UNITED STATES COPYRIGHT OFFICE

Long Comment Regarding a Proposed Exemption Under 17 U.S.C. § 1201

ITEM A. COMMENTER INFORMATION

As the leading trade association representing the manufacturers of medical imaging equipment, contrast agents, radiopharmaceuticals, and focused ultrasound devices, the Medical Imaging & Technology Alliance (MITA) is writing in response to the eighth triennial rulemaking proceeding under the Digital Millennium Copyright Act. Commenter may be reached through the following individuals:

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ITEM B. PROPOSED CLASS ADDRESSED

Proposed Class 12: Computer Programs—Repair.

ITEM C. OVERVIEW

Petitioners Transtate Equipment Company and Summit Imaging, Inc., seek an exemption under 17 U.S.C. § 1201 to allow the circumvention of technological protective measures (TPMs) for purposes of diagnosis, modification, and repair of medical imaging devices. These petitions come within Proposed Class 12: Computer Programs—Repair. The below comments submitted by MITA address the proposed exemption regarding medical imaging devices, including magnetic resonance imaging (MRI) scanners, computed tomography (CT) scanners, and X-Ray machines.

ITEM D. TECHNOLOGICAL PROTECTION MEASURE(S) AND METHOD(S) OF CIRCUMVENTION

Medical imaging device manufacturers (OEMs) use a range of TPMs to protect copyrighted material from being accessed and copied without authorization from the copyright holder. These TPMs include passwords, encryption, access codes, physical access keys with embedded authorization codes, and digital signatures. The methods currently used to circumvent TPMs include copying or cloning physical access keys, "brute force" password cracking, improperly accessing passwords or access keys from authorized users, and the use of passcode-generating algorithms.

ITEM E. ASSERTED ADVERSE EFFECTS ON NONINFRINGING USES

I. The users of the copyrighted works are not adversely affected by the prohibition in their ability to make noninfringing uses of the copyrighted works

Under 17 U.S.C. § 1201(a)(1)(C), the Librarian of Congress and Register of Copyrights shall consider whether "persons who are users of a copyrighted work are, or are likely to be in the succeeding 3-year period, adversely affected by the prohibition under subparagraph (A) in their ability to make noninfringing uses under this title of a particular class of copyrighted works." In conducting such rulemaking, the Librarian shall examine—

(i) the availability for use of copyrighted works;
(ii) the availability for use of works for nonprofit archival, preservation, and educational purposes;
(iii) the impact that the prohibition on the circumvention of technological measures applied to copyrighted works has on criticism, comment, news reporting, teaching, scholarship, or research;
(iv) the effect of circumvention of technological measures on the market for or value of copyrighted works; and
(v) such other factors as the Librarian considers appropriate.

These criteria apply only with respect to "noninfringing uses." For the reasons discussed below, the intended uses are broadly infringing. Even assuming such uses were non-infringing, the petitioners fail to establish any of these elements, and several of these elements weigh strongly against the petitioners.

In applying these factors, the Register "balances '[t]he harm identified by a proponent of an exemption . . . with the harm that would result from an exemption.'" Section 1201 Rulemaking: Seventh Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Acting Register of Copyrights, October 2018, at 15. The rulemaking should consider the positive as well as the adverse effects of TPMs on the availability of copyrighted materials. *Id*.

As a threshold matter, MITA encourages the Register to construe the phrase "users of a copyrighted work" in its appropriate breadth. Medical service providers operate medical imaging equipment, but the ultimate "users" are the patients themselves undergoing the medical imaging

procedures. This consideration is appropriate because considering "adverse effects" solely with regard to the operator of a medical imaging device but without regard to the actual user of that device—the patient—would fail to take full and appropriate account of the adverse effects of granting the petition.

The petitioners fail to establish the first factor of adverse harm because the availability for use of the copyrighted works is not impacted by the TPMs. The medical imaging device software is broadly licensed and available to medical service providers. A TPM does not restrict medical service providers from using the medical imaging device software, it simply limits what aspects of the device software may be viewed and copied. If a hardware component needs maintenance or repair, an unregulated independent service operator (unregulated ISO) may have an interest in accessing that software to more readily determine how to repair the device hardware, but that interest extends beyond "the availability for use" of the copyrighted work. The copyrighted work itself remains usable even though a physical component of the medical imaging device needs maintenance or repair.

The petitioners cannot establish the second factor of adverse harm because the copyrighted works do not implicate nonprofit archival, preservation, and educational purposes. Similarly, with respect to the third factor, the proposed exemption would not impact criticism, comment, news reporting, teaching, scholarship or research. These factors highlight the degree of incompatibility between the statutory factors and the commercial nature of the interest of the petitioners in seeking this exemption.

Regarding the fourth statutory factor of adverse harm, an exemption would damage the market for or value of medical imaging device software and materials. Disabling of TPMs would expose intellectual property, including valuable know-how in addition to the copyrighted information, to competitors and the general public. That itself would severely harm OEMs by allowing competitors to view and replicate valuable innovations. Although patented innovations could be defended, replication of uncovered intellectual property protected by copyright would be extremely difficult to detect in copycat products. Such exposure would also chill future innovation because the innovations themselves would be unprotected. There is a massive cost to develop and secure premarket clearance from the U.S. Food and Drug Administration (FDA) for medical imaging devices. If innovators are not able to recoup those costs by protecting their valuable intellectual property embodied in software and related materials, the incentives for future innovations will be weakened.

The value of medical imaging device software and materials would also be harmed because the disabling of TPMs would lead to an increase in medical imaging device repairs by unregulated ISOs, thereby increasing patient risk and contributing to a loss of public confidence in the safety and reliability of medical imaging devices and the constituent software. As discussed in more depth below, unregulated ISOs are not subject to the FDA regulations that apply to OEMs, and they are not subject to the same training and quality control measures. Together, this disparate level of FDA regulation, training, and quality control will risk patient safety and public confidence in medical imaging procedures. A representative sample of faulty repairs appears in

Appendix 1. These negative impacts will extend to medical imaging devices and the market for the embedded device software and related materials that allow those devices to function.

The fact that there is no independent market for the medical imaging device software beyond the devices themselves undermines the basis for the requested exemption. In considering whether to grant a Section 1201 exemption for motor vehicles in 2015, the Register concluded that the lack of an independent market for the vehicle's software weighed in favor of granting the exemption. Section 1201 Rulemaking: Sixth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation to the Register of Copyrights, October 2015 (2015 Register Report) at 236. That reasoning does not extend to medical imaging devices because harm to patients and loss of public confidence in the safety and efficacy of medical imaging harms the market for the integrated software to the same extent as the market for the device itself.

