MAILING COVER SHEET

Tenth Triennial Section 1201 Rulemaking — 2027 Cycle
Docket No. 2026-4

TO:

U.S. Copyright Office
Office of the General Counsel
Attn: Section 1201 Rulemaking — Docket No. 2026-4
101 Independence Avenue SE
Washington, DC 20559-6000

FROM:
Marshall R. Shannon
1468 Meadowlark Lane
Lancaster, Texas 75146
214-707-4440
Regulations@21cfr820.net

RE: Petition materials concerning medical-device diagnosis, installation, maintenance, repair, calibration, and return to service

ENCLOSURES: Copies only—not originals—of the petition and supporting exhibits identified in the accompanying exhibit index.

ONLINE FORM UNAVAILABLE: The Regulations.gov form would not allow online submission and stated that it was not currently accepting feedback. I am therefore mailing this package. Please let me know if I must file online again once the online form is functional, and I will promptly do so.

REQUEST: Please associate any authorized hard-copy submission with Docket No. 2026-4. The submitter remains available to provide additional information or participate in any authorized hearing, roundtable, technical conference, oral questioning, or other formal proceeding.

Respectfully submitted,

Signature: _____
Marshall R. Shannon
Date: 24 JULY 2026

SUBMISSION AND EXHIBIT-DELIVERY INSTRUCTIONS

Submission method used: The Regulations.gov form was unavailable, so this package is being mailed. Retain a complete copy and delivery tracking. If electronic resubmission is requested after the online form is restored, submit the same materials online as directed.

BEFORE THE UNITED STATES COPYRIGHT OFFICE
LIBRARY OF CONGRESS

TENTH TRIENNIAL SECTION 1201 RULEMAKING
2027 CYCLE — DOCKET NO. 2026-4

PETITION TO RENEW AND SUPPORTING STATEMENT AND PETITION FOR A NEW OR MODIFIED EXEMPTION FOR MEDICAL-DEVICE DIAGNOSIS, INSTALLATION, MAINTENANCE, REPAIR, CALIBRATION, AND RETURN TO SERVICE

Submitted by

MARSHALL R. SHANNON

1468 Meadowlark Lane
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214-707-4440
Regulations@21cfr820.net

FDA-regulated medical-device manufacturer, medical-imaging engineer, installer, and independent servicer with nearly thirty years of MRI, CT, and X-ray experience installing, restoring, testing, and safely returning new, used, and resold systems to service throughout the United States and internationally

IMPORTANT NOTICE REGARDING OPTIONS, OPINIONS, AND LEGAL ADVICE

This submission is not legal advice. The opinions, interpretations, factual characterizations, and policy positions expressed are those of Marshall R. Shannon alone. They do not create, establish, or adjudicate legal standing, legal status, liability, immunity, or entitlement to relief, and they should not be understood as findings by the Copyright Office, the Library of Congress, Congress, FDA, HHS, FTC, DOJ, or any court.

Mr. Shannon understands that the Copyright Office requires separate forms for (1) renewal of an existing exemption as currently written and (2) any proposed new or modified exemption. He further understands that the petition phase is an initial, limited phase; the fuller legal and evidentiary record for a proposed new or expanded exemption is developed during the later public-comment phase. He may request to participate in the Office's public hearings when participation procedures are announced, and the Office may accept, reject, narrow, group, or otherwise address the proposed class.

Mr. Shannon believes that his repeated reporting of potential medical-device safety, regulatory, competition, and access concerns to federal authorities may qualify as protected whistleblower activity under one or more laws. He does not assert that any agency or court has formally determined that he is a whistleblower or that any specific statutory protection applies. He reserves any rights and protections that may lawfully exist.

Public docket entries, complaints, motions, letters, and party submissions are cited as records of what was filed, asserted, requested, or ordered. Unless this submission expressly identifies a holding, judgment, or finding, those materials should not be read as adjudicated facts. Docket status is stated only through the most recent public record reviewed and may later change.

I. PETITIONER AND PROFESSIONAL BACKGROUND

Marshall R. Shannon is an FDA-regulated medical-device manufacturer, veteran medical-imaging engineer, installer, independent service professional, and author of Through Fire: The Story of an MRI Engineer. For more than three decades, he has worked to keep MRI, CT, and X-ray systems properly installed, accurately calibrated, safely maintained, and available to the patients and communities that depend on them.

His field experience spans nearly every state in the United States and international work in India, Russia, China, Costa Rica, Argentina, Germany, Switzerland, Spain, Canada, Mexico, and other countries. He has supported rural clinics where a single scanner serves an entire region, major hospitals with complex imaging operations, and developing communities receiving advanced medical-imaging capability for the first time.

His work includes installation and reinstallation of new, used, and resold systems; relocation and commissioning; software installation and restoration; magnet shimming; cryogenics; ramping and de-ramping; coldhead rebuilding; gradient and magnet maintenance; calibration; FDA-related performance testing; mobile MRI support; diagnosis; repair; and final return-to-service verification. He has trained engineers and supported hospital personnel when equipment failure delayed patient care.

His continuing advocacy for device and patient safety grew directly from that field experience. He has documented missing installation steps, restricted service functions, blocked safety procedures, disappearing diagnostic tools, remote-service pathways, and access changes that affect lawful service. He has pursued clarification through FDA and DICE, submitted concerns to FTC, HHS, DOJ, Congress, and other federal bodies, provided regulatory materials to Philips, maintained 21CFR820.net, and offered his records and technical knowledge for formal review.

Because Mr. Shannon installs and restores used and resold medical-imaging systems, much of his work occurs after the original OEM sale and outside an active OEM service contract. The equipment owner nevertheless remains responsible for placing the device into safe and lawful operation. Installers and service providers must therefore be able to obtain and use the procedures, software functions, calibration pathways, records, and technical information necessary to complete that work.

II. RELIEF REQUESTED

A. Renewal of the Existing Exemption

Mr. Shannon requests renewal of the existing exemption for circumvention of technological protection measures on lawfully acquired medical-device software when necessary for diagnosis, maintenance, or repair.

B. Clarification or Modified Exemption

He also requests clarification or a modified exemption expressly covering owner-authorized installation, reinstallation, software setup, operating-system and application restoration, relocation, commissioning, calibration, performance verification, service-data access, cybersecurity-related reconfiguration, and return to service for new, used, and resold medical devices.

The requested clarification should not be limited to replacing a failed component. Modern medical-device work often involves a connected sequence: assessment, disassembly where necessary, transportation, software and configuration restoration, reassembly, installation, inspection, calibration, performance testing, documentation, and final return to clinical service. Each step may require interaction with copyrighted software or a technological access control.

The exemption should remain technology-neutral. Protection should not depend on whether the manufacturer calls the same function a service tool, installation utility, diagnostic application, configuration interface, certificate, credential, log viewer, commissioning program, or cybersecurity feature.

III. PROPOSED CLASS OF WORKS

Computer programs that operate, control, diagnose, monitor, configure, calibrate, install, service, maintain, test, or restore medical devices or systems, including related service interfaces, logs, configuration data, certificates, credentials, utilities, and technical materials, when circumvention is performed by the owner or an authorized service provider solely for lawful diagnosis, installation, maintenance, repair, calibration, cybersecurity, or return to service.

IV. NONINFRINGING USES AND PRACTICAL CIRCUMVENTION

Modern medical devices cannot be safely installed or serviced without interacting with embedded software, service modes, configuration files, logs, certificates, credentials, and diagnostic utilities. Circumvention may require more than entering a password. It may require technically necessary creation, modification, replacement, renaming, movement, reset, restoration, or deletion of files, registry entries, certificates, credentials, settings, scheduled tasks, or network destinations.

