI/AAMI ST90, ANSI/AAMI ST91, ISO 17664, ISO 13485, and ISO 14971.
- Supplier credentialing standards, including ANSI/NEMA SC 1-2020, and the joint recommendations developed by AdvaMed, hospital associations, and the Consortium for Universal Healthcare Credentialing.
- Professional practice guidelines, including AORN Guidelines for Perioperative Practice and HSPA educational standards.
- Manufacturer standard operating procedures and field service policies.
- Facility policies, vendor credentialing programs, and supply agreements.

The observation motivating this paper is narrower and, HWASC believes, more useful: **these sources were each developed to govern a party, not the handoff between parties.** FDA requirements attach principally to the manufacturer. CMS requirements attach principally to

the facility. Consensus standards for reprocessing address what the facility does once a device is in its hands. Contracts address commercial obligations between two named entities.

The handoff itself — the moment at which responsibility for a device passes from a manufacturer-controlled quality system into a facility-controlled patient safety system — is addressed indirectly by many documents and directly by few. Where a process is addressed indirectly by many documents, variation is a predictable outcome.

That variation is not, in itself, evidence of harm. It is evidence of an opportunity. Voluntary consensus standardization is the customary and appropriate instrument for reducing unwarranted variation in an operational process that spans organizational boundaries.

Section 2 — The FDA Framework: The Device and the Manufacturer

FDA's authority over medical devices is exercised principally over the device and the entity that manufactures, labels, or distributes it. Elements most relevant to clinical deployment include the following.

Quality management systems. Manufacturers are subject to quality system requirements under 21 CFR Part 820. Under the Quality Management System Regulation (QMSR) final rule, these requirements incorporate ISO 13485:2016 by reference, with a compliance date of February 2, 2026. Relevant elements include design controls, purchasing controls, production and process controls, handling, storage, distribution and installation, servicing, records, and corrective and preventive action.

Labeling and instructions for use. Device labeling requirements appear in 21 CFR Part 801, including requirements for adequate directions for use and, for prescription devices, information for practitioner use. For reusable devices, FDA's guidance on reprocessing medical devices in healthcare settings addresses the validation and labeling of reprocessing instructions. ISO 17664 provides internationally recognized structure for the information a manufacturer supplies to the processor of a reusable device.

Unique device identification. Part 830 and related labeling provisions establish UDI requirements and the Global Unique Device Identification Database (GUDID), creating a standardized identifier infrastructure that clinical deployment processes can build upon.

Risk management. ISO 14971 provides the recognized framework for identifying hazards, estimating and evaluating risk, and implementing risk controls across the device lifecycle, including risks arising in use.

Human factors and usability. FDA guidance on applying human factors engineering addresses use-related risk, including the environments and users a device will encounter.

Complaint handling and postmarket surveillance. Complaint handling obligations, medical device reporting under 21 CFR Part 803, and corrections and removals reporting under 21 CFR Part 806 establish a structured pathway for information about device problems to return to the manufacturer and to FDA.

Traceability and distribution records. Quality system requirements address device traceability, distribution records, and, for certain devices, tracking obligations.

Together these elements produce a device that has been designed, validated, labeled, and documented. They do not principally govern the operational conditions under which that device arrives at a specific facility on a specific afternoon for a specific case.

Section 3 — The CMS Framework: The Facility and the Delivery of Care

CMS establishes health and safety requirements that facilities must meet to participate in Medicare and Medicaid. For hospitals these appear at 42 CFR Part 482; for ambulatory surgical centers, at 42 CFR Part 416. Compliance is assessed through state survey agencies or through accrediting organizations granted deeming authority. Provisions most relevant to clinical deployment include the following.

Governing body and contracted services. The governing body is responsible for services furnished under contract or arrangement, including ensuring that such services are provided in a safe and effective manner. Loaner instrumentation, consigned implants, and vendor field support frequently fall within this scope.