The fifth statutory factor provides for consideration of "such other factors as the Librarian considers appropriate." MITA asks the Register to consider the patient safety aspects of unregulated ISO repair that this exemption would implicate. MITA also asks the Register to consider the regulatory implications to this proposed exemption. MITA recommends that the Register communicate with the FDA Center for Devices and Radiological Health on the relevant regulatory and policy issues governing medical devices, particularly medical imaging device software.

Improper repair or servicing of a medical imaging device presents a wide range of risks for patients and medical service providers. These risks would be exacerbated by granting the petitions and allowing unregulated ISOs and the general public to access medical device software and related materials protected by TPMs. There are numerous risks associated with improper servicing of medical imaging devices, depending on the imaging modality in question.

- **Electrical shock.** All medical imaging devices require electricity to function. If, after servicing, the device has not been properly rewired or has unvalidated parts installed, there is an increased risk of shock to patients and those operating the device.
- **Overexposure to ionizing radiation.** Some imaging devices, including X-Ray and CT scanners, emit ionizing radiation, resulting in potential over-exposure if not properly calibrated or maintained. Improper servicing can inadvertently bypass internal safeguards and severely harm or kill patients.
- **Mechanical failure.** If a medical imaging device suffers a mechanical failure due to improper servicing, significant and irreversible harm to the patient or user can occur, including pinching or crushing.
- **Air embolism.** In the case of injection devices (such as imaging contrast agent power injectors), if the device has undergone improper servicing, the patient could experience a potentially fatal air embolism.

- **Improper dosing.** For injection devices, if the device has undergone improper servicing, a patient could experience a potentially fatal underdose or overdose of medication.
- **Infection.** For ultrasound probes and other patient contact devices, if the device has not been properly sterilized or disinfected as specified by the OEM requirements and instructions, transfer of infection or disease between patients could result.
- **Burns.** Incorrect replacement materials or parts in an MRI system may disrupt the path of radiofrequency energy, causing excessive heating and potentially resulting in significant and irreversible patient burns.
- **Interference with other equipment.** If a device's electromagnetic interference shielding has undergone improper servicing, operation of the device could potentially interfere or degrade the proper operation of other equipment in the surrounding area.
- **Cybersecurity.** Whenever software is installed or adjusted for a medical imaging device, or if software tools are used to access a device for diagnostic and maintenance purposes, the integrity of the software may be compromised. Unvalidated software without confirmed authenticity or system integration may present significant potential security vulnerabilities and operational issues. Expanded and uncontrolled access to medical imaging device operating systems and software applications creates the potential for increased cybersecurity risks, as the opportunity to intentionally or unintentionally introduce security vulnerabilities to the device and to any networks to which the device is connected (e.g. hospital) also expands.
- **Delay in patient care.** Any failure in a device to perform when needed as a result of improper servicing, or to provide accurate results, may result in a delay of care, including incorrect diagnosis, resulting in delayed or incorrect treatment of a patient's condition.
- **Misdiagnosis.** Improper servicing could cause a medical imaging device to perform in a manner that does not produce diagnostic-quality images. This could lead to a missed diagnosis or a misdiagnosis.

OEMs have difficulty upgrading medical imaging devices if the service history is unknown, improper parts have been used, or if the device has otherwise been altered. The lack of required regulatory reporting by unregulated ISOs can impair the tracking of significant events for the device and can complicate root cause investigations of device malfunctions. Unauthorized repair can also void electrical safety certifications.

Because of these patient risks, the FDA requires OEMs to comply with a range of regulatory requirements. ***These requirements do not, however, extend to unregulated ISOs***. The regulatory requirements that apply to OEMs include the following.

- Establishment Registration (21 CFR Part 807)

- Manufacturers (both domestic and foreign), remanufacturers, and initial distributors (importers) of medical imaging devices must register their establishments with the FDA.

- Medical Device Listing (21 CFR Part 807)
  - Manufacturers must list their devices with the FDA. Establishments required to list their devices include: manufacturers; contract manufacturers that commercially distribute the device; contract sterilizers that commercially distribute the device; repackagers and relabelers; specification developers; reprocessors of single-use devices; remanufacturers; manufacturers of accessories and components sold directly to the end user; and U.S. manufacturers of "export only" devices.

- Premarket Notification (21 CFR Part 807 Subpart E) or Premarket Approval (21 CFR Part 814)
  - Devices requiring the submission of a Premarket Notification 510(k) cannot be commercially distributed until the manufacturer receives a letter of substantial equivalence from FDA authorizing it to do so. A 510(k) must demonstrate that the device is substantially equivalent to one legally in commercial distribution in the United States: (1) before May 28, 1976; or (2) to a device that has been determined by FDA to be substantially equivalent.
  - Devices requiring Premarket Approval (PMA) are high risk devices that pose a significant risk of illness or injury, or devices found not substantially equivalent to Class I and II predicate through the 510(k) process.
  - Modifications to devices that impact the safety or performance specifications of the device require the manufacturer to file a 510(k) or PMA.
  - Servicing activities that significantly change the safety or performance of the device cross over into remanufacturing require submission of a 510(k) or PMA. As noted in the FDA May 2018 report (https://www.fda.gov/media/113431/download) on device servicing, many instances of improper servicing appear to cross the line into remanufacturing.

- Quality System Regulation (21 CFR Part 820)
  - Includes requirements related to designing, purchasing, manufacturing, packaging, labeling, storing, installing and servicing of medical imaging devices.
  - Manufacturing facilities undergo periodic FDA inspections to assure compliance with the quality system requirements.
  - Manufacturers develop training curricula for employees to then implement and maintain training records subject to internal audits by qualified auditors.

- The entire quality system is audited periodically, and the results are reviewed by the Management Review process in a predetermined interval.

- Labeling (21 CFR Part 801)
    - Labeling includes labels on the device as well as descriptive and informational literature that accompanies the device.

- Medical Device Reporting (21 CFR Part 803)
    - Incidents in which a device malfunction has caused or may have caused or contributed to a death or serious injury must to be reported to FDA under the Medical Device Reporting program. The MDR regulation is a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical imaging devices. The goals of the regulation are to detect and correct problems in a timely manner.

