

The Patient Is Asleep

A Patient Safety Inquiry into How Instruments, Implants, and Technical Guidance Reach the Operating Room

A White Paper and Call for Participation

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About this document. This white paper is a discussion document and a patient safety inquiry. It does not establish requirements, does not represent the position of any regulatory agency, and does not constitute legal, clinical, or regulatory advice. It describes, in general and composite terms, how surgical instruments, implants, and the technical guidance to use them commonly reach the operating room today, and it asks a series of questions that the healthcare system should be able to answer with verified information. The scenario presented is a composite drawn from common practice patterns; it does not describe any specific manufacturer, facility, professional, or case.

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.

Companion document. This paper is a companion to *Bridging FDA Medical Device Regulation and CMS Patient Safety Through Clinical Deployment Standards* (HWASC, August 2026), which proposes HWASC-1000, a Clinical Deployment Standard for Manufacturer-Supplied Loaner Medical Devices and Implants. Where that paper makes the regulatory argument, this paper asks the patient safety question.

Executive Summary

Tomorrow morning, in hospital operating rooms and ambulatory surgery centers across the United States, patients will be anesthetized and surgical teams will open trays of instruments and implants that were not in the building last week. Many arrived last night. Some arrived in several deliveries, from several places, handled by several sets of hands. Standing at the table will be a professional employed by none of the facilities involved, providing technical guidance on the devices about to be used.

Every clinician at that table practices under a verified framework: licensure, credentialing, and facility-granted privileges. The instruments arrived under a different framework: shipping labels, courier manifests, and facility-specific credentialing documents that verify access — not competence, and not the readiness of the devices themselves.

This paper walks the ordinary timeline of one composite case — the order, the sourcing, the delivery, the preparation, the schedule, the case coverage, and the return — and at each step asks a simple question: **what does the system actually know here, and how does it know it?** The observation that emerges is not that any party is failing. It is that the questions themselves, reasonable as they are, largely cannot be answered today with verified, portable, consistent information. Where a reasonable safety question cannot be answered with verified information, there is work for voluntary consensus standards to do.

1. The Order — A Phone Call

A surgeon schedules a procedure that requires instrumentation and implants the hospital does not own. Someone — the surgeon, the clinic, the OR scheduler, supply chain — contacts the manufacturer's representative. The order may be a phone call, a text message, an email, or an entry in a scheduling portal. It may specify the system and size range precisely, or it may say, in effect, "bring what we usually use."

No common standard governs what this request must contain, how it is confirmed, or how changes to the case are communicated back to whoever is assembling the sets.

One part of this exchange is already receiving attention — and that attention is itself evidence. The Healthcare Standards Institute (HSI), a fellow ANSI-accredited standards developer, has undertaken standards work addressing the **"bill-only" implant workflow** — the administrative process by which patient-specific implants delivered for a particular case are documented and billed after use, rather than held in hospital inventory. HWASC welcomes that work and cites it here as

confirmation, not contrast: when an accredited developer takes up the bill-only implant workflow, it confirms that how implants move into patient care is a recognized national need — not a niche concern.

It also sharpens why the Job Task Analysis matters. A bill-only record is only as reliable as the work behind it: the delivering, verifying, documenting, and case support performed by people whose role has never been formally defined.

Transaction standards define **what must be recorded**; the Job Task Analysis defines **the work — and the competency — of the people the record depends on**. The two efforts need each other.

Questions the system should be able to answer — with verified information:

- What exactly was requested, by whom, and for which patient and procedure?
- How was the request confirmed — and how would a change in the case reach the people preparing the trays?
- Who is accountable for translating the surgeon's request into the physical sets that arrive?

2. The Sourcing — Three Chains of Custody, One Tray

The instruments and implants for this single case may come from more than one place. Some sets ship from the manufacturer's distribution center. Some come from the representative's own inventory — sets that live in a vehicle, a garage, or a local depot between cases. Some are borrowed from another hospital that used the same system on Tuesday.

Each source implies a different history: how the set was cleaned and maintained, what was replaced after its last use, where it has been, and who has handled it. When the trays converge at the receiving dock, those histories converge too — largely undocumented in any common format.

Ask a simpler question first: **where is home for this set?** For some, home is a manufacturer distribution center with environmental controls, inventory systems, and documented handling. For others, home is wherever the representative keeps inventory between cases — a home, an office, a self-storage unit, the trunk of a car. No standard defines what a suitable storage environment for surgical instrumentation in field inventory is, and no record travels with the set to say where it has been living.

Questions the system should be able to answer — with verified information:

- Where has each tray been, and what is its processing and maintenance history?
- Where is the set stored between cases — and to what environmental and security conditions?