Those acts should be covered when they are owner-authorized, technically necessary, and limited to lawful service. They should not be treated as unlawful merely because the OEM placed necessary lower-level functions behind the same control as unrelated higher-level material.

Ordinary service activity may also cause the system itself to update timestamps, logs, caches, configuration records, registry values, and service-history entries. A technically necessary or automatically generated change should not be characterized as evidence destruction or unlawful modification merely because the device electronically records the service event.

A manufacturer-prescribed software reload or restoration should not, by itself, support an inference of evidence destruction. OEM service procedures may direct personnel to reload operating software, applications, configuration files, or system images when software is corrupted, unstable, nonfunctional, or otherwise unable to support safe device operation.

The same analysis may apply when a software update changes the access architecture, introduces additional technological controls, or makes a previously available service pathway unavailable. A reload or restoration performed in accordance with documented manufacturer procedures may be necessary to diagnose the condition, restore intended functionality, complete installation or service, and return the device to safe operation.

Such a reload may replace or alter temporary files, cached data, software components, logs, or configuration artifacts as an ordinary and expected technical consequence of the procedure. That result should be evaluated in context rather than treated as dispositive of spoliation or wrongful deletion. Any preservation or evidence issue should depend on the applicable legal duty, notice, intent, timing, the availability of other records or backups, and the specific facts surrounding the service event.

V. COMMINGLING OF SERVICE FUNCTIONS AND RESTRICTED MATERIAL

Mr. Shannon's experience is that Philips moved or placed lower-level and customer-facing service functions behind the same access environment used for Level 1, Level 2, or other restricted materials. This architecture allows the OEM to argue that entry into the combined environment proves access to every work within it, even where the servicer used only the lower-level function and did not open, copy, disclose, or use higher-level material.

The legal result should turn on purpose and actual use, not on the manufacturer's unilateral design of the gate. Commingling protected and unprotected works should not allow an OEM to remove otherwise lawful repair, installation, testing, or safety functions from the exemption.

Philips's November 2018 R3.2.3 Service Pack 5 newsletter provides a concrete example of this architecture. The document is itself labeled CSIP Level 1 and states that SP5 was intended to implement changes relating to Customer Support Intellectual Property. It explains that an IST dongle would thereafter be required to access on-device software tools, except certain configuration tools, and that users would need a Philips IST smartcard, a valid IST account, and the appropriate system entitlements.

The same newsletter states that customer biomedical engineers would receive only a restricted set of service documentation and software tools. It further explains that tasks previously accessible under certain customer service arrangements would no longer be available to customer biomedical engineers and would instead be placed at Level 2 for Philips field service engineers and authorized trade partners.

The newsletter also identifies document reclassification: SMI manuals were moved from CSIP Level 0 to CSIP Level 1, and SPD manuals were moved from CSIP Level 1 to CSIP Level 2. It directs that the newsletter not be shared with customers. These statements are significant because they show that the access level was not merely describing the inherent character of a tool or manual; Philips affirmatively changed which level controlled material that had previously been available at a lower level.

The CSIP and IST materials further show that access depends on a mapping among CSIP level, IST entitlement, and the service level recognized by the software. A user may therefore confront one technological gate controlling multiple layers of service functionality. Where a basic installation or service function is moved behind that gate, entering the environment can later be characterized in litigation as access to a higher-level protected area even when the servicer's actual purpose and use were limited to the basic function.

Mr. Shannon does not ask the Copyright Office to determine that every reclassification was improper or that every higher-level item must be disclosed. He asks the Office to recognize the practical consequence: an OEM should not be able to relocate an otherwise lawful installation, configuration, diagnostic, or service function behind a higher technological level and then rely solely on entry through that level as proof that the servicer accessed or used unrelated protected material.

A workable rule should separate access from use. Entering a combined service environment should not create an irrebuttable presumption that the servicer opened, copied, or used every protected work available within that environment. The relevant questions should include the owner's authorization, the service purpose, the functions actually used, and whether any protected expression was copied, disclosed, or exploited.

VI. PRIVATE LITIGATION AS A PRACTICAL SUBSTITUTE FOR REPEAL

Medical-imaging manufacturer trade associations challenged the medical-device exemption by arguing that third-party circumvention threatens control over software, access restrictions, safety, cybersecurity, and proprietary material. Mr. Shannon contends that Philips uses the same basic theory in private disputes: access is treated as

unlawful because Philips did not authorize the method, and entry into a combined environment is treated as evidence of access to all material.

In Philips North America LLC v. Image Technology Consulting, LLC et al., No. 3:22-cv-00147 (N.D. Tex.), Philips asserted DMCA, CFAA, trade-secret, fraud, and related claims concerning service access. The November 10, 2025 Carla M. Wirtschafter letter used service-related terms—including sale, repair, service, refurbishment, modification, and installation—while describing Philips's enforcement position concerning certificates, registry changes, files, keys, passwords, service tools, and log files.

The Jose Pons and Imaging Service Solutions correspondence provides a documented example. Philips's letters asserted DMCA, CFAA, trade-secret, and related concerns, stated that the company's account had been blocked, and described circumstances under which reconsideration might occur. Philips then filed Philips North America, LLC v. Imaging Service Solutions, LLC and Jose Pons, No. 1:26-cv-01497 (D. Md.), on April 17, 2026. The public docket reviewed through May 26, 2026 reflected service and scheduling activity, not a merits determination. These materials are cited only as evidence of asserted claims, expense, and potential chilling effect; they are not findings that either side's allegations are true or false.

The practical concern is that an exemption may remain formally valid while an ISO must still endure years of overlapping litigation to establish whether the protected service activity can be performed. A small ISO may be forced out of business before the legal issue is resolved.

Mr. Shannon filed a declaratory-judgment action on April 21, 2026, docketed as No. 3:26-cv-01276 in the Northern District of Texas. As he describes the requested prospective relief, the action does not ask the Copyright Office to overturn the prior judgment or privately enforce the Federal Food, Drug, and Cosmetic Act. It asks a federal court to address where lawful federal pathways remain for future medical-device installation and service, and whether private restrictions or litigation positions may practically displace exemptions, regulations, or federal requirements. This paragraph describes Mr. Shannon's pleaded position, not a judicial finding.

The issues identified in that action include, where applicable, 21 C.F.R. requirements governing medical-device installation and servicing; 21 U.S.C. § 360k, which addresses state or local requirements different from or additional to federal device requirements; and the electronic-product-radiation-control provisions in 21 U.S.C. §§ 360kk and 360oo concerning federal performance standards, certification, testing, information, records, and prohibited acts. These authorities are cited as part of the federal framework and not as a request that the Copyright Office adjudicate an FDCA violation or the merits of the pending case.

The filing of that declaratory action illustrates the burden Mr. Shannon identifies: an individual service professional has asked a federal court to define a prospective lawful path where copyright, computer-access, medical-device, safety, and regulatory obligations overlap. No statement here predicts or represents the court's ultimate disposition of that action.

VII. REMOTE MONITORING, AUTOMATIC DATA TRANSMISSION, AND OWNER CONTROL

Philips medical-imaging systems may include integrated remote-service and monitoring functions capable of transmitting status notifications, error logs, utilization information, service events, and related data through network or SMTP-type processes. Depending on configuration, transmissions may occur automatically rather than through an affirmative owner action each time information is sent.

An owner or authorized service provider should be permitted to disable, block, reconfigure, or remove remote monitoring, automatic uploads, SMTP destinations, credentials, certificates, scheduled tasks, and related pathways for cybersecurity, privacy, service transition, or data-governance reasons. Continued OEM access should depend on clear owner authorization, particularly where the customer is not under an active OEM service contract.

This request does not assert that every historical transmission was unlawful or that every remote-service connection is unsafe. It asks the Office to recognize that owner-authorized disabling of a remote pathway can itself be a legitimate maintenance or cybersecurity action and should not become circumvention liability or computer crime.