The application of these requirements to OEMs but not to unregulated ISOs leads to greater regulatory control, oversight, and accountability for OEMs as compared to unregulated ISOs. This in turn leads to a higher degree of quality in the repair and maintenance activity and a corresponding risk to patients and the public in the use of unregulated ISOs.

II. The intended uses broadly infringe the copyrights of OEMs

To obtain the requested exemption, the petitioners must demonstrate that users of a copyrighted work are adversely affected by the prohibition on circumvention in their ability to make *noninfringing* uses of a class of copyrighted works or are likely to be so adversely affected in the next three years. The intended uses that the granting of this petition would allow would nearly uniformly infringe. The petitioners have a high burden of proof to establish noninfringing uses:

> The Register will look to the Copyright Act and relevant judicial precedents when analyzing whether a proposed use is likely to be noninfringing. The statutory language requires that the use is or is likely to be noninfringing, not merely that the use might plausibly be considered noninfringing. As the Register has indicated previously, there is no "rule of doubt" favoring an exemption when it is unclear that a particular use is a fair or otherwise noninfringing use. Thus, [the record] must show more than that a particular use could be noninfringing. Rather, the [record] must establish that the proposed use is *likely to qualify* as noninfringing under relevant law.

Section 1201 Rulemaking: Seventh Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Acting Register of Copyrights, October 2018 (2018 Register Report), at 15 (emphasis added).

The petitioners argue that the fair use doctrine, codified at 17 U.S.C. § 107, would allow unauthorized ISOs to access and copy the full range of medical imaging device software and materials currently protected by TPMs. For the reasons described below, fair use will almost never permit such copying and use.

As a threshold matter, however, a fair use determination is a richly fact-specific inquiry and is therefore fundamentally incompatible with a categorical application. The plain text of the statute requires its application in a "particular case." 17 U.S.C. § 107. In litigation, fair use claims can prevail or fall based on slender contextual nuances. The factors that courts apply in individual cases before them do not lend themselves to categorical application, especially considering the complexity and varied applications of medical imaging devices. "[F]air use analysis must always be tailored to the individual case. The nature of the interest at stake is highly relevant to whether a given use is fair." *Harper & Row v. Nation Enterprises, Inc.*, 471 U.S. 539, 553 (1985) (internal citations omitted). The U.S. Copyright Office itself has recognized that "fair use is a fact-intensive inquiry, and [] the outcome of a particular lawsuit does not guarantee a similar outcome in cases involving other types of products." United States Copyright Office, Software-Enabled Consumer Products, A Report of the Register of Copyrights (December 2016) (2016 Software Report) at 39 (available at https://www.copyright.gov/policy/software/software-full-report.pdf).

It would therefore not be appropriate to base the requested exemption on fair use grounds in these circumstances. Even if, however, it were appropriate to apply a fair use analysis to the access and copying of medical imaging device software and materials, nearly all cases would fail the test. The statute provides:

> Notwithstanding the provisions of sections 106 and 106A, the fair use of a copyrighted work, including such use by reproduction in copies or phonorecords or by any other means specified by that section, for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright. In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include—
>
> (1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
>
> (2) the nature of the copyrighted work;
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> (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
>
> (4) the effect of the use upon the potential market for or value of the copyrighted work.
>
> The fact that a work is unpublished shall not itself bar a finding of fair use if such finding is made upon consideration of all the above factors.

17 U.S.C. § 107. Critically, the fair use must be "for purposes such as criticism, comment, news reporting, teaching … scholarship, or research." That provision, standing alone, is fatal to the fair

use argument for these petitions. The petitioners are not political or social critics, news reporters, teachers, scholars, or researchers. They are for-profit companies seeking to use the copyright laws to promote their commercial interests.

Because the petitioners do not satisfy the purposes of the fair use exception, the remaining four statutory factors are inapposite. Nonetheless, even if those factors were to apply, they do not support a fair use determination. First, the "purpose and character of the use" is clearly of a commercial nature rather than for a nonprofit educational purpose. The purpose of disabling the TPMs and copying the information protected by the TPMs is to further the business interests of unregulated ISOs. The "character of the use" is inherently commercial. Petitioner Summit Imaging, for example, advertises on its website homepage: "Lowering healthcare facilities' total cost of ownership." https://www.mysummitimaging.com/. Transtate asserts that it is making it "more affordable for every hospital, clinic and medical practice to have the very best equipment, supplies and service." https://avantehs.com/.

In examining fair use arguments in this very context, the U.S. Copyright Office itself has recognized that "[r]epairs conducted by a company or a technician engaged in the business of repairing embedded software or software-enabled devices would likely be considered a commercial use." 2016 Software Report at 40.

In considering the "purpose and character of the use," courts in individual cases consider whether the use of the copyrighted work is transformative in some manner. There is nothing transformative about an unregulated ISO accessing and copying medical imaging device software and materials for a commercial purpose. No new intellectual property is created. For this reason, the Register's prior finding of fair use for "transformative" changes to motor vehicle computer programs does not extend to medical imaging devices. The 2015 recommendations for motor vehicle computer programs noted: "These uses include copying the work to create new applications and/or tools that can interoperate with ECU software and facilitate functionalities such as diagnosis, modification and repair. Such uses may also extend to modification of ECU computer programs to "interoperate" with different auto parts." 2015 Register Report at 234. Such tinkering would be dangerous with respect to medical imaging devices. Given the nature of medical imaging devices, the repair must *not* be transformative because it would remove the device from its FDA-approved function and performance and would risk patient safety. Crowd-sourced coding, while innovative and useful in some contexts, has no place in medical imaging device repair and maintenance.

The nature of the copyrighted work as a whole is also protected as a creative expression. Courts consider "whether the work is imaginative and original, or whether it represented a substantial investment of time and labor made in anticipation of a financial return." *Hustler Magazine, Inc. v. Moral Majority, Inc*., 796 F.2d 1148, 1154 (9th Cir. 1986). The petitioners take an unreasonably narrow view of "creative expression." Such a concept is not limited to musical or artistic works. It extends to the creativity inherent in animating and controlling devices that create medical images and other diagnostic information to support human life and health. Each developer of medical imaging device software approaches the challenges of aiding the diagnoses of patients in its own way, based on its unique set of institutional learnings, preferences,

inventiveness, and look-and-feel elements. Even if, for the sake of argument, the medical imaging device software and related materials fall closer to the informational-side of the spectrum rather than the expressive side, such software and materials reflect a substantial investment of time and labor in anticipation of a final return. *See Allen-Myland, Inc. v. IBM,* 746 F. Supp. 520, 534 (E.D. Pa. 1990) (reversed on other grounds) (finding that copying of computer code, including portions that were purely informational in nature, was not fair use because the code overall was the product of the substantial creative effort of the copyright holder in anticipation of financial returns).