Quality assessment and performance improvement (QAPI). Facilities must maintain a data-driven QAPI program that tracks adverse events, analyzes their causes, and implements preventive actions. Device availability, set completeness, and reprocessing failures are recurring subjects of such analysis.

Infection prevention and control. Facilities must maintain an active program for the prevention, control, and investigation of infections and communicable diseases, including for the cleaning, disinfection, and sterilization of equipment and supplies. This program depends directly on the availability and accuracy of manufacturer-supplied processing instructions.

Physical environment. Requirements addressing facilities, supplies, and equipment maintenance support safe receipt, storage, and handling of devices.

Surgical services. Requirements addressing the organization and staffing of surgical services, and the conduct of operative procedures, presuppose that necessary instrumentation and implants are available, complete, and ready.

Medical records. Documentation requirements support the ability to determine what was used in the care of a patient.

CMS requirements are directed at the facility and at the care it delivers. They do not principally govern the internal processes of a manufacturer or the conduct of that manufacturer's field personnel prior to the device entering the facility's custody.

Section 4 — The Bridge: Clinical Deployment

Clinical deployment is the operational bridge between FDA-regulated medical devices and CMS-governed healthcare delivery.

Clinical deployment encompasses the activities required to move a device from a manufacturer-controlled state into a condition of readiness for patient use within a healthcare facility, and to return it afterward.

Manufacturer-side personnel and their agents commonly support activities such as:

- Transporting or arranging transport of loaner instrumentation and implant sets;
- Coordinating delivery timing with facility receiving and sterile processing;
- Providing the current version of instructions for use and validated processing instructions applicable to the specific set configuration delivered;
- Verifying set completeness and identifying missing, damaged, or substituted items;
- Supplying inventory manifests, count sheets, and set identification;
- Supporting technical setup and equipment configuration within the limits of manufacturer instructions and facility policy;
- Providing product information and technical clarification to clinical staff on request;
- Facilitating communication with the manufacturer when a device problem, discrepancy, or field action arises;
- Coordinating post-procedure return, ensuring decontamination expectations are met before shipment, and supporting traceability of what was implanted or used.

The emphasis throughout is on **manufacturer-supported operational processes, not clinical decision-making**. Clinical judgment, patient selection, surgical technique, and the practice of medicine remain the exclusive province of licensed clinicians and the facility. A clinical deployment standard should reinforce that boundary, not blur it.

4.1 A deliberately technology-neutral scope

This paper avoids framing the issue as a question about manufacturer representatives. Representatives are one important participant in clinical deployment, but they are not the process.

Deployment today may be supported by manufacturer employees, independent distributors, third-party logistics providers, field service engineers, facility-employed vendor coordinators, or consignment models in which no external personnel are present at all. Deployment tomorrow may be supported by automated tracking, digital instruction delivery, remote technical support, or models not yet in commercial use.

A standard scoped to the **process** rather than the **personnel** will have a longer useful life, align more naturally with the respective responsibilities of FDA and CMS, and invite participation from a broader range of interested parties.

4.2 The undefined workforce

A large workforce performs clinical deployment activities today. Its members enter operating rooms, handle implants and instrumentation, and support procedures on a scheduled basis. Two systems currently govern their presence, and neither defines their work.

Credentials verification for clinicians. Credentials verification organizations operating under NCQA or URAC standards perform primary source verification of a practitioner's education, licensure, training, and work history. That verification is meaningful because something sits underneath it: a state license defines a scope of practice, and the facility's medical staff grants delineated privileges for specified procedures. The verification points at a defined body of work.

Supplier credentialing for non-employees. Supplier credentialing programs, and the American National Standard that now governs them, verify a different class of documents — identity, immunization status, background screening, training attestations, insurance, and confidentiality agreements — and organize requirements around access tiers defined by the areas of the facility an individual may enter.