VIII. FDA AND FDCA REGULATORY CONFLICT

Medical-device installation, servicing, quality controls, complaint handling, calibration, testing, labeling, and safe return to use are governed by federal law and FDA regulation. A private access restriction should not make technically impossible, or legally perilous, the work required or contemplated by that federal framework.

The January 14, 2025 FDA response to Mr. Shannon's letter to Commissioner Robert Califf explained that 21 C.F.R. § 820.170(a) concerns installation and inspection instructions and requires those instructions to be available to installers. This is especially relevant because Mr. Shannon operates as an FDA-regulated manufacturer and installer and installs used and resold medical-imaging systems.

The administrative, technical, and litigation records may appropriately be compared for consistency. Philips's manuals, installation materials, and service documentation describe installation, testing, configuration, maintenance, and service procedures used to place and keep devices in operation. In litigation and related communications, Philips has asserted that access to particular tools, instructions, or service environments was unauthorized, proprietary, outside the asserted entitlement, or not material to the legal issue presented.

Mr. Shannon respectfully contends that these positions can create a practical tension even when they address different legal questions: technical and regulatory-facing materials describe procedures used for installation and service, while litigation positions may treat access to the same or related pathways as actionable. The Copyright Office need not decide that Philips made a false or inconsistent statement to any agency. The narrower point is that the record demonstrates uncertainty capable of chilling independent service.

The Copyright Office is not being asked to enforce the FDCA or decide an FDA violation. It is being asked to recognize the adverse effect created when an OEM invokes private claims to make access prohibitively dangerous even where that access may be necessary for lawful installation, servicing, testing, or safety work.

Section 360k must be used with precision because it expressly addresses state and local device requirements. Mr. Shannon relies on it only where a private or state-law theory would impose a device-related requirement that conflicts with the governing federal framework. Sections 360kk and 360oo apply specifically to electronic-product radiation-control standards and prohibited acts and are relevant to covered imaging equipment only where their statutory subject matter and technical requirements apply.

IX. GOOD-FAITH EFFORTS TO REDUCE LITIGATION

Mr. Shannon did not begin by seeking additional litigation. He sought regulatory clarification, agency review, and direct resolution. FDA responded to his letter to Commissioner Califf, clarified relevant installation requirements, directed him to servicing guidance, and shared his concerns with its Division of Regulatory Programs.

Mr. Shannon and personnel acting with him then provided the FDA and DICE correspondence to Philips through communications titled "Regulatory Request" and "21CFR820-170 Compliance Request." Those communications sought a prospective compliance path, specific installation and service information, and a practical resolution intended to reduce legal conflict.

Philips's November 10, 2025 response confirms receipt of the FDA and DICE materials but relied on the prior judgment and injunction, rejected further engagement, and reserved Philips's rights. This chronology supports Mr. Shannon's position that he attempted to narrow the dispute before seeking broader federal intervention.

X. FEDERAL OUTREACH AND THE ENFORCEMENT GAP

Mr. Shannon's records reflect outreach to FDA, DICE, FTC, HHS, DOJ, congressional offices, the Copyright Office and Library of Congress process, and other authorities with potential responsibility for medical-device safety, competition, cybersecurity, copyright policy, or oversight.

The problem crosses agency boundaries. The Copyright Office administers the exemption; FDA and HHS oversee medical-device safety and health policy; FTC addresses competition; cybersecurity authorities address network risks; and Congress has legislative and oversight authority. Yet no current mechanism guarantees that an ISO can rely on the exemption without first surviving private litigation.

Mr. Shannon has not received an enforcement response that prevents an OEM from continuing to assert overlapping DMCA, CFAA, trade-secret, fraud, contract, or related claims against individual ISOs and service professionals. The agencies may clarify rules, receive complaints, or preserve the exemption, while the cost of defending those federal policies remains with the private servicer.

A multibillion-dollar manufacturer can treat multiyear litigation expense as a recurring cost of enforcement. A small ISO cannot. The process may become the punishment, producing business failure, employee losses, reduced service competition, greater OEM dependence, and delayed patient-safety work before the exemption is ever meaningfully applied.

Whether a private enforcement theory has displaced the practical effect of a Library of Congress exemption or an FDA-regulated service pathway should not depend on the financial endurance of one individual ISO. An individual engineer or small service company should not be required to carry, alone, the cost of defining the boundary among copyright law, computer-access law, medical-device regulation, owner authorization, and patient-safety obligations.

That is a governmental policy question. The Copyright Office, Congress, and the agencies responsible for medical-device safety should have a formal mechanism to examine the issue before private litigation expenses eliminate the service provider whose conduct presents the question. Otherwise, the exemption and regulatory pathway may be circumvented in practice through cost and delay without ever being formally repealed.

The resulting market effect reaches beyond the named litigants. Hospitals may lose experienced service providers, employees may lose their jobs, used equipment may become more difficult to place back into service, and rural or resource-limited facilities may face longer downtime. The exemption's public benefit is reduced whenever fear of litigation prevents people from accepting otherwise lawful work.

XI. ADVERSE EFFECTS ON THE MEDICAL-DEVICE COMMUNITY

- ISOs and engineers decline lawful service work because access methods may trigger litigation.
- Owners lose meaningful control over service choices, remote access, and data generated by their own equipment.
- Hospitals and clinics face longer downtime, fewer service options, and increased cost.
- Engineers may be unable to perform installation, calibration, testing, and return-to-service work required for safe operation.
- Small service providers may be spent out of business before a court reaches the exemption question.
- The exemption becomes a theoretical defense rather than a practical authorization.

XII. REQUESTED SAFEGUARDS AND LIMITATIONS

The requested exemption should protect only owner-authorized, noninfringing activity undertaken for lawful diagnosis, installation, maintenance, repair, calibration, cybersecurity, testing, or return to service.

For clarity, an OEM-prescribed software reload, restoration, or reinstallation performed for a legitimate service purpose should remain within the exemption even when the procedure necessarily replaces or modifies system files. This proposed protection would not alter any otherwise applicable preservation obligation or resolve a separate evidentiary issue, which would remain subject to the governing law and the facts of the particular matter.

It should not protect:

- copyright infringement or distribution of copyrighted works;
- trade-secret theft or unauthorized disclosure;
- fraud, impersonation, or trafficking in access tools;
- destruction or concealment of evidence;
- falsification or concealment of service history;
- disabling safety controls or activating unlicensed clinical functionality; or
- use of unrelated higher-level materials beyond the lawful service purpose.

XIII. REQUEST FOR FORMAL REVIEW AND INVESTIGATIVE FOLLOW-UP

Mr. Shannon respectfully requests a formal stakeholder meeting, technical conference, roundtable, evidentiary hearing, or other proceeding addressing how access controls, combined service levels, remote monitoring, automatic data transmission, litigation threats, account restrictions, and overlapping CFAA and trade-secret claims affect the practical use of the medical-device exemption.

He further requests that the record be preserved for congressional and interagency review of whether additional statutory protections, fee-shifting, a safe harbor, an enforcement mechanism, or formal coordination are needed to prevent litigation cost and delay from nullifying the exemption.

XIV. AVAILABILITY FOR HEARING, TESTIMONY, AND CONTINUING ASSISTANCE

Mr. Shannon is willing, able, and available to assist in any formal manner the Copyright Office, the Library of Congress, Congress, a committee or subcommittee, or another authorized federal body considers useful. He will participate in virtual or in-person public hearings, roundtables, technical conferences, oral questioning, congressional inquiries, demonstrations, or other proceedings that the responsible body formally authorizes.