The third factor—the amount and substantiality of the portion used in relation to the copyrighted work—also weighs against the petition because granting a TPM exemption would expose the full range of programs, manuals, computer code, logs, and other intellectual property to public view. Under this third factor, courts in individual cases consider both the quantity and quality of the copyrighted material used. If the use includes a large portion of the copyrighted work, fair use is less likely to be found; if the use employs only a small amount of copyrighted material, fair use is more likely when the other factors also support fair use. Here, allowing unauthorized third parties to bypass TPMs would expose medical imaging device software and the related materials to public view.

The fourth fair use factor considers the impact of the use upon the potential market for or value of the copyrighted work. This captures "not only the extent of market harm caused by the particular actions of the alleged infringer, but also 'whether unrestricted and widespread conduct of the sort engaged in by the [user] . . . would result in a substantially adverse impact on the potential market.'" 2018 Register Report at 198 (citing *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 590 (1994)). By disabling TPMs on medical imaging devices, the valuable intellectual property of medical imaging device innovators will be exposed to the general public and to competitors. Once certain intellectual property is exposed to the market and to competitors, the value that intellectual property will be compromised.

Moreover, given the breadth of the requested exemption, there could also be confidential patient information within the materials accessed by the unregulated ISO. The legal and reputational risk that the disclosure of such information could produce would harm the market for medical imaging devices and erode public trust and confidence in medical imaging procedures.

Although there is no separate market for the medical imaging device software beyond the medical imaging devices containing that software, disabling of TPMs would damage the market for the medical imaging devices *and* the software contained therein. That is because, as the petitioners themselves recognize, the hardware and software are an integrated whole. One cannot function without the other. If the petition is granted, repair and maintenance by regulated ISOs would likely increase. That would risk patient safety and undermine public confidence in the safety and efficacy of medical imaging procedures. The resulting harm to the medical imaging device market would impact the embedded software in equal measure.

In manner and degree, this risk differs from the disabling of TPMs for motor vehicle operating software. The 2015 Register Report noted: "Vehicle owners have long repaired and modified

their automobiles and farm equipment— adjusting brakes and enhancing suspensions, for example—including before the advent of computerized vehicle systems. It is thus not readily apparent these activities would cause unusual or undue harm." 2015 Register Report at 236. The long history of vehicular self-repair does not translate to medical imaging device self-repair, and the risks of faulty repair are far graver in the medical imaging device context. A faulty vehicle repair usually only risks the safety of the vehicle owner and any passengers (and, to a lesser degree, other motorists and pedestrians). By contrast, a faulty repair of an CT scanner or X-ray machine by an unregulated ISO poses far greater risk to the general public. A botched repair may expose hundreds or even thousands of patients to excessive levels of radiation. Other faulty repairs may instead compromise the visual or other informational outputs from the scan. That misinformation could contribute to missed diagnoses or incorrect diagnoses, leading to unnecessary medical procedures and even death.

III. An exemption is not warranted under 17 U.S.C. § 117(a)(1)

Section 117(a)(1) does not support an exemption allowing the circumvention of TPMs for medical imaging devices. Under 17 U.SC. § 117(a)(1), "it is not an infringement for the owner of a copy of a computer program to make or authorize the making of any other copy or adaptation that computer program provided: (1) that such a new copy or adaptation is created as an essential step in the utilization of the computer program in conjunction with a machine and that it is used in no other manner." A categorical exemption under this provision is not available because OEMs generally license the operating software and related materials to medical service providers rather than convey ownership of the software and materials. The licensing agreements also generally impose substantial restrictions on the allowed uses for such programs and materials.

The legislative history makes clear that Section 117(a)(1) is intended simply to allow the owner of a computer program to activate the computer program on a computer—and thereby cause a copy of the program to be made between the computer's hard drive and the computer's RAM—without triggering a copyright infringement. See Final Report on the National Commission on New Technological Uses of Copyrighted Works, National Commission on New Technological Uses of Copyrighted Works (1981) at 13 (available at https://repository.law.uic.edu/cgi/viewcontent.cgi?article=1573&context=jitpl).[1] Under this provision, it would not be an act of copyright infringement for the owner of a computer program contained within a medical imaging device to simply activate the medical imaging device, whereby the activation of the device causes copyrighted software to be copied within the device itself from the hard drive to the RAM.

[1] Congress established the National Commission on New Technological Uses of Copyright Works (CONTU) in 1974 to consider and make recommendations concerning, among other matters, the extent to which computer programs should be protected by copyright law. Because Congress adopted the recommendations of the majority of CONTU virtually unchanged, courts look to the CONTU final report as the legislative history of provisions recommended by CONTU. *Allen-Myland, Inc. v. IBM*, 746 F. Supp. 520, 532 n.8 (E.D. Pa. 1990).

Critically, this exemption extends only to owners of copies of the copyrighted material. In considering the application of Section 117(a)(1), courts scrutinize whether the entity copying the computer program is in fact the "owner" of the copyright program. In the Ninth Circuit, "a software user is a licensee rather than an owner of a copy [under Section 117(a)(1)] where the copyright owner (1) specified that the user is granted a license; (2) significantly restricts the user's ability to transfer the software; and (3) imposes notable use restrictions." *Vernor v. Autodesk, Inc.*, 621 F.3d 1102, 1111 (9th Cir. 2010); *see also MDY Indus., LLC v. Blizzard Entm't, Inc.*, 629 F.3d 928, 938 (9th Cir., 2010) (applying the *Vernor* factors to conclude that software users were licensees rather than owners because the copyright owner held title, provided a non-exclusive and limited license to the licensee, imposed transfer restrictions, and imposed a variety of use restrictions).

In *Krause v. Titleserv, Inc.,* 402 F.3d 119 (2d Cir. 2005), the Second Circuit, in determining whether a software user was a licensee or owner under Section 117(a)(1), considered: (1) whether substantial consideration was paid for the copy; (2) whether the copy was created for the sole benefit of the purchaser; (3) whether the copy was customized to serve the purchaser's use; (4) whether the copy was stored on property owned by the purchaser; (5) whether the creator reserved the right to repossess the copy; (6) whether the creator agreed that the purchaser had the right to possess and use the programs forever regardless of whether the relationship between the parties terminated; and (7) whether the purchaser was free to discard or destroy the copy anytime it wished. *Id*. at 124.