- If a set came from another facility, who verified its condition and completeness when it left — and against what?
- Is there a chain of custody for the implants that will remain in the patient?

A documented case — not a hypothetical.

In May 2013, a loaner neurosurgical tray arrived at a VA medical center. Instruments from that tray were used in two patients' brain procedures that spring. Nearly three months later, the manufacturer notified the facility that the same instruments had previously been used on a patient at another institution who was later diagnosed with Creutzfeldt-Jakob disease — a fatal condition caused by prions, which resist standard sterilization. The facility, which had no loaner tracking process at the time, notified the patients, extended its sterilization protocols, and implemented tracking of all loaner instruments from receipt to return. The VA Office of Inspector General investigated and made no recommendations, finding the facility had responded appropriately.

That is the point. No one failed once the information arrived — and the architecture still allowed instruments with an unknowable history into neurosurgery, with disclosure of that history depending on a manufacturer's notification months after the fact. Where the questions above cannot be answered at the moment of receipt, even a system full of people doing their jobs well is depending on the loop closing later — if it closes at all.

Source: VA Office of Inspector General, Healthcare Inspection — Potential Exposure to Creutzfeldt-Jakob Disease, VA Connecticut Healthcare System, West Haven, Connecticut, Report No. 13-04520-201 (July 1, 2014).

3. The Delivery — Trays in the Night

The sets may arrive in one delivery or several. They may be driven in by the representative, dropped by a commercial courier, shipped by freight — or, at the last mile, moved by whatever transportation is available, including rideshare and on-demand couriers. Sets are handed from representative to representative in parking lots when territory or coverage changes, and travel directly from one hospital to another when a borrowed set is needed for the next case. They may arrive 48 hours before the case — or after midnight, the night before, received by a night shift that was not told they were coming and may not know which case they belong to.

And the mode of delivery decides something more important than logistics: **whether any knowledge arrives with the trays.** When the representative delivers, the sets arrive with someone who knows them — which case they belong to, what was substituted, how they assemble, what sterile processing should expect. When a courier delivers, the sets arrive alone. Couriers deliver; they do not set up. The boxes reach the dock carrying everything except the information the

facility needs — and whoever holds that knowledge is somewhere else, on the other end of a phone that may or may not be answered at 2 a.m.

Each arrival is a handoff: from a manufacturer-controlled quality system, through transportation, into a facility-controlled patient safety system. The handoff is the moment responsibility changes hands — and it is the moment least governed by any common standard.

Questions the system should be able to answer — with verified information:

- How many trays were expected, how many arrived, and for which case?
- Who received them, at what hour, and was receiving told they were coming?
- Was there communication between the sender and the facility — or only a label on a case cart?
- Did the devices arrive 24 to 48 hours ahead, as reprocessing realistically requires — or hours before the incision?
- When the delivery arrives without the person who knows the sets — who performs the setup, who answers sterile processing's questions, and when?

4. The Preparation — Sterile Processing Against the Clock

Whatever arrives, sterile processing must make it surgical. That requires the current instructions for use for each device; a manifest to verify completeness against; staff who have been trained on these specific sets; and enough time to inspect, assemble, and sterilize — correctly, not just quickly.

Each of those requirements raises its own question, because each depends on information and training that today arrives inconsistently, if it arrives at all.

Consider the most basic of them. A tray arrives at midnight without its instructions for use, and the case is at 7 a.m. What does the technician actually do? Search the manufacturer's website — and hope the document found matches the revision of the set on the table. Check a commercial subscription service, if the facility pays for one. Pull a binder of printouts of unknown currency. Or call the representative, who is asleep. The sterilization parameters, disassembly instructions, and cycle times that the entire process depends on must be located, verified as current, and followed — in hours, in the middle of the night.

Here the pattern of this paper repeats at the level of documents: **there is no authoritative national source of truth for the instructions themselves.** The information that determines whether a device can be made safe for a patient lives scattered across manufacturer websites, subscription databases, binders, and phone calls — with no single place where a facility can verify, at 2 a.m., that the IFU in hand is the IFU in force.

Questions the system should be able to answer — with verified information:

- Are the IFUs for every device in the tray available, current, and complete — and how does the facility know?
- Against what count sheet or manifest is completeness verified, and which revision of the set does it describe?
- Was the sterile processing staff trained on these sets — by whom, when, and is that training documented anywhere portable?
- Is there enough time — and if there is not, who is told, and who decides what happens next?

5. The Schedule — Elective and Emergent

For an elective case, the timeline above is compressible but plannable. For an emergent case — trauma in the night, a revision that cannot wait — every step happens at once, at speed, with less communication and fewer hands available to receive, process, and verify.