He is willing to travel to Washington, D.C., or another requested location if an in-person appearance is authorized, and he is equally willing to participate virtually. He is prepared to testify under oath when the governing procedure permits, answer questions, explain the service architecture in plain technical terms, distinguish access levels from actual use, and authenticate documents and events within his personal knowledge.

He can provide or help organize service manuals, screenshots, timelines, public docket records, PACER documents lawfully obtained, agency correspondence, certified-mail evidence, technical declarations, system-access examples, remote-monitoring information, installation and calibration records, and demonstrations of the service processes discussed in this submission, subject to applicable confidentiality restrictions and court orders.

Mr. Shannon also offers continuing assistance after any initial filing or hearing. He will answer follow-up questions, submit supplemental declarations when procedurally permitted, identify additional witnesses or technical sources, report material public-docket developments in relevant proceedings, and assist staff in understanding how the exemption operates in hospitals, clinics, imaging centers, and service organizations.

His purpose is not to dictate the outcome. It is to ensure that the responsible governmental bodies have access to a complete field-based record from someone who has installed, repaired, calibrated, relocated, and returned medical-imaging systems to service for nearly thirty years.

Mr. Shannon also intends to remain an active and responsible advocate for safe medical devices, protection of patient safety, and continued governmental attention to unresolved patient and device-safety concerns. His advocacy will continue through lawful reporting, technical education, participation in public proceedings, preservation of relevant records, and cooperation with regulators, legislators, investigators, device owners, hospitals, and service professionals.

He recognizes that reasonable people and institutions may disagree about the legal or technical conclusions to be drawn from particular events. His continuing role is to present the facts within his knowledge, explain the field consequences of restricted service access, and encourage solutions that place safe device operation and patient protection at the center of the federal policy discussion.

XV. CONCLUSION

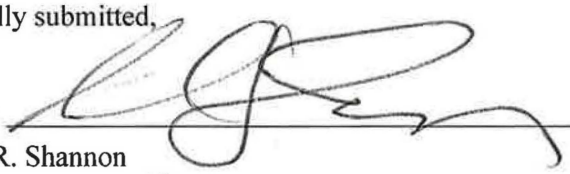
The medical-device exemption should protect real-world service, including OEM-prescribed software reloads and restorations used to address malfunctioning software or changes in access architecture, rather than exist merely as a paper defense available only after years of costly litigation. The Office should renew the existing exemption, clarify the covered service activities, address commingled access controls and owner-authorized remote-service changes, and preserve a complete record for congressional and interagency review.

Without practical protection against litigation-based elimination, the medical-device community may lose the independent providers the exemption was intended to protect, while device owners, hospitals, and patients bear the consequences.

Mr. Shannon respectfully asks that this submission, the supporting agency correspondence, the documented private-litigation examples, and the limited purpose of his declaratory-judgment action be considered together as evidence that a clear governmental pathway is needed. He remains available to help the Copyright Office, the Librarian, Congress, or another authorized body develop that record.

Regardless of the outcome of this particular petition, Mr. Shannon will remain available as an advocate and technical resource whenever medical-device access, service restrictions, device performance, or continuing patient-safety concerns warrant formal review.

Respectfully submitted,

Signature: 

Marshall R. Shannon

Date: 24 JULY 2026

EXHIBIT LIST

- Exhibit 1 — 2024 Register of Copyrights Recommendation and Final Rule.
- Exhibit 2 — Avante Health Solutions, Transtate Equipment Company, and Global Medical Imaging renewal petition.
- Exhibit 3 — MITA and AdvaMed challenge materials and judicial decisions.
- Exhibit 4 — Philips v. Shannon public filings, judgment, and material orders.
- Exhibit 5 — November 10, 2025 Carla M. Wirtschafter letter.
- Exhibit 6 — Jose Pons / Imaging Service Solutions February 6 and April 23, 2025 letters.
- Exhibit 7 — PACER docket and material filings in No. 1:26-cv-01497 (D. Md.).
- Exhibit 8 — Philips v. TEC Holdings materials.
- Exhibit 9 — FDA and DICE correspondence, including the January 14, 2025 FDA response.
- Exhibit 10 — FTC, HHS, DOJ, congressional, and other federal outreach and certified-mail records.
- Exhibit 11 — Philips R3.2.3 Service Pack 5 newsletter (DEP151282, Rev. 00); CSIP Level 0, Level 1, and Level 2 materials; IST smartcard, account, certificate, and entitlement materials; software installation manuals; and technical records showing the mapping among CSIP level, IST entitlement, and software service level.
- Exhibit 12 — Declarations and examples showing service, safety, downtime, and economic effects.

SELECTED SUPPORTING EXHIBITS

Prepared in Support of the Petition to Renew and Supporting Statement and Petition for a New or Modified Exemption

Marshall R. Shannon

Tenth Triennial Section 1201 Rulemaking (2027 Cycle)

Submitted July 2026

Introduction

This appendix contains the principal portions of the supporting materials cited or relied upon in the accompanying petition. Only the portions of each exhibit directly relevant to the petition are included in this appendix to facilitate efficient review. A substantially larger exhibit archive, including complete source documents and additional supporting materials, has been maintained by the Petitioner.

The Petitioner is prepared to provide the complete exhibit archive, additional supporting documentation, or any underlying source materials upon request by the Copyright Office or as otherwise permitted during subsequent stages of this rulemaking proceeding.

The Petitioner has made every effort to provide complete and accurate excerpts. Any omissions are intended solely to eliminate unnecessary duplication or unrelated material and should not be construed as altering the meaning or context of the original source documents.

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SELECTED SUPPORTING EVIDENCE

Appendix to Petition for Renewal and Supporting Statement
and Petition for a New or Modified Exemption
for Medical-Device Diagnosis, Installation, Maintenance, Repair, Calibration, and Return to Service

Tenth Triennial Section 1201 Rulemaking
2027 Cycle - Docket No. 2026-4

Marshall R. Shannon
Petitioner

Curated appendix of petitioner-specific evidence. Copyright Office materials already in the administrative record are cited in the Petition and are not reproduced here.

INTRODUCTION AND CHRONOLOGY

This appendix contains selected evidence unique to the Petitioner's experience, regulatory outreach, and the practical conflict described in the accompanying Petition. It does not reproduce the Copyright Office's own final rules, recommendations, or prior medical-device petition materials. Those authorities are referenced directly in the Petition.

Only relevant portions of longer documents are included. Excerpts are reproduced from the source documents without substantive alteration. The Petitioner maintains complete source documents and a substantially larger supporting archive and is prepared to provide additional materials upon request.

Chronology

Date	Event
2023-2025	Petitioner sought FDA/DICE clarification concerning installation, servicing, and access to manufacturer instructions.
January 14, 2025	FDA responded to Petitioner's letter to Commissioner Robert Califf and addressed former 21 C.F.R. §§ 820.170 and 820.
November 3, 2025	Regulatory and compliance requests, with FDA/DICE materials, were provided to Philips.
November 10, 2025	Philips counsel responded, relied on the prior judgment, rejected further engagement, and reserved rights.
2026	Petitioner submitted the present Section 1201 petition seeking a clear, usable exemption for lawful medical-device work.

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

PHILIPS NORTH AMERICA LLC
Plaintiff,

v. Case No.: 3:22-cv-00147-B

IMAGE TECHNOLOGY CONSULTING, LLC; MARSHALL R. SHANNON, IMAGE TECHNOLOGY CONSULTING II, LLC and AXIOM IMAGING SOLUTIONS, INC.,
Defendants.

NOTICE TO THE COURT OF FDA AND FCC INVESTIGATIONS AND IN SUPPORT OF THE AMICUS BRIEF

Quinn, co-founder of CAPS, respectfully asks this court to accept this notice to the court of FDA and FCC investigations and in support of the amicus brief to questions directly related to the Amicus Brief and in an effort to assist this court in granting the amicus brief.