In *DSC Communications Corporation v. Pulse Communications,* 170 F.3d 1354 (Fed. Cir., 1999), the Federal Circuit scrutinized the legal relationship between a copyright holder and a licensee under Section 117(a)(1). The court concluded that ownership was not established—and therefore the defense to infringement under Section 117(a)(1) was unavailable—because of the restrictions on the software user's rights in the program, which included restrictions on disclosing or making the software available to any third parties and using the software on hardware other than that provided by the copyright holder. *Id*. at 1362. Because the license "substantially limit[ed] the rights" of the licensee, the court did not consider the licensee an "owner" for purposes of Section 117(a)(1). *Id*.

The U.S. Copyright Office itself has recognized the "ownership" requirement under Section 117(a):

> In section 117, the Copyright Act provides a number of limitations on exclusive rights for computer programs. Section 117(a) allows copies or adaptations of computer programs to be made either "as an essential step in the utilization of the computer program in conjunction with a machine" or for archival purposes. It also allows for the transfer of any copies prepared in accordance with the exceptions, though adaptations may only be transferred with the authorization of the copyright owner. Section 117(a), like the provision regarding first sale, may only be invoked by "the owner of a copy of a computer program." This raises complex questions

> regarding whether a consumer owns a copy of software installed on a device or machine for purposes of section 117(a) when formal title is lacking or a license purports to impose restrictions on the use of the computer program.

2016 Software Report at 19. The variability and fact-specific nature of this inquiry makes a general exemption to TPMs inappropriate. Although in some cases a court might find that the relevant factors support ownership under the copyright laws, in many other cases a court may find that the license is simply a license and therefore Section 117(a)(1) is unavailable.

Medical imaging device manufacturers generally license the operating software and other materials to medical providers rather than sell copies of the software and convey ownership of the copy. Certain diagnostic tools may be licensed together with or separately from the operating software, or not licensed at all. Medical imaging device manufacturers impose a range of significant use restrictions on that software and other materials. A blanket exemption pursuant to Section 117(a)(1) would therefore not be supported because the ownership requirement is generally not satisfied.

IV. An exemption is not warranted under 17 U.S.C. § 117(c)

The statutory defense to copyright infringement under Section 117(c) for "machine maintenance and repair" provides that it is not a copyright violation for the owner of a machine to make or authorize the making of a copy of a computer program: (1) if the copy is made "solely by virtue of the activation of a machine" that contains an authorized copy of the program; (2) if the copy is made "for purposes only of maintenance or repair of the machine;" (3) if the new copy is not used in any other manner and is destroyed immediately after the maintenance or repair is completed; and (4) with respect to any computer program or part of the program that is not "necessary for [the] machine to be activated," the program "is not accessed or used other than to make a new copy by virtue of the activation of the machine." 17 U.S.C. § 117(c).

This provision is principally aimed at protecting independent repair technicians from copyright liability when they turn on a machine that results in the automatic copying of software from the machine's hard drive onto the machine's RAM. 2016 Software Report at 37. By its plain terms, the statute authorizes making copies only upon "activation" of a machine, and therefore would not extend to any copying after initially turning on a machine.

The legislative history of this provision makes clear that the scope of protection is far narrower than the petitioners argue. The full relevant provisions of the Senate report are reproduced below, with key language emphasized.

> Title III of the bill amends section 117 of the Copyright Act (17 U.S.C. 117) to ensure that independent service organizations do not inadvertently become liable for copyright infringement ***merely because they have turned on a machine in order to service its hardware components***. When a computer is activated, that is when it is turned on, certain software or parts thereof (generally the machine's operating system software) is automatically copied into the machine's random access memory, or ''RAM.' During the

course of activating the computer, different parts of the operating system may reside in the RAM at different times because the operating system is sometimes larger than the capacity of the RAM. Because such copying has been held to constitute a ''reproduction'' under section 106 of the Copyright Act (17 U.S.C. 106), a person who activated the machine without the authorization of the copyright owner of that software could be liable for copyright infringement. ***This legislation has the narrow and specific intent of relieving independent service providers, persons unaffiliated with either the owner or lessee of the machine, from liability under the Copyright Act when, solely by virtue of activating the machine in which a computer program resides, they inadvertently cause an unauthorized copy of that program to be made***. ***This title is narrowly crafted to achieve the foregoing objective without prejudicing the rights of copyright owners of computer software***. Thus, for example, 1201(k) does not relieve from liability persons who make unauthorized adaptations, modifications, or other changes to the software. ***This title also does not relieve from liability persons who make any unauthorized copies of software other than those caused solely by activation of the machine***.

S. Rep. No. 105-190, at 21-22 (1998) (emphasis added).

This section effects a minor, yet important clarification in section 117 of the Copyright Act (17 U.S.C. 117) to ensure that the lawful owner or lessee of a computer machine may authorize an independent service provider—a person unaffiliated with either the owner or lessee of the machine—to activate the machine for the sole purpose of servicing its hardware components. When a computer is activated, certain software or parts thereof is automatically copied into the machine's random access memory, or ''RAM.''A clarification in the Copyright Act is necessary in light of judicial decisions holding that such copying is a ''reproduction'' under section 106 of the Copyright Act (17 U.S.C. 106), thereby calling into question the right of an independent service provider who is not the licensee of the computer program resident on the client's machine to even activate that machine for the purpose of servicing the hardware components. This section does not in any way alter the law with respect to the scope of the term ''reproduction'' as it is used in the Copyright Act. ***Rather, this section it is narrowly crafted to achieve the objectives just described—namely, ensuring that an independent service provider may turn on a client's computer machine in order to service its hardware components, provided that such service provider complies with the provisions of this section designed to protect the rights of copyright owners of computer software***.