The emergent case is precisely when the patient is most vulnerable, and precisely when today's informal arrangements are under the most strain. A framework that works only when there is time is not a framework; it is good weather.

Questions the system should be able to answer — with verified information:

- Do the answers to any of the questions in this paper change when the case is emergent — and should they?
- What is the minimum verified information a facility should insist on even at maximum speed?

6. The Case Coverage — The Patient Is Asleep

The morning of surgery, the healthcare industry representative arrives to cover the case: to provide technical product guidance on the instruments and implants — and, depending on the procedure, on robots, navigation systems, biologics, human tissue, and more. The patient is asleep.

Look around the table. The surgeon is licensed, credentialed, and privileged — a defined list of what they may do in this facility, anchored to verified qualifications. Anesthesia, nursing, and the surgical technologists practice under the same architecture. The representative — the person whose guidance shapes how the technology is used in this patient — stands inside that room under a different system entirely: vendor credentialing that verified documents and granted access.

Everyone at the table is verified for what they do — except the person guiding the technology.

This is no criticism of the representative, who may be deeply experienced and superbly trained by their manufacturer. FDA's framework reaches the product, and

manufacturer training reaches product knowledge. But product knowledge is not job competency in a healthcare environment — and no license, no privileges, and no accredited, portable certification currently attests to that competency for this workforce.

An operating room runs on trust — and for nearly everyone in it, that trust is verified: the license checked against the state board, the privileges granted by the governing body, the competency documented and current. What the system asks of the team with respect to the representative's guidance is something different: trust without an instrument of verification. No clinician would call it blind faith — the representative is often well known, experienced, and manufacturer-trained. But **known and trusted is not the same as defined and verified** — and patient safety architecture is built on the second precisely so that it never has to depend on the first.

Questions the system should be able to answer — with verified information:

- What defined role is the representative performing in this case — and where is that role defined?
- What competency has been verified, by whom, against what standard — and can the facility check it the way it checks a license?
- Are the trays on the back table complete and ready — and who attested to that?
- If guidance today spans instruments, implants, robots, navigation, biologics, and human tissue — does one undefined role really cover all of it?
- And the patient, whose consent named the surgeon and the procedure — what, if anything, do they know about who else is guiding the technology used in their care?

7. The Person at the Table — Continuity, Training, and Representation

Stay in that operating room a moment longer, because the patient safety questions about the person do not end with verification. Three more deserve to be asked.

Continuity. The professional who received the trays, verified what arrived, knows which set came from which source, what was substituted, and what is missing — is that the person covering the case? Not necessarily. Coverage is assigned by territory, availability, and workload; a colleague may step in at the last minute. Everything the first person learned about these specific trays exists in their head and their text messages. There is no standard handoff — no equivalent of the structured handoffs clinical teams use precisely because informal transfer of critical information is where errors live.

Training. How does a new healthcare industry representative become ready for that room? Commonly: hired, trained by the manufacturer on the product — often rigorously — then sent to observe cases alongside a senior representative, then judged ready, then solo. Compare the two pathways that meet at the operating table. The clinician's: education, examination, licensure, supervised training with defined milestones, then privileges. The representative's: hired, product training, ride-alongs, solo. There is no common curriculum for the healthcare environment itself, no supervised progression with independent assessment, and no common definition of ready. The first unsupervised case is a live patient.

Representation. Whom does the representative represent? Some are direct employees of a single manufacturer. Others — distributor representatives and independent contractors — carry the lines of several manufacturers at once, covering different systems, from different companies, in the same week. In some procedures, one person supports products from more than one source in the same case. Each manufacturer trains on its own products; no one verifies competency across the portfolio. And the accountability question sharpens: for each product in use in this patient, whose authorization and whose quality system stand behind the person providing the guidance?

Notice the form every available answer takes. Trained — says the manufacturer. Ready — says the employer. Experienced — says the representative. These are **attestations**: declarations made by parties with an interest in the answer. They may all be true. But healthcare accepts attestation from no one else at the table. The surgeon's competence is not established by the surgeon, or the surgeon's employer, saying so; it is examined and verified by independent parties against defined, public standards. That is the line this paper keeps arriving at: **attestation declares competence; certification tests it** — through an accredited third party, against a standard everyone can read. Until third-party assessment exists for this workforce, every answer to the questions below is someone attesting on their own behalf.

Questions the system should be able to answer — with verified information:

- Is the person covering the case the person who prepared and delivered the sets — and if not, what information about these specific trays travels between them?
- How was the representative trained for the healthcare environment, as distinct from the product — by whom, against what curriculum, documented where?
- What defines readiness for a first unsupervised case — and who decided this representative had reached it?
- Does this representative represent one manufacturer or several — and for each product in use, whose authorization and quality system stand behind them?