NEW FDA CORRESPONDENCE FOR THIS COURT'S CONSIDERATION

Exhibit 1 is the January 14, 2025 correspondence between Mr. Marshall Shannon and FDA Deputy Commissioner for Regulatory Policy Ms. Angela Krueger.

To be very clear, I had no personal knowledge or involvement in Mr. Shannon's written correspondence with FDA Commissioner Robert Califf or Deputy Commissioner Krueger or any other persons.

Once again, the FDA has clarified 21CFR 820.170 and the fact that Mr. Shannon is an installer and a manufacturer, exactly as Philips is an installer and manufacturer equal to Mr. Shannon.

There can be no doubt that Philips is required and responsible, by virtual of FDA clearance for the 510k's for Philips devices, to comply with 21CFR 820.170 to assure all Philips devices meet performance standards when installed by installers (third parties as defined in the

DICE letters) to protect patients' safety.

Indeed, this court found, as did the First Circuit court in Puerto Rico, that Philips has a responsibility under 21CFR 820.170.

Ms. Krueger and other correspondence from the FDA regarding 820.170 is very clear and without ambiguity.

Yet Philips offers nothing more in response to 820.170 issues in this court than a personal slanderous attack on Quinn followed up with a contempt motion in Boston, a red herring for dubious evil reasons, over the amicus brief filing in this court on issues of 820.170.

The FDA and FCC make the final investigatory determination of any legal issues involving Philips FDA and FCC filings and, if any, fraud is involved in those filings.

The case is then referred to the courts for prosecution.

NEW FCC CORRESPONDENCE FOR THIS COURT'S CONSIDERATION

Exhibit 2 is a filing made on January 31, 2025 with the FCC IG by Quinn.

The FCCIG allows "FCC employees, contractors, grantees, and members of the public may submit a complaint allegations fraud, waste or abuse to the OIG."

In this filing Quinn is alleging fraud in the Philips North America and/or Philips Netherlands FCC filings 47CFR Part 18, 207 and 213 that requires operational, installation and maintenance instructions similar to 21CFR 820.170 and other sections of 21CFR, as Quinn understands in the FCC response email filed in this court.

CONCLUSION

Ms. Krueger paragraph makes it clear that the 820.170 subject is important to the FDA.

"As a general matter, the agency does not comment on ongoing litigation. We are, however, able to clarify two regulations relevant to your letter."

This subject, 820.170 and 820.200, was of such importance that the FDA commissioner responded through his Deputy on litigation matters, as has DICE in the letters submitted to this court, knowing these letters would be used in this court and other courts for all time.

In essence, an argument could be made that the FDA is allowing and expecting the courts to make a ruling on 21CFR 820.170 by answering the 820.170 and going beyond FDA policy.

This court has ruled Philips has a responsibility under 820.170 and this court has received every communication from the FDA in regards to 820.170 in violation of the FDA policy not to be involved in litigation.

I respectfully ask this court to rule on the amicus brief as the court's time permits and in the interest of patient safety as soon as time permits.

Date January 31, 2025

Thank you.

Thomas J. Quinn
Co-founder CAPS
PO Box 4420
Irvine, CA 92616
(724) 272 9953

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

PHILIPS NORTH AMERICA LLC
Plaintiff,

v. Case No.: 3:22-cv-00147-B

IMAGE TECHNOLOGY CONSULTING, LLC; MARSHALL R. SHANNON, IMAGE TECHNOLOGY CONSULTING II, LLC and AXIOM IMAGING SOLUTIONS, INC.,
Defendants.

Certificate of Service

I, the undersigned, certify that I have served or caused to serve, on the 31th day of January 2025. A copy of this the response to the Notice to the courts on FDA FCC matters, was served upon each of the following persons and parties in interest at their address shown below. In addition, the lawyers for Philips did not respond to my confer notice.

Ms. Carla M. Wirtschafter, Esq
ReedSmith LLP
1901 Avenue of the Stars, Suite 700
Los Angeles, CA 90067
Via email and regular mail

Via email, as directed, for each of the lawyers listed by Ms. Wirtschafter

Method of Service: regular mail to Ms. Wirtschafter and the Texas court and email to all other Philips attorneys, Defendants attorneys

Thomas J. Quinn Cofounder CAPS
724 272 9953

January 14, 2025

Marshall Shannon
[redacted]

Dear Mr. Shannon,

This letter is in response to your letter to Commissioner Robert Califf, MD, U.S. Food and Drug Administration (FDA), describing your concerns and the challenges you have faced as a manufacturer and installer of medical devices. As a general matter, the agency does not comment on ongoing litigation. We are, however, able to clarify two regulations relevant to your letter.

FDA regulation 21 CFR 820.170(a), relevant part shown below, is limited to instructions for the installation and inspection of a medical device. It requires these instructions be available to installers.

> Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device. Section 21 CFR 820.170(a).

FDA regulation 21 CFR 820.200(a), relevant part shown below, applies to the instructions and procedures for the servicing that the manufacturer has specified as a requirement..

> Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements.

Information about the best practices the FDA recommends with regards to servicing medical devices and labeling considerations is available in the May 10, 2024,

and FDA's May 9, 2024, statement "

".

Thank you for contacting the FDA. We also shared your letter with our Division of Regulatory Programs to review for any allegations of regulatory misconduct. The acknowledgement letter dated November 19, 2024, sent to you provides further information. We hope you find this reply informative.

Sincerely,

Angela C. Krueger -S

Digitally signed by Angela C. Krueger -S
Date: 2025.01.14 09:47:10 -05'00'

Angela Krueger
Deputy Director for Regulatory Policy
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

tom.joseph.quinn@gmail.com

From:	tom.joseph.quinn@gmail.com
Sent:	Friday, January 31, 2025 2:34 AM
To:	hotline@fcc.gov
Subject:	Philips NA and Philips NZ
Attachments:	FCC response 207 213.pdf; Philips NZ FCC filings.pdf; Philips NZ list to certificate.pdf; Philips NA FCC filings.jpeg

IG:

Enclosed is the recent correspondence with the FCC OTE, Mr. Ira Keltz acting Chief of OTE.

Additional enclosures are Philips North America (NA) grantee under code PDC filings and Philips Netherlands (NZ) Grantee name 2AQ4B and listing of information filed by Philips NZ under 2AQ4B.

A cursory review of Philips NA does not show any SDoC granted to Philips NA for RF devices used in MRI's.

A review of Philips NZ does show filings consistent with RF devices that may be used in MRI's.

From my understanding of Mr. Keltz email response of January 14, 2025 , "Mr. Quinn – 18.207 only refers to what a manufacturer would supply to the Commission as part of a report should such a report be requested by the Commission. As previously noted, 18.213 refers to what is required to be provided to users; unless exempted under 18.113. I hope that helps."

A reading of Philips NA and Philips NZ FCC filings it is unclear which company has filed for a SDoC as required by FCC 47CFR part 18, sections 207 and 213, for use in MRI's.

The exemptions, cited by Mr. Keltz, under 18.213 or the exemption in part 18.121 not cited by Mr. Keltz does not apply to the filings of an SDoC by Philips NA or Philips NZ.

One thing is clear, Philips NA and Philips NZ does not comply with the mandatory requirements of 207 and 213 to provide Users of MRI's with installation and maintenance instructions as is mandatorily required.

Therefore, a case could be made, if proven, that Philips NA or/and Philips NZ committed fraud in the filings used to be a grantee for an SDoC.

I respectfully request a complete investigation and referral to the appropriate authority of Philips NA and Philips NZ for violations of FCC laws and regulations for fraud in the filing of SDoC applications and the failure to comply with 207 and 213.