S. Rep. No. 105-190, at 56-57 (1998) (emphasis added).

Subsection (c)—Machine maintenance or repair.—The bill creates a new subsection (c) in section 117 of the Copyright Act (17 U.S.C. 117), which delineates the specific circumstances under which a reproduction of a computer program would not constitute infringement of copyright. The goal is to maintain undiminished copyright protection afforded under the Copyright Act to authors of computer programs, while making it possible for third parties to perform servicing of the hardware. This new subsection states

that it is not an infringement of copyright for the owner or lessee of a machine to make or authorize the making of a copy of a computer program provided that the following conditions are met:

> First, subsection (c) itself makes clear that the copy of the computer program must have been made ***solely and automatically by virtue of turning on the machine*** in order to perform repairs or maintenance on the hardware components of the machine. Moreover, the copy of the computer program which is reproduced as a direct and sole consequence of activation must be an authorized copy that has lawfully been installed in the machine. Authorized copies of computer programs are only those copies that have been made available with the consent of the copyright owner. Also, the acts performed by the service provider must be authorized by the owner or lessee of the machine.
>
> Second, in accordance with paragraph (c)(1), the resulting copy may not be used by the person performing repairs or maintenance of the hardware components of the machine in any manner other than to effectuate the repair or maintenance of the machine. Once these tasks are completed, the copy of the program must be destroyed, which generally will happen automatically once the machine is turned off.
>
> Third, as is made clear in paragraph (c)(2), ***the amendment is not intended to diminish the rights of copyright owners of those computer programs, or parts thereof, that also may be loaded into RAM when the computer is turned on, but which did not need to be so loaded in order for the machine to be turned on***. A hardware manufacturer or software developer might, for example, provide diagnostic and utility programs that load into RAM along with or as part of the operating system, even though they market those programs as separate products—either as freestanding programs, or pursuant to separate licensing agreements. Indeed, ***a password or other technical access device is sometimes required for the owner of the machine to be able to gain access to such programs***. In other cases, it is not the hardware or software developer that has arranged for certain programs automatically to be reproduced when the machine is turned on; rather, the owner of the machine may have configured its computer to load certain applications programs into RAM as part of the boot-up process (such as a word processing program on a personal computer). ***This subsection is not intended to derogate from the rights of the copyright owners of such programs. In order to avoid inadvertent copyright infringement, these programs need to be covered by subsection (c), but only to the extent that they are automatically reproduced when the machine is turned on***. ***This subsection is not intended to legitimize unauthorized access to and use of such programs just because they happen to be resident in the machine itself and are reproduced with or as a part of the operating system when the machine is turned on. According to paragraph (c)(2), if such a program is accessed or used without the authorization of the***

copyright owner, the initial reproduction of the program shall not be deemed exempt from infringement by this subsection.

S. Rep. No. 105-190, at 57-58 (1998) (emphasis added).

The leading case that interprets the scope of Section 117(c) illustrates exactly why a categorical exemption to TPMs for medical imaging devices is not supported by the law and why its application would result in widespread copyright infringement. *Storage Tech Corp. v. Custom Hardware Engineering and Consulting*, 421 F.3d 307 (Fed. Cir., 2005) involved a company, StorageTek, that manufactures automated tape cartridge libraries that store large amounts of computer data. The tape backup and management system are controlled by a computer program. Upon computer startup, a "maintenance code" and "functional code" are automatically copied from the computer's hard drive to the computer's RAM, thereby allowing the computer to perform its programmed tasks.

Custom Hardware Engineering & Consulting, Inc. (CHE), is an independent business that repairs data tape libraries manufactured by StorageTek. In order to diagnose problems with the libraries, CHE intercepts and interprets error codes produced by the maintenance code. StorageTek protects those error codes through password protection to disallow unauthorized access to the error codes. CHE uses technologies to "crack" the password and to mimic functions of the system to generate error codes that can be intercepted.

StorageTek sued CHE, alleging that CHE committed copyright infringement when CHE rebooted and reconfigured the computer program to reveal and generate the error codes that CHE then used to repair the systems. StorageTek sought a preliminary injunction, which a federal district court granted. On appeal to the Federal Circuit, CHE defended against the copyright infringement claims by arguing that its actions are protected by 117(c) because the owners of the tape libraries authorize CHE to turn on the computer program to maintain and repair the tape libraries, and the duplication of the software into RAM is necessary for the machine to function. StorageTek responded that CHE's activities fail to satisfy 117(c) because the maintenance code is not "necessary for the machine to be activated."

The court considered whether the copying of the maintenance code—in addition to the functional code—into RAM at computer startup violated Section 117(c)'s requirement that "with respect to any computer program or part therof that is not necessary for the machine to be activated, such program or part thereof is not accessed or used." StorageTek argued that the copying of the maintenance file onto the computer system's RAM at startup was not necessary for the machine to be activated, and therefore the access and use of that program violated StorageTek's copyright and was not exempted by Section 117(c). The court disagreed, finding that "[i]n this case, however, both parties agree that the maintenance code is so entangled with the functional code that the entire code must be loaded onto RAM for the machine to function at all. That is, loading the maintenance code into RAM is necessary for [the machine] 'to be turned on.'" 421 F.3d at 1314. The court further held that an anti-circumvention claim under Section 1201 would be foreclosed because the underlying copying itself was not copyright infringement. *Id*. at 1318.

This holding does not, however, establish the general proposition that any file that is loaded from a computer system's hard drive to RAM during system startup is subject to access and copying by a third-party repair company. Quite the contrary, the court was careful to explain that its holding was grounded in the fact that the part of the system code necessary for the machine to turn on was entangled with other code that did more than simply allow the computer to turn on.

In that regard, the court noted that "separate, 'freestanding programs' that load into RAM upon startup *clearly may not be accessed* under section 117(c)(2)." *Id.* (emphasis added) Additionally, "[a]ccessing software programs, such as freestanding diagnosis and utility programs, that are not needed to boot up the computer and make that determination, *goes too far*…." *Id.* (emphasis added). The court also noted that "[i]n some instances, it may be difficult to determine whether particular software is necessary to make the computer function and to ascertain whether the computer is working properly." *Id.*

As this decision makes clear, an analysis of whether copies made by reason of turning on a computer are covered by Section 117(c) is a fact-based inquiry that turns on the specific nature of the program at issue and how the programs may interrelate or not with other programs that may also be activated at system startup. This decision also makes clear, however, that Section 117(c) does not authorize access to any program or part of a program that is not required to turn on the machine.

This fact-based and case-specific inquiry is fundamentally incompatible with the blanket exemption to TPMs that the petitioners seek. A blanket exemption to allow circumvention of TPMs would only be appropriate if Section 117(c) were uniformly available to unauthorized ISOs for the vast array and diversity of medical imaging devices that they seek to repair. As the *StorageTek* court made clear, the application of Section 1201 depends on whether the underlying copying itself is infringement. That fact-dependent inquiry would be vitiated by a categorical exemption under Section 1201.