- When coverage changes hands at the last minute, what does the incoming representative know about this patient's case, these trays, and this facility?

8. The Return — The Journey Runs in Reverse

The case ends. The patient goes to recovery. And the journey this paper has followed now runs in reverse — with one profound difference: the instruments are no longer merely unfamiliar. They have been used. They carry bioburden.

Professional guidelines direct facilities to decontaminate loaner instrumentation before it leaves the building, and many facilities do exactly that. But the set is needed for another case, at another hospital, sometimes the next morning — and the return leg travels the same informal network the arrival did: the representative's vehicle, a courier, occasionally a rideshare, a parking-lot handoff to another representative, or a direct run to the next hospital's dock. The arrival at least had a case attached to it. The return often has only momentum.

Contaminated medical devices in a personal vehicle are not an abstraction. They are a question of containment, documentation, and accountability that today has no common answer: no standard manifest that says decontaminated, by whom, when, to what point — and no defined framework for what the transport of instrumentation bearing bioburden requires of the person and vehicle carrying it.

Questions the system should be able to answer — with verified information:

- Was the set decontaminated before release — and who attested to that, in what record, that travels with the set?
- What containment, labeling, and handling does the transport of used surgical instrumentation require — and who is trained on it?
- When a set goes directly from one hospital to another, what does the receiving sterile processing department know about its status when it arrives?
- If a representative's vehicle carries contaminated instruments in the morning and processed sets in the afternoon, what governs the separation?
- When the set finally goes home — wherever home is — what condition is it in, and who verifies it before the next case?
- And a year from now, could the facility reconstruct which sets, from which sources, were used in this patient — and who provided the guidance? The documented case in Section 2 shows how much depends on that answer.

9. The Tier Without a Task — A Licensed Plumber at the Scrub Sink

The healthcare industry has, in fact, already recognized that where work is performed inside a facility matters. ANSI/NEMA SC 1-2020, the American National Standard for supplier credentialing in healthcare, established a risk-based

structure of three facility access tiers — escalating from general public areas, through patient care areas, to restricted and procedural environments. It defined the *where*.

What it never did — what no standard has yet done — is assign **job tasks** to those locations: a definition of what work is actually performed in each tier, and what competency each task, in each tier, requires. The tiers are a map with no destinations. Consider what that means through the trade with the strongest credential the current system can offer.

A plumber is licensed. A state board has verified their competence in the trade — a real license, with real teeth, anchored to a real source of truth. Send that plumber to repair a sink in the hospital lobby — a Tier 1, public-facing space — and the license plainly covers the work.

Now send the same plumber to the scrub sink outside the operating rooms — a Tier 3 environment, where surgical teams perform hand antisepsis before entering sterile procedures. The plumbing is the same trade. The environment is not the same job. The work now sits adjacent to infection prevention, water quality and contamination pathways, restricted access protocols, and the operating schedule itself. **Does a plumbing license, issued without any reference to healthcare environments, qualify its holder for that job?** The license verifies the trade. Nothing verifies the tier.

If that is true for a licensed trade — and it is — it is true many times over for the workforce this paper has followed through the timeline, most of whom hold no license at all. Location tiers without job tasks leave every facility to answer the question alone, differently, at every door. Assigning the tasks — defining what is performed in each environment and what competency it demands — is precisely what a Job Task Analysis does, and precisely what has never been done for the non-hospital workforce.

Questions the system should be able to answer — with verified information:

- For each access tier a facility maintains, what job tasks are actually performed there — and where is that written?
- What competency does each task, in each tier, require beyond the trade or product knowledge the worker already holds?
- When a license or credential was issued without reference to healthcare environments, what closes the gap between the trade and the tier?

10. The Questions, Assembled

None of the questions in this paper is exotic. Each is the kind of question a patient's family member might ask, the kind a board quality committee might ask,

the kind a surveyor might ask. Assembled, they describe a single gap with two faces:

The devices. No widely recognized consensus framework governs the deployment handoff — the ordering, sourcing, delivery, communication, documentation, and preparation of manufacturer-supplied sets — from the manufacturer's quality system into the facility's patient safety system.

The people. No license, no privileges, and no accredited, portable certification defines and verifies the competency of the non-hospital professionals who transport, support, and guide the use of those devices in clinical settings.