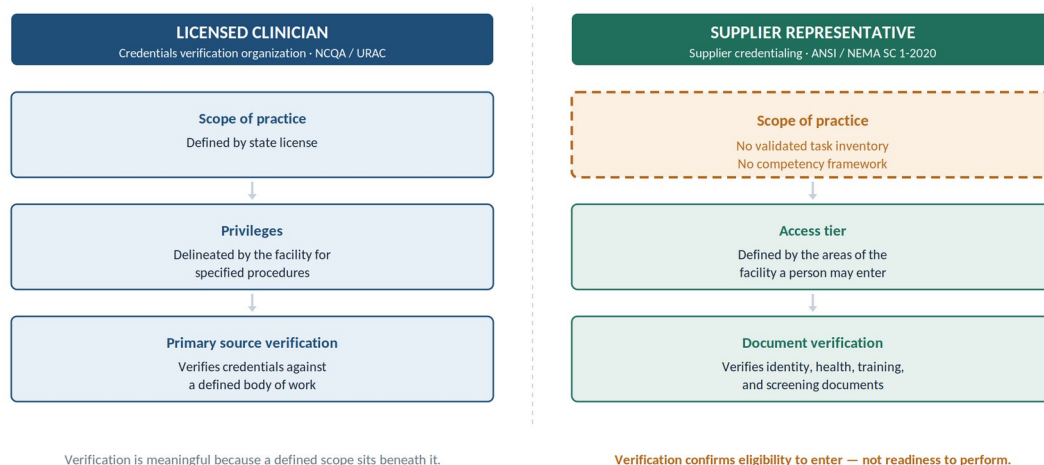


Figure 2. Two credentialing systems compared. Both verify documents. Only one rests on a defined scope of practice.

Supplier credentialing answers the question *may this person enter, and where*. It does not answer the question *what is this person qualified to do once inside*.

The affirmative content of the role has, to date, been articulated principally in the negative. Widely circulated joint recommendations state that representatives may not scrub in, may not have hands-on patient contact, and may not operate equipment being used on a patient, with a carve-out permitting technical support, troubleshooting, calibration, and programming at the request of the attending physician. These are appropriate boundaries. They are prohibitions with an exception, not a scope of practice.

ASTM F565-21, *Standard Practice for Care and Handling of Orthopedic Implants and Instruments*, illustrates the same seam from the opposite direction. The standard identifies

hospital receiving personnel, central supply personnel, operating room personnel, and surgeons as the individuals who will handle orthopedic implants and instruments — and then adds a residual category, “occasionally other individuals.” Its scope also states that the practice does not cover producer-level handling and packaging procedures.

Read together, those two provisions describe the gap precisely. Producer-level handling is out of scope on the manufacturer side. Facility personnel are enumerated on the provider side. The individual who transports a loaner set from a vehicle to a receiving dock, reconciles it against a manifest, delivers the applicable processing instructions to sterile processing, and returns for the case appears only as a residual clause — despite performing a share of the handling activity that is neither occasional nor incidental.

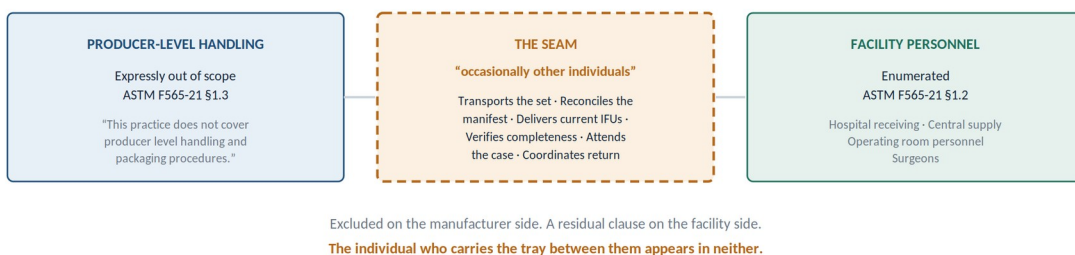


Figure 3. The seam in ASTM F565-21. Producer-level handling is excluded; facility personnel are enumerated; the individual between them appears as a residual clause.