Thank you,

Thomas J.. Quinn
724 272 9953

76 Grantees Were Found That Match the Search Criteria:
Grantee Name:

Displaying records 71 through 76 of 76.

2AOGX	Philips Healthcare - Connected Sensing Venture	2 Canal Park 3rd Floor	N/A	CAMBRIDGE	Massachusetts	United States	02141	Paul Branche	12/01/2017
2APFC	Philips Consumer Lifestyle B.V.	Tussendiepen 4	N/A	Drachten	N/A	Netherlands	9206 AD	Robert Vermanen	04/07/2018
2AQ4B	Philips Medical Systems Nederland B.V.	Veenpluis 6	N/A	Best	N/A	Netherlands	5684 PC	Jeannette Becker	08/31/2018
2ATC9	Philips Health Systems	222 Jacobs St	N/A	Cambridge	Massachusetts	United States	02141	Mark Nolin	05/13/2019
2AWTR	Philips Goldway (Shenzhen) Industrial Inc.	No.2 Keji North 3rd Road, Nanshan District	N/A	Shenzhen	N/A	China	518057	Disment Yu	07/02/2020
2AW4T	PHILIPS Electronics Hong Kong Ltd	G/F, Building 5E, No. 5, Science Park East Avenue, Phase One, Hong Kong Science	N/A	Park, Pak ShekKok, New Territories, Hong Kong	N/A	China	N/A	Mr Jeff Chau	07/29/2020

Please use the Submit Inquiry link at to send any comments or suggestions for this site

Federal Communications Commission
45 L Street NE
Washington, DC 20554

Phone: ( ) -
TTY: ( ) -
Fax: -
E-mail: -

17 Matches found for FCC ID

Attestation Statements	Adobe Acrobat PDF	72927	Attestation Letter US agent	07/27/2023	No	No	07/27/2023
Attestation Statements	Adobe Acrobat PDF	107967	Attestation Letter Antenna Info	07/27/2023	No	No	07/27/2023
Attestation Statements	Adobe Acrobat PDF	128854	Attestation Letter covered equipment	07/27/2023	No	No	07/27/2023
Block Diagram	Adobe Acrobat PDF	74547	Block Diagram	07/27/2023	Yes	No	
External Photos	Adobe Acrobat PDF	782224	ext photos	07/27/2023	No	No	07/27/2023
ID Label/Location Info	Adobe Acrobat PDF		label and Location	07/27/2023	No	No	07/27/2023
Internal Photos	Adobe Acrobat PDF		int photos	07/27/2023	No	No	07/27/2023
Operational Description	Adobe Acrobat PDF	270231	operational description	07/27/2023	Yes	No	
Parts List/Tune Up Info	Adobe Acrobat PDF	455386	Parts List I	07/27/2023	Yes	No	
Parts List/Tune Up Info	Adobe Acrobat PDF	271003	Parts List II	07/27/2023	Yes	No	
Parts List/Tune Up Info	Adobe Acrobat PDF	233396	Parts List III	07/27/2023	Yes	No	
RF Exposure Info	Adobe Acrobat PDF	474793	RF Expsoure	07/27/2023	No	No	07/27/2023
Schematics	Adobe Acrobat PDF	98632	Schematics	07/27/2023	Yes	No	
Test Report	Adobe Acrobat	674413	Test Report	07/27/2023	No	No	07/27/2023

	PDF						
Test Setup Photos	Adobe Acrobat PDF	674413	test setup photos	07/27/2023	No	No	07/27/2023
Users Manual	Adobe Acrobat PDF	2480860	User Manual	07/27/2023	No	No	07/27/2023
Users Manual	Adobe Acrobat PDF	4147032	User Manual	07/27/2023	No	No	07/27/2023

Please use the Submit Inquiry link at to send any comments or suggestions for this site

Federal Communications Commission
45 L Street NE
Washington, DC 20554

Phone: ( ) -
TTY: ( ) -
Fax: -
E-mail: -

Technology

> > > Search

230 results were found that match the search criteria:
Grantee Code:

Displaying records 1 through 25 of 230.

View Form	Display Exhibits	Display Grant	Display Correspondence	Applicant Name	Address	City	State/Country	Zip Code	FCC ID	Application Purpose	Final Action Date	Lo Pr In
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQCM2601A	Change in Identification	07/13/2001	59
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQCM3813A	Change in Identification	08/01/2001	91
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQCM3815A	Change in Identification	08/06/2001	91
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQCM3816A	Change in Identification	08/06/2001	91
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQCM2600	Change in Identification	10/22/2001	46
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQCM1310A	Change in Identification	10/18/2001	40
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQCM2601B	Original Equipment	11/10/2004	60
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQCM2601A-95	Original Equipment	09/19/2002	60
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQC-4852	Original Equipment	03/17/2007	24
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQCM4842A	Original Equipment	11/04/2004	13
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQC-WMTS-MODULE	Class II Permissive Change	02/28/2006	13
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQC-MDL4851	Original Equipment	03/23/2007	24
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQC-WMTS-MODULE	Original Equipment	04/27/2005	13
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQCM2720A	Original Equipment	11/20/2002	
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQC-4851	Original Equipment	03/23/2007	24
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQCM4841A	Original Equipment	11/10/2004	13
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQCM3815A2	Original Equipment	10/17/2001	91
				Philips Medical Systems North America Co.	222 Jacobs Street	Cambridge	MA United States	02141	PQC-MX40WL3	Class II Permissive Change	12/24/2015	24
				Philips Medical Systems North	222 Jacobs	Cambridge	MA United	02141	PQC-5000W1	Original Equipment	12/16/2009	24

Appendix Page 15 of 47

Marshall R. Shannon - Selected Supporting Evidence

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Driving progress
through partnership

Carla M. Wirtschafter
Direct Phone: +1 310 734 5253
Email: cwirtschafter@reedsmith.com

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1901 Avenue of the Stars
Suite 700
Los Angeles, CA 90067-6078
+1 310 734 5200
Fax +1 310 734 5299
reedsmith.com

November 10, 2025

Via Email (benton.williams@bentonwilliamspllc.com; austin.champion@championllp.com)

Benton Williams
Benton Williams PLLC
100 Crescent Ct
Suite 700
Dallas, Texas 75201

Austin Champion
CHAMPION LLP
2200 Ross Avenue
Suite 4500W
Dallas, Texas 75201

Re: David Milligan November 3, 2025 Communications

Dear Benton and Austin:

We are directing this letter to you based on our understanding that you continue to represent Marshall Shannon, Image Technology Consulting, LLC, Image Technology Consulting II, LLC and Axiom Imaging Solutions, Inc. (collectively "Image Tech"). If you no longer represent Image Tech and are not aware of them being represented by other counsel in relation to these matters, please promptly advise us of that so we can direct this letter to Image Tech directly.

On November 3, 2025, David Milligan sent two emails via his imagetechnology.net email and cc'ed Mr. Shanonn, at his imagetechnology.net email address. One email chain contained the subject "Regulatory Request" and included an undated letter. The second email chain contained the subject "21CFR820-170 Compliance Request" and attached correspondence with DICE from 2023 and a January 14, 2025 letter to Mr. Shannon from Angela Krueger, Deputy Director for Regulatory Policy Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration.