V. Conclusion

In conclusion, the requested exemption is not warranted because users of the copyrighted works are not adversely affected by the TPMs and the legal arguments under fair use and Sections 117(a)(1) and 117(c) are without merit.

- **Users of the copyrighted works are not, under the factors of Section 1201, adversely affected by the prohibition on circumvention and are not likely to be adversely affected.** Medical imaging device software is widely available and broadly licensed to medical service providers. Medical imaging device software and the related materials protected by TPMs do not implicate nonprofit archival, preservation, and educational purposes because such software is used in a commercial setting among commercial parties. An exemption is not necessary for criticism, comment, news reporting, teaching, scholarship, or research because medical imaging device software is unrelated to those endeavors. An exemption would also negatively impact the market value for medical imaging device software because it would undermine the intellectual property protections that lead to innovation and would lead to greater use of unregulated ISOs that are not

required to implement the same quality, safety, and regulatory requirements as OEMs, thereby risking patient safety and contributing to a public loss of confidence in medical imaging devices. The risks to patient safety weigh against granting the exemption.

- **The proposed exemption would infringe the protected works and is not supported by the fair use doctrine.** The fair use doctrine generally allows transformational use of copyrighted works for purposes of criticism, comment, news reporting, teaching, scholarship, or research. The petitioners seek to access and copy medical imaging device software and related materials to better sell their repair services to customers. Applying the individual fair use factors also demonstrates why the exemption does not apply: the purpose and character of the use is purely commercial; medical imaging device software and related materials are protected works; the petitioners seek to access and copy the full range of medical imaging device software and materials protected by TPMs rather than a minor part; and the impact of the copying will negatively impact the market for medical imaging device software by disincentivizing innovation, risking patient safety, and undermining the public's confidence in medical imaging devices.

- **The proposed exemption is not supported by 17 U.S.C. § 117(a)(1).** Section 117(a)(1) provides simply that the owner of a computer program is not liable for a copyright violation if the owner turns on his or her computer and thereby causes a software copy to be made as certain programs are loaded from the computer hard drive to the computer's RAM to enable the computer to function. That provision does not support the proposed exemption because nearly all users of medical imaging device software license, rather than own, the software and related materials.

- **The proposed exemption is not supported by 17 U.S.C. § 117(c).** Section 117(c) protects third party repair technicians from copyright liability when they turn on a computer and thereby cause software to be automatically copied from the computer's hard drive to the computer's RAM. This provision does not apply to the proposed exemption because by its plain terms Section 117(c) does not extend beyond computer code that is automatically copied from a computer's hard drive to RAM during system startup. Moreover, the legislative history makes clear that this provision is not intended to undermine TPMs and allow copying of software beyond those aspects that are necessary to start a computer.

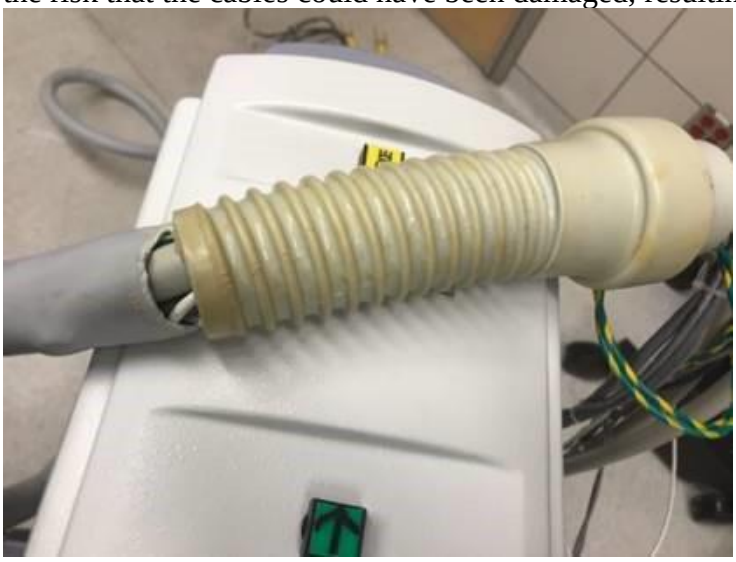
DOCUMENTARY EVIDENCE

Appendix 1: Examples of Improper Servicing by Unregulated Third Parties

Hole drilled into X-Ray system
A third-party servicer drilled out the holes on an X-Ray system in order to get a replacement X-Ray tube to fit, creating a patient safety issue if the tube had fallen out.

High voltage cables wrapped in hardware store vacuum hose

These high voltage cables for an X-Ray system had been wrapped in vacuum hose from a local hardware store. Use of this kind of unqualified part created infection control issues and increased the risk that the cables could have been damaged, resulting in fire or electrocution hazards.