The consequence is a workforce that is screened but not defined. There is no validated inventory of the tasks its members perform, no consensus statement of the knowledge required to perform them competently, and therefore no defensible basis on which competency could be assessed, trained toward, or improved. Document verification without an underlying task definition verifies eligibility to enter a building. It does not establish readiness to perform the work.

Document verification without an underlying task definition establishes eligibility to enter a building. It does not establish readiness to perform the work.

This is not a criticism of supplier credentialing, which addresses a real and costly problem within its own scope. It is an observation that the two questions are different, that only one of them has been answered, and that the unanswered one is closer to patient safety.

Section 5 — Proposal: HWASC-1000

HWASC proposes the development of:

HWASC-1000 — Clinical Deployment Standard for Manufacturer-Supplied Loaner Medical Devices and Implants

5.1 Proposed objectives

1. **Standardize chain of custody.** Define documented transfer points, responsible roles, and minimum records at each handoff from manufacturer to facility and back.
2. **Improve device readiness.** Establish good practice for delivery lead time, set completeness verification, condition assessment, and communication of exceptions before a case is scheduled to begin.
3. **Improve IFU and processing instruction management.** Define how the current, version-controlled instructions applicable to the specific configuration delivered are conveyed to and confirmed by the receiving facility.
4. **Improve communication.** Establish common terminology, escalation pathways, and expected timeframes for notification of discrepancies, defects, substitutions, and field actions.
5. **Improve documentation.** Identify the minimum deployment record set, its content, and its retention, in a form usable by both manufacturer quality systems and facility QAPI programs.
6. **Improve traceability.** Define practices for linking set identity, UDI where applicable, lot and serial information, and implanted device identity to the procedure record.
7. **Support risk reduction.** Provide a structure for identifying and controlling deployment-related hazards consistent with ISO 14971 principles.
8. **Facilitate quality improvement.** Define measurable indicators — such as on-time delivery, set completeness at receipt, instruction availability, and reprocessing turnaround — that both parties can use for improvement.
9. **Clarify roles and boundaries.** Articulate the distinction between operational support and clinical practice, and the respective accountabilities of manufacturer, agent, and facility.
10. **Define the work itself.** Produce a validated task inventory for clinical deployment activities, developed through job task analysis methodology, as the empirical foundation for any subsequent competency, training, or credentialing framework.
11. **Define competency expectations.** Establish a baseline for the training and qualification of personnel performing deployment activities, complementing rather than duplicating existing supplier credentialing programs.

5.2 What HWASC-1000 is intended to be

- A **voluntary consensus standard** developed under ANSI Essential Requirements.
- **Process-focused**, applicable regardless of who performs deployment activities.
- **Complementary** to existing standards, adopting rather than restating ANSI/AAMI ST79, ISO 17664, and related documents wherever they already address a subject.
- **Auditable**, in the sense that conformance can be objectively assessed.
- **Scalable**, so that a critical access hospital and a large academic center can both implement it.

5.3 What HWASC-1000 is not intended to be

- Not a regulation, and not a substitute for FDA or CMS requirements.

- Not a clinical practice guideline, and not a statement about surgical technique or patient management.
 - Not a reprocessing standard; reprocessing is addressed by existing consensus documents.
 - Not a replacement for or competitor to ANSI/NEMA SC 1-2020; supplier credentialing for facility access remains within that standard's scope.
 - Not itself a credentialing or certification program for individuals, although its task inventory is intended to be capable of supporting one.
 - Not a commercial or contracting framework, and not a vehicle for restricting competition or market access.
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Section 6 — FDA-CMS Crosswalk

The following crosswalk illustrates the interface. For each deployment activity, it identifies the FDA framework applicable to the device and manufacturer, the CMS framework applicable to the facility and care delivery, and the interface question that HWASC-1000 is proposed to address.