As you are well aware, there is a judgment against Image Tech that was entered on March 21, 2025 in Case No. 3:22-cv-0147-B filed in the Northern District of Texas. As set forth in the judgment, Image Tech was found liable to Philips for fraud, violations of the Computer Fraud and Abuse Act, violations of the Digital Millenium Copyright Act and misappropriation of Philips' trade secrets in violation of the Defend Trade Secrets Act and the Texas Uniform Trade Secrets Act. Philips was awarded $6.05 million in damages (plus pre-judgment and post-judgment interest at the applicable rate). Image Tech and their employees (*i.e.* Mr. Milligan) were further enjoined from all of the following:

a. Accessing, using, or providing others with access to, Philips' Restricted

Proprietary Software and Information,[1] including without limitation the use of Unauthorized Access Methods,[2] including in connection with the sale, repair, service, refurbishment, modification, or installation of any Philips System,[3] part installation of any Philips System, changing, modifying, upgrading, or downgrading software; modifying software; or enabling options without authorization from Philips on Philips Systems.

b. Using or directing, causing or allowing anyone else to use:
   i. unauthorized IST Certificates and fake IST Certificates, including but not limited to the Donald Trump certificate, the Level 3 certificate used in at least April 2018 on Philips Systems in Puerto Rico and the 00000 certificate,
   ii. the computer inspected by Philips on February 8, 2023 and any other computers in Defendants' possession, custody or control that contain a fake or unauthorized IST certificate, modified registry files or other tools, scripts or files to obtain access to CSIP Level 1 and higher tools,
   iii. IST "certificate generator" software,
   iv. the "signature generator" software,

---

[1] "Restricted Proprietary Software and Information" means Philips' confidential or proprietary software and other technologies and information in or relating to a Philips System that has been restricted by Philips through contract, confidentiality markings, access controls, or technological means (including Philips' Integrated Security Tool ("IST")), including but not limited to (i) software and other information within a Philips System (including service tools and log files), (ii) Philips' standalone software (including standalone service tools distributed through Philips' Zeppelin platform or InCenter offline), and (iii) Philips' confidential or proprietary documents and information (including servicing documents distributed on InCenter online or InCenter offline), Restricted Proprietary Software and Information includes, without limitation, Philips Level 1, Level 2, and higher levels of Customer Service Intellectual Property ("CSIP").

[2] "Unauthorized Access Methods" means unauthorized access to, copying, distribution, or use of Restricted Proprietary Software and Information, including without limitation, by impersonating or using the login credentials of any Philips employee or former employee, using any IST certificate generated by anyone other than Philips (including IST certificates like the one on the computer in your possession, custody and control that was imaged by Philips on February 8, 2023, or generated by any software alleged to be built by Kalish or by any other "certificate generator" software), using any IST certificate intended by Philips for another person or to which a person has not been provided legitimate entitlements by Philips, decrypting Philips' encrypted files, using software programs to gain unauthorized access to Restricted Proprietary Software and Information, using keys or password from any key generator or other program other than keys or passwords provided directly by Philips, modifying files or information on Systems (including modifying registry files or keys) to gain access to Restricted Proprietary Software and Information, modification of clinical software, including clinical options, and possessing, selling, providing or using unauthorized copies of Philips operating software for Philips Systems.

[3] "Philips Systems" or "Systems" means all medical imaging devices and health care equipment manufactured by Philips, including but not limited to ultrasound, computer tomography (CT), diagnostic x-rays, Image Guided Therapy (IGT), magnetic resonance (MR), and advanced molecular Imaging (AMI) systems, including any and all related peripheral hardware and supporting technologies and anything that is manufactured or sold by Philips.

v. InCenter offline,
vi. all tools, programs, software, files, credentials or scripts located on the computer inspected by Philips on February 8, 2023 capable of providing access to Restricted Proprietary Software and Information, including all copies, backups or similar computers or drives,
vii. all copies of modified registry files capable of providing access to Restricted Proprietary Software and Information,
viii. and any conduct described in paragraph a, above, and any other substantially similar programs or files and any virtual machines, computers, or computer images containing the same.

c. Engaging in any other conduct that constitutes unauthorized access or use of Philips' proprietary, trade secret and copyright protected information.
d. Deleting, decrypting without authorization or modifying log files, including without limitation all service log files or entries, on Philips System. For avoidance of doubt, this does not limit the Defendants from performing legitimate servicing of Philips System which may cause the systems to create or modify log files or entries as part of their ordinary operation.
e. Turning off or disabling Philips remote monitoring unless the owner of the Philips System on which Philips remote monitoring is enabled has advised Philips, in writing, that it requests Philips disable remote monitoring.
f. The Court further finds that because the conduct described in this Paragraph 2 applies to computers used in or affecting interstate or foreign commerce or communication, the forgoing injunction applies to conduct involving a computer located outside the United States that is used in a manner that affects interstate or foreign commerce or communication of the United States.

Mr. Milligan's correspondence demands that Philips provide Image Tech with access to the very proprietary tools and trade secret information that Judge Boyle enjoined them from accessing and determined, when she granted Philips spoliation sanctions and summary judgment, that Image Tech had unlawfully accessed and misappropriated in violation of Philips' rights.

Disregarding these orders and the judgment, Mr. Milligan's correspondence continues to repeat the same misinterpretation of the law that Judge Boyle rejected over and over again. As you know, in her order granting Summary Judgment Judge Boyle stated:

> Defendants next argue that a regulation promulgated by the Federal Drug Administration ("FDA"), 21 C.F.R. § 820.170, serves as a defense. Doc. 245, Defs.' Br. Mot. Summ. J., 11–12. The Court has previously rejected this argument and held that "§ 820.170 does not grant Defendants access to

ReedSmith

> unauthorized information." Doc. 27, Mem. Op. & Order, 12. The Court will not revisit its prior Order and again concludes that § 820.170 does not serve as a defense to Philips' claim under the CFAA. Dkt. 334, p. 16.

Indeed, Mr. Milligan's "21CFR820-170 Compliance Request" attempts to resurrect the contentions about 3.2.3.5/ SP5 that were raised in the litigation and dismissed with prejudice, and he even attaches documents that were part of the litigation record. *See* Dkt. 348-2. Similarly, Mr. Milligan's "Regulatory Request" merely repeats these issues and again attempts to suggest that Image Tech is entitled to proprietary and trade secret information that is the subject of the injunction described above.

In addition, as Philips advised Mr. Milligan and Mr. Shannon in response to a similar letter they sent on July 26, 2023:

> 21 CFR 820.170 provides that manufacturers, such as Philips, that require installation of MR systems they sell make installation instructions available at the time an MR system is sold. When Philips sells an MR system, it either installs the system itself or, in limited circumstances, uses a Philips' authorized installer. When Philips authorizes a third party installer to install an MR system it has sold, Philips provides such instructions to its authorized installers. 21 CFR 820.170 does not apply to used and resold Philips MR systems because Philips may not know the condition of the device once it has been sold to a third party. Image Technology Consulting has never been a Philips' authorized installer of MR systems nor has it been authorized by Philips to install a new Philips MR system. Pursuant to 21 CFR 820.170, Philips has no obligation to provide installation instructions, which are Philips' proprietary information, to Image Technology.

Philips declines to continue to engage with Image Tech about issues that have been litigated to final judgment in favor of Philips and against Image Tech and refers Mr. Milligan and Mr. Shannon to the final judgment and Judge Boyle's orders throughout the litigation, including at Dkts. 328 and 334 in response to the emails and attachments sent on November 3, 2025.

Philips reserves all rights should Mr. Milligan, Mr. Shannon or anyone else continue to harass Philips with issues that have been litigated and found to have no merit.

Very truly yours,

Carla M. Wirtschafter
CMW:hv
Enclosures



From: dave imagetechnology.net <dave@imagetechnology.net>
Sent: Monday, November 3, 2025 12:46 PM
To: cdrhdeviceallegations@fda.hhs.gov; dsma@cdrh.fda.gov; cdrhenforcement@fda.hhs.gov; dice@fda.hhs.gov; abiy.desta@fda.hhs.com; Jakobs, Roy <Roy.Jakobs@philips.com>; steve.debaca@philips.com; Heiling, Maria <maria.heiling@philips.com>
Cc: marshall imagetechnology.net <marshall@imagetechnology.net>
Subject: Regulatory Request

You don't often get email from dave@imagetechnology.net. Learn why this is important

Caution: This e-mail originated from outside of Philips, be careful for phishing.