And here is what makes the gap so striking: the system is not failing to record. It records constantly — in fragments. Vendor credentialing platforms record that the representative entered the building — but not the job performed once inside. Sterile processing records its acceptance of the loaner trays. The operating room records its visitors. The implant log records what was implanted; the tissue log records human tissue. Every one of those fragments exists because some discipline, at some point, decided patient safety required it. But the fragments live in separate systems, kept by separate parties, defined by no common standard — and no one can lay them side by side and read the whole sentence: who performed what job, on which patient's case, with which devices, prepared how, guided by whom. **The data is there. The answer is not.** Patient safety demanded each record; it should demand that they connect.

And the first of those fragments deserves a second look. Vendor credentialing does not produce one record of a professional — it produces many, because each hospital chooses which credentialing platform it uses. The same representative exists in several competing proprietary systems at once, each holding a different slice: entered here, cleared there, documents on file somewhere else. **For the non-hospital workforce there is no national source of truth** — only fragments, held by whichever platform each facility happened to choose. Compare that with every clinician in the building, whose license, board certification, and history resolve to authoritative national sources any facility can query. One workforce has a single verifiable identity everywhere; the other has a different partial identity at every door.

Variation across facilities and manufacturers is the predictable result — and, as HWASC's companion paper argues, variation in a process that spans organizational boundaries is not evidence of harm; it is evidence of an opportunity for voluntary consensus standardization.

And one more asymmetry deserves naming, because it explains who carries the weight of every unanswered question. **Hospitals are measured on quality and patient safety.** Under the CMS Conditions of Participation, the governing body is accountable for the care delivered in its facility — including services furnished

under contract. Hospital-acquired conditions are tracked and penalized under federal quality programs. Surgical site infections are counted through national surveillance, publicly reported, and reflected in payment and in ratings. When an outcome goes wrong, it lands in the hospital's data, the hospital's penalties, the hospital's reputation.

Now set that against the timeline this paper has walked. The tray that arrived at midnight. The set processed against the clock. The courier delivery with no knowledge attached. The return that had only momentum. The guidance from a role no third party has ever assessed. **None of it appears in any measure.** The outcome is measured to two decimal places; the inputs are not measured at all. A system that counts every surgical site infection, but cannot count whether the implant trays arrived in time to be processed properly, is measuring the harvest while ignoring the field. Bringing the inputs under the same discipline as the outcomes is precisely what the work described next exists to do.

11. From Questions to Verifiable Answers

Every question in this paper is answerable. What is missing is not good intent — it is architecture: common definitions, common requirements, and verified, portable attestations that any facility can check. That architecture is being built in two connected efforts:

HWASC-1000 — Clinical Deployment Standard for Manufacturer-Supplied Loaner Medical Devices and Implants. A proposed voluntary consensus standard defining good practice for the safe transfer, preparation, documentation, communication, and support of manufacturer-supplied devices before, during, and after patient use — including how the current version of the processing instructions travels with the set — turning the ordering, sourcing, delivery, and preparation questions into requirements with verifiable answers.

The National HCIR Job Task Analysis and ISO/IEC 17024 certification. A national, psychometrically facilitated effort to define — for the first time — the job tasks and competencies of the non-hospital workforce in healthcare facilities, providing the evidence base for accredited, portable personnel certification: a verified answer to the question the operating room cannot answer today. A defined role also gives training something to aim at — you cannot build a curriculum, a supervised progression, or a definition of ready for an undefined job. Where ANSI/NEMA SC 1-2020 defined the tiers, the Job Task Analysis assigns the tasks — completing the sentence the industry started: this work, in this environment, requires this verified competency.

It bears saying plainly: many manufacturers, representatives, facilities, and credentialing programs already do much of what this paper asks about, and do it well. Voluntary consensus standards do not invent burden — they capture existing

best practice and make it common, verifiable, and portable. Together, these efforts close the loop the timeline exposes: qualified devices, delivered under a common standard, supported by people whose competency is defined, assessed, and verifiable — at every facility, every time, including at 2 a.m.

12. A Call for Participation

HWASC is not publishing conclusions. It is publishing questions — and an invitation. Surgeons and perioperative nurses; sterile processing professionals; hospital supply chain, quality, and patient safety leaders; manufacturers, distributors, and their representatives; couriers and logistics providers; vendor credentialing organizations; regulators, accreditors, insurers, and patient advocates: if you recognize this timeline, you are qualified to help fix it.

Participation in HWASC standards development is open to all directly and materially affected parties, through an open, balanced consensus process. To participate, comment, or be notified of milestones, contact info@hwasc.org or visit www.hwasc.com.

Healthcare Workforce Access Standards Commission · 400 Chapel Road, Unit 1-L, South Windsor, CT 06074 · info@hwasc.org · www.hwasc.com

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