#	Deployment activity	FDA framework (device / manufacturer)	CMS framework (facility / care delivery)	Interface question for HWASC-1000
1	Scheduling and delivery lead time	Distribution and handling controls under the quality system	Surgical services organization; QAPI	What lead time and confirmation practice allows adequate inspection and reprocessing before the scheduled case?
2	Physical transfer and receipt	Handling, storage, and distribution records	Governing body responsibility for contracted services; physical environment	What constitutes a documented custody transfer, and who acknowledges it?
3	Set identification and manifest	Device identification, labeling, UDI	Medical record; supply management	How is the specific set configuration identified so that the correct instructions apply?
4	Instructions for use and processing instructions	21 CFR Part 801; reprocessing labeling guidance; ISO 17664	Infection prevention and control program	How is the <i>current version</i> applicable to <i>this configuration</i> delivered to and confirmed by sterile processing?
5	Completeness and condition verification	Complaint handling; production and process controls	Infection control; surgical services readiness	Who verifies completeness, against what document, and how are exceptions communicated and resolved?
6	Reprocessing before first use	Validated reprocessing instructions	Infection prevention and control; ANSI/AAMI ST79	How does the facility confirm it holds validated instructions before processing begins?
7	Delivery to the procedural area	Labeling; human factors considerations in use environment	Surgical services; infection control	What condition, documentation, and communication

#	Deployment activity	FDA framework (device / manufacturer)	CMS framework (facility / care delivery)	Interface question for HWASC-1000
				accompany the set into the OR?
8	Technical setup and product support	Labeling; servicing and installation provisions	Contracted services; patient rights; infection control	What operational support is within scope, and how is the boundary with clinical practice maintained?
9	Implant and device traceability	UDI and GUDID; device tracking where applicable	Medical record; implant documentation	How is device identity captured and linked to the patient record at the point of use?
10	Device problem identification	Complaint handling; MDR under 21 CFR Part 803	QAPI; adverse event analysis	How does a problem observed in the OR reach the manufacturer's complaint system, and how is closure communicated back?
11	Recalls and field corrective actions	Corrections and removals under 21 CFR Part 806	QAPI; governing body oversight	How does a field action reach sets already in transit or in facility custody?
12	Personnel training and qualification	Personnel and training provisions of the quality system	Contracted services oversight; infection control training	What baseline competency should deployment personnel demonstrate?
13	Post-procedure decontamination and return	Reprocessing instructions; handling controls	Infection prevention; OSHA bloodborne pathogens; DOT transport requirements	What decontamination and documentation precede release of a set for shipment?
14	Records and retention	Quality system records	Medical record and QAPI documentation	What is the minimum deployment record, who holds it, and for how

#	Deployment activity	FDA framework (device / manufacturer)	CMS framework (facility / care delivery)	Interface question for HWASC-1000
15	Performance measurement	CAPA and postmarket data	QAPI data collection and analysis	long? What shared indicators allow both parties to see the same picture of deployment performance?

The pattern visible across these rows is consistent. In most cases, both an FDA framework and a CMS framework exist. What is less consistently defined is the **connective tissue**: the artifact, the acknowledgment, the timeframe, or the record that carries information across the boundary between them. That connective tissue is the subject matter of a clinical deployment standard.

Section 7 — A Call for Consensus

HWASC is not announcing a completed standard. HWASC is asking whether others see the same opportunity and are willing to help address it.

HWASC invites manufacturers, healthcare organizations, clinicians, sterile processing and perioperative professionals, distributors and logistics providers, regulators, accrediting organizations, standards experts, researchers, insurers, and patient representatives to participate in developing a voluntary consensus standard through an open, balanced process.

7.1 Relationship to existing standards work

HWASC does not propose to restate or replace work that has already been done.

ANSI/NEMA SC 1-2020 establishes a national approach to supplier credentialing, addressing a genuine and expensive problem: inconsistent, duplicative facility-by-facility credentialing requirements. It has been endorsed by AdvaMed and by supply chain organizations, and it resolves the access question. HWASC regards it as prior art to be referenced normatively, not displaced.