Thank you,

David Milligan
dave@imagetechnology.net

For part requests please use
parts@imagetechnology.net

Image Technology Consulting, LLC
P.O. Box 40
DeSoto, TX 75123

972-223-3008 Office
972-223-0586 Fax
214-263-0670 Cell

Best regards,

Industry Team
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This communication is intended for the exclusive use of the recipient(s) named in this correspondence. It may contain information that is protected, privileged, or confidential, and it should not be modified. It may not be disseminated, distributed, reproduced, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you have received this communication in error, please immediately delete all copies from the saved sources and notify DICE by email at:DICE@fda.hhs.gov immediately.

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

https://www.research.net/r/cdrhcustomerservice?O=800&D=870&B=872&E=&S=E

Original Message
From: tgeske@thetagammatech.com
Sent: 7/19/2023

Subject: Clarification on 820.170
Message:

To Whom It May Concern,

The last sentence of paragraph (a) 820.170 states:

"The manufacturer shall distribute the instructions and procedures with the device

or otherwise make them available to the person(s) installing the device."

Question:

Shall manufacturers who install devices distribute instructions and procedures with the device, regardless of who does the installation?

Best Regards,

Tommy

Sent from my iPhone 13 Pro Max

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. PHILIPS RS NORTH AMERICA LLC, RESPIRONICS CALIFORNIA LLC, and PHILIPS HOLDING USA INC., corporations, and ROY JAKOBS, STEVEN B. C DE BACA, THOMAS FALLON, DANIEL LEONARD, and JEFF DILULLO, individuals, Defendants.	No. *2:24-cv-505-RJC* CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Philips RS North America LLC, Respironics California LLC, and Philips Holding USA Inc., corporations, and Roy Jakobs, Steven B. C de Baca, Thomas Fallon, Daniel Leonard, and Jeff DiLullo, individuals (collectively, "Defendants"), and Defendants, without admitting the allegations in the Complaint, having appeared and having consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED AS FOLLOWS:

1. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332, and has personal jurisdiction over all parties. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c).

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 301-399i.

3. For purposes of this Decree, the following definitions shall apply:

manufacturing Devices (as defined in subparagraph 3.I. below) on or before December 31, 2022 and that they withdrew the establishment registration for that facility on or before January 31, 2023. If Defendants determine to resume manufacturing (as defined in subparagraph 3.P. below) at the Carlsbad Facility or transfer manufacturing operations from the Carlsbad Facility to another facility owned or operated by Defendants or an Affiliated Legal Entity, then they shall give notice to FDA and such facility shall become subject to all the provisions of this Decree applicable to the Covered Respironics Facilities. Defendants may not transfer any Device manufacturing operations at a Covered Respironics Facility to a facility owned by an Affiliated Legal Entity unless the owner of the transferee facility agrees to become a party to this Decree with regard to the transferred Device manufacturing operations and this Decree has been amended to reflect that agreement.

E. "Days" means calendar days, unless otherwise specified.

F. "Defendants' Devices" means all Devices manufactured at the Defendants' Facilities (as defined in subparagraph 3.H. below).

G. "Defendant Entities" means (i) Philips RS North America LLC ("Philips Respironics"), (ii) Respironics California LLC, and (iii) Philips Holding USA Inc.

H. "Defendants' Facilities" means (i) the Covered Respironics Facilities; (ii) the Other SRC Facilities (as defined in subparagraph 3.S. below); (iii) any facility where Rework (as defined in subparagraph 3.Y. below) operations on Defendants' Devices to effectuate Recalls RES 88058 and RES 88071 have taken or are taking place; and (iv) any facility added to this Decree pursuant to paragraph 22. However, this Decree does not apply to Devices manufactured at any Defendants' Facility to the extent that those Devices are subject to the 2017 Consent Decree (as defined in subparagraph 3.CC. below). A facility performing Rework operations as

described in clause (iii) of this subparagraph that is not owned or operated by the Defendant Entities is a Defendants' Facility for purposes of this Decree only with respect to its Rework operations on behalf of the Defendant Entities, and such a facility and the Devices manufactured therein other than the Rework Devices (as defined in subparagraph 3.Z. below) are otherwise not within the scope of this Decree.

I. "Device" shall have the meaning given to the term in 21 U.S.C. § 321(h)(1) and shall include service/repair kits that may be used to manufacture the Rework Devices.

J. "Discontinued Devices" shall include all Devices that were formerly manufactured at any of the Covered Respironics Facilities that are no longer being manufactured for United States distribution. Defendants shall submit a list of the Discontinued Devices to FDA within ten (10) days of entry of this Decree.

K. "FDA" means the United States Food and Drug Administration.

L. "Form FDA 483" means the list of inspectional observations provided by an FDA investigator at the close of an inspection.

M. "Good-Faith Attempt Process" shall have the meaning set forth in the Recall Remediation Plan.

N. "Individual Defendants" means (i) Roy Jakobs, (ii) Steven B. C de Baca, (iii) Thomas Fallon, (iv) Daniel Leonard, and (v) Jeff DiLullo.

O. "Long-Term Remediation Watch" shall have the meaning set forth in the Recall Remediation Plan.

P. "Manufacture" or "Manufacturing" or "Manufacturing operations" includes designing, manufacturing, fabricating, packing, assembling, processing, contract

months, in which case the export amount to implement the correction or removal shall not exceed the excess Recall Remediation Devices for that model in addition to the proportionate ex-U.S. market share. For purposes of this provision, "ex-U.S. market share" means the ex-U.S. percentage of total unit sales in the full year preceding June 1, 2021;

(iii) Are intended solely for the purpose of: (1) conducting any clinical investigations and testing in accordance with 21 C.F.R. Part 812; or (2) exporting Devices for use in clinical investigations performed outside of the United States provided that Defendants also satisfy all of the conditions in subparagraph 8.B.;

(iv) Are intended solely for the purpose of performing routine service or maintenance on, or are intended as a service replacement or service loaner for, Devices that are in the possession of customers and consignees of Defendants or other users, or are consumables, accessories, or replacement parts intended to support the use of Devices in the possession of customers or other users, as set forth at Appendix 4;

(v) Are intended solely for use in nonclinical research (including bench testing, market research, validation, human factors, and animal testing) or other non-human or nonclinical use, provided that Defendants label such Devices as "For [Research Use/Animal Use/Demonstration/Validation Testing] Only – Not for Human or Clinical Use" and they are used in a manner that does not involve use on human beings; or

(vi) Have been requested by Defendants in writing pursuant to this subparagraph, provided that: (1) Defendants submit to FDA the documentation and justification for such request that FDA deems necessary; and (2) the Defendants' request has been granted by FDA in writing. In no circumstance shall FDA's silence be construed as a substitute for written approval.

PHILIPS

MRI news

Service



Introduction of Release 3.2.3. Service Pack 5

November 2018

INTRODUCTION

This newsletter is intended to inform you on the changes made in R3.2.3 Service Pack 5

R3.2.3 SP5 will be made available for the Installed Base via FCO78100492.

For a high level overview of issues resolved in R323 SP5, refer to next chapter. For a complete overview of reported issues via field feedback that are resolved in this Service Pack, refer to the content of FCO78100492 available on InCenter.

This newsletter is especially intended to inform you on the changes made in this service pack related to CSIP.

A recording of the Webinar on introduction of R3.2.3 SP5 will be made available in the MR Download section on InCenter.

Document ID: DEP151282 rev 00

In this issue:

Introduction of R3.2.3 Service Pack 5

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