ASTM F565-21 addresses care and handling of orthopedic implants and instruments within the facility and is recognized by FDA as a consensus standard. AAMI's ST-series and ISO 17664 address processing and the information required to support it. AORN and HSPA address perioperative and sterile processing practice.

HWASC-1000 is proposed to occupy the space these documents individually exclude or address only residually: the operational handoff itself, and the definition of the work performed at it. A formal gap analysis against SC 1, F565-21, ST79, ST90, ST91, and ISO 17664 is proposed as the consensus body's first work item, with a published finding on the scope boundary before drafting begins. If that analysis concludes that existing documents adequately cover the subject, HWASC will say so.

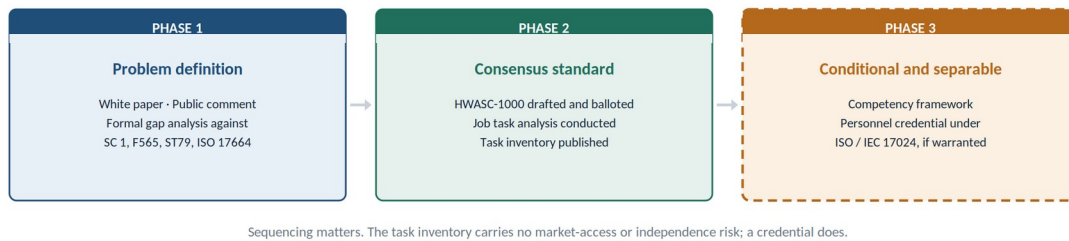


Figure 5. Proposed sequencing. Each phase is a separable decision, and Phase 3 proceeds only if the consensus body concludes it is warranted.

7.2 Proposed development process

Development is proposed to follow ANSI Essential Requirements, including:

- **Openness** — participation available to all materially affected and interested parties.
- **Balance** — no single interest category dominating the consensus body; deliberate recruitment of user, general interest, and patient representation alongside producer interests.
- **Due process** — written procedures, notification of standards development, public comment, documented consideration of views and objections, and a right of appeal.
- **Consensus** — substantial agreement reached through a documented ballot process, with unresolved objections recorded and addressed.
- **Harmonization** — coordination with existing standards to avoid conflict and duplication.

7.3 Ways to participate

1. **Join the consensus body** as a voting member in an appropriate interest category.
2. **Serve on a working group** addressing a specific subject area.
3. **Submit written comment** on this white paper, including disagreement with its premise.
4. **Contribute data** on deployment performance, near misses, or delays, in de-identified form.
5. **Participate as an observer** to monitor the work without a voting role.

7.4 Questions HWASC is specifically asking

1. Is the interface described in this paper a real and material source of variation in your organization?
2. Are there existing standards or programs that already address it adequately, in whole or in part?
3. Which of the fifteen crosswalk rows are most consequential, and which are least?
4. What is the correct scope boundary between HWASC-1000 and ANSI/AAMI ST79, ISO 17664, and related documents?

5. Is the distinction drawn in Section 4.2 — between verifying eligibility to enter and defining readiness to perform — the right way to frame the boundary with ANSI/NEMA SC 1-2020?
6. Should a job task analysis for this workforce be undertaken, and if so, who should hold and maintain it?
7. What unintended consequences — cost, delay, reduced access to technology, competitive distortion, barriers to entry for small distributors and independent representatives — would a standard of this kind risk creating, and how should the drafting process guard against them?

Comments and expressions of interest may be directed to info@hwasc.com by November 6, 2026.

Conclusion

Medical devices are not deployed solely through manufacturing processes or hospital workflows. Their successful clinical use depends on coordinated activities occurring at the interface between the manufacturer and the healthcare facility. As medical technologies become increasingly sophisticated, there is an opportunity to develop voluntary consensus standards that promote consistency, transparency, traceability, and patient safety throughout the clinical deployment process. The proposed Clinical Deployment Standard for Manufacturer-Supplied Loaner Medical Devices and Implants is intended to begin that conversation.

Appendix A — Working Definitions

These definitions are proposed for discussion and would be refined by the consensus body.

Clinical deployment. The set of activities by which a medical device transitions from a manufacturer-controlled state to a condition of readiness for patient use within a healthcare facility, and returns thereafter.

Loaner device. A medical device, instrument set, or implant system supplied by or on behalf of a manufacturer to a healthcare facility on a temporary basis for use in one or more procedures, and returned thereafter.

Consigned inventory. Devices, typically implants, physically located at a facility but owned by the manufacturer or distributor until used.

Deployment personnel. Any individual performing clinical deployment activities, whether employed by a manufacturer, distributor, logistics provider, service organization, or the facility itself.

Custody transfer. A defined point at which responsibility for a device passes from one organization to another, evidenced by a record.

Set configuration. The specific composition of an instrument or implant set, as identified by the manufacturer, to which a particular set of instructions applies.

Job task analysis (JTA). A structured research method that identifies and validates the tasks performed in a role and the knowledge required to perform them, typically through subject matter expert panels and a practitioner survey, producing a weighted content outline.

Supplier credentialing. The process by which a healthcare facility verifies documentation submitted by non-employees seeking access to its premises, addressed by ANSI/NEMA SC 1-2020.

Scope of practice. The defined set of activities an individual is qualified and authorized to perform in a role.

Deployment record. The documentation generated by clinical deployment activities, including manifests, custody acknowledgments, exception reports, and instruction transmittals.

Appendix B — Relationship to Existing Standards and Programs

HWASC-1000 is intended to reference rather than replace existing work, including:

- **ANSI/AAMI ST79** — comprehensive guide to steam sterilization and sterility assurance in healthcare facilities, including provisions addressing loaner instrumentation.
- **ANSI/AAMI ST90** — processing of health care products, quality management systems for processing in health care facilities.
- **ANSI/AAMI ST91** — flexible and semi-rigid endoscope processing.
- **ISO 17664** — information to be provided by the medical device manufacturer for the processing of medical devices.
- **ISO 13485** — quality management systems for medical devices.
- **ISO 14971** — application of risk management to medical devices.
- **AORN Guidelines for Perioperative Practice** — including guidance relevant to instrument processing and to the role of health care industry representatives.
- **HSPA** — educational and certification standards for sterile processing personnel.
- **ANSI/NEMA SC 1-2020** — American National Standard for Supplier Credentialing in Healthcare; credentials required of supplier representatives entering healthcare facilities, organized by access tier.
- **ASTM F565-21** — Standard Practice for Care and Handling of Orthopedic Implants and Instruments; FDA-recognized consensus standard (Recognition No. 11-425), superseding F565-04 (Reapproved 2018) subject to a transition period.
- **AdvaMed / hospital association / C4UHC joint recommendations** — recommended practices for healthcare industry representative credentialing and conduct.
- **ISO/IEC 17024** — general requirements for bodies operating certification of persons; relevant if a personnel credential is pursued.

- **Commercial supplier credentialing programs** — existing platforms governing facility access and documentation of representative qualifications.

A gap analysis against these documents is proposed as an early work item of the consensus body, so that HWASC-1000 addresses only what is not already addressed.

Appendix C — Proposed Job Task Analysis Framework

C.1 Purpose

A job task analysis (JTA) is the accepted method for establishing what a role actually consists of. It is the foundation on which training curricula, competency frameworks, and — where warranted — certification examinations are built, and it is what gives any such instrument content validity. Professional certification bodies routinely repeat the exercise every five to seven years to keep the definition current.

No JTA has been published for the workforce that performs clinical deployment activities. HWASC proposes that conducting one be an early deliverable, independent of whether a personnel credential is ultimately pursued. The task inventory has standalone value: it gives facilities, manufacturers, and the individuals themselves a shared description of the work.

C.2 Proposed methodology

1. **Subject matter expert panel.** Convene a balanced panel including manufacturer and distributor field personnel, sterile processing professionals, perioperative nurses and surgical technologists, supply chain and value analysis staff, surgeons, quality and risk professionals, and patient representatives.
2. **Task and knowledge statement generation.** Draft a comprehensive inventory of discrete tasks performed and the knowledge required to perform each.
3. **Practitioner validation survey.** Field the inventory to a broad sample of practicing individuals, collecting frequency, criticality, and consequence-of-error ratings for each task.
4. **Analysis and weighting.** Use the survey data to eliminate low-relevance tasks and produce a weighted domain structure.
5. **Publication and periodic review.** Publish the resulting task inventory and re-validate on a defined cycle.

C.3 Candidate domains for validation

These are proposed as a starting point for the SME panel, not as findings.

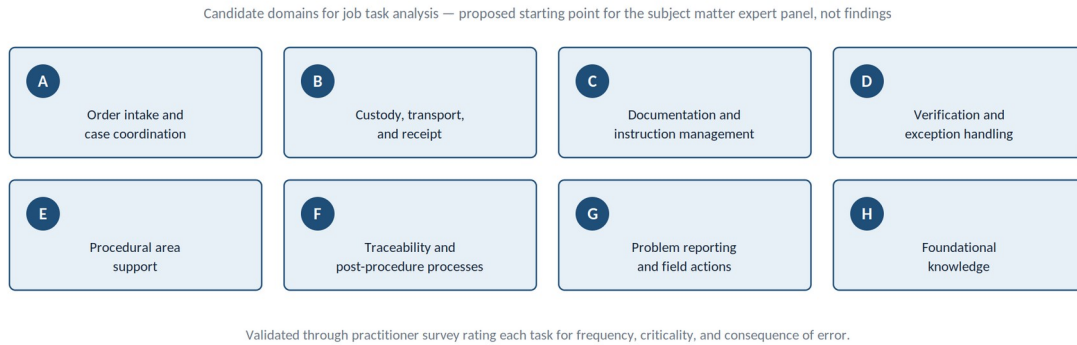


Figure 4. Candidate domain structure for the job task analysis.

Domain	Illustrative task areas
A. Order intake and case coordination	Interpreting case requirements; confirming set requirements against the procedure; scheduling delivery to facility lead-time expectations
B. Custody, transport, and receipt	Handling and transport conditions; delivery to the correct receiving point; documented custody transfer
C. Documentation and instruction management	Identifying the set configuration; supplying the current applicable IFU and processing instructions; version confirmation
D. Verification and exception handling	Reconciling against manifest and count sheet; identifying missing, damaged, or substituted items; escalating and resolving exceptions before the case
E. Procedural area support	Operating within defined role boundaries; technical support within manufacturer instructions and at clinician request; infection prevention and aseptic-field conduct
F. Traceability and post-procedure processes	Capture of device identity for the record; decontamination expectations before return; return logistics
G. Problem reporting and field actions	Recognizing reportable device problems; routing to the manufacturer complaint system; supporting field corrective actions affecting sets in facility custody
H. Foundational knowledge	Applicable regulatory framework; privacy obligations; facility policy; limits of the role relative to clinical practice

C.4 Relationship to personnel certification

If the consensus body concludes that a personnel credential is warranted, it would be developed as a separate instrument conforming to ISO/IEC 17024, with its own accreditation pathway.

HWASC notes two governance considerations at the outset. First, independence: a body that writes a standard and also certifies individuals against it must manage that relationship carefully, and separation of those functions should be assumed unless the consensus body determines otherwise. Second, market effects: any credential that conditions entry to a procedural area has consequences for competition, for small distributors and independent representatives, and for the individuals employed in these roles. Those consequences are legitimate subjects for the consensus process and should be addressed on the record rather than discovered later.

The task inventory itself carries neither of these risks. That is a further reason to treat the JTA as the first deliverable and the credentialing question as a later, separable one.