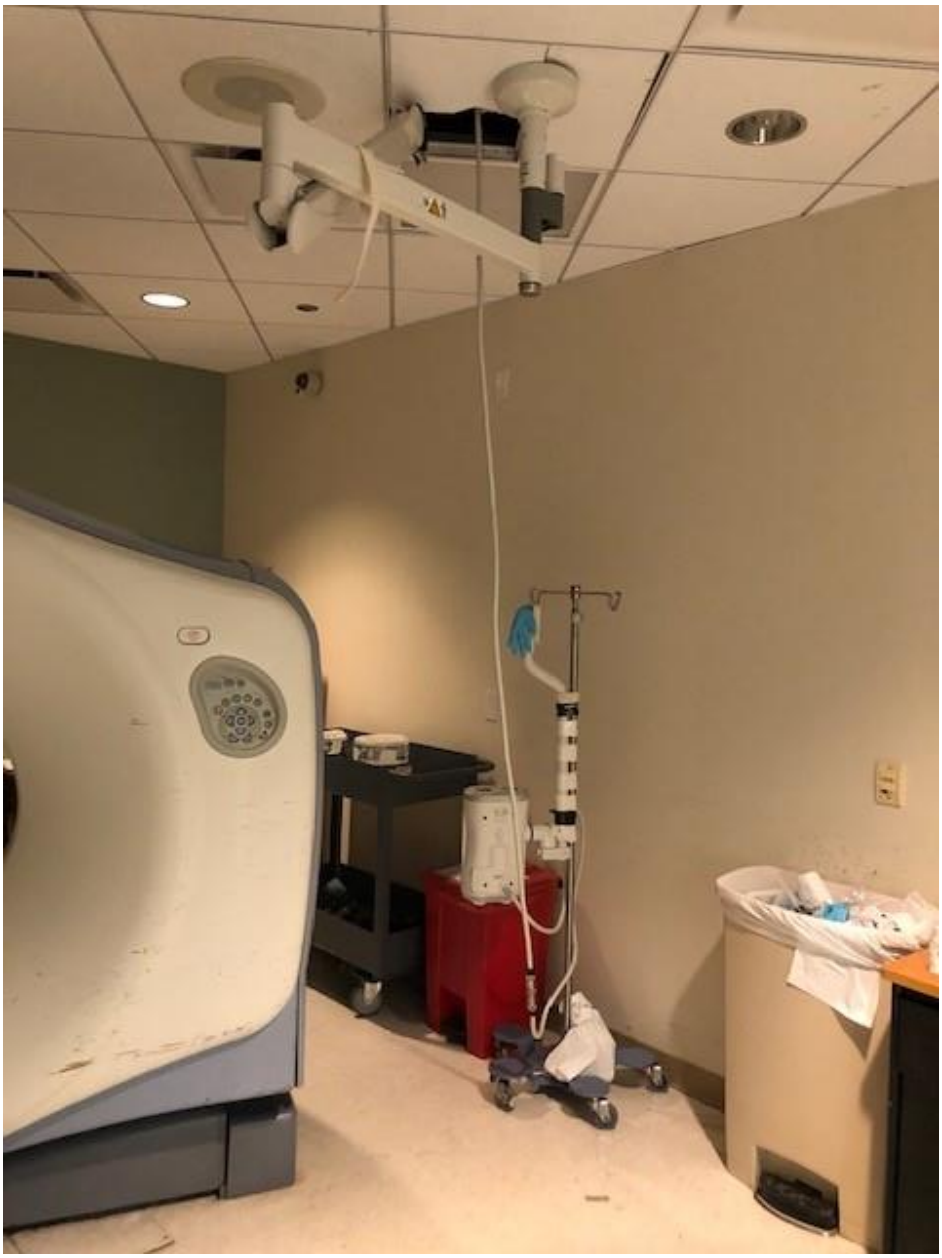


Improper venting of MR system

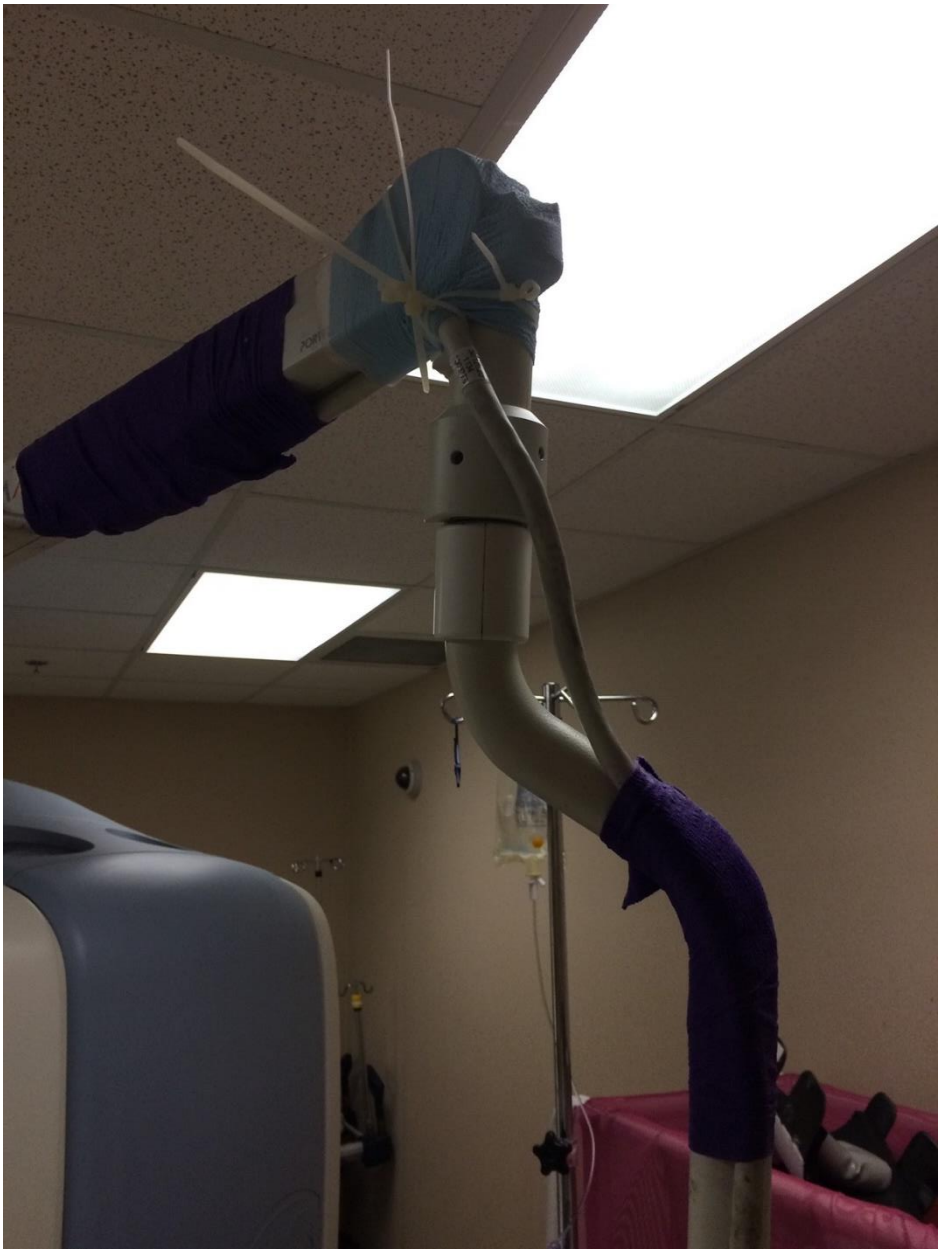
A third-party servicer installed an MRI ventilation system such that it ventilated into the attic above the imaging suite. If the MR magnet had quenched, liquid helium would have ventilated into the attic, creating an asphyxiation hazard and potentially resulting in structural damage to the building.

Power injector duct taped to IV pole

A third-party servicer removed a power injector from its usually support system and duct taped it to an IV pole. This jerry-rigged system could fall apart mid-procedure, delaying patient care or causing improper dosing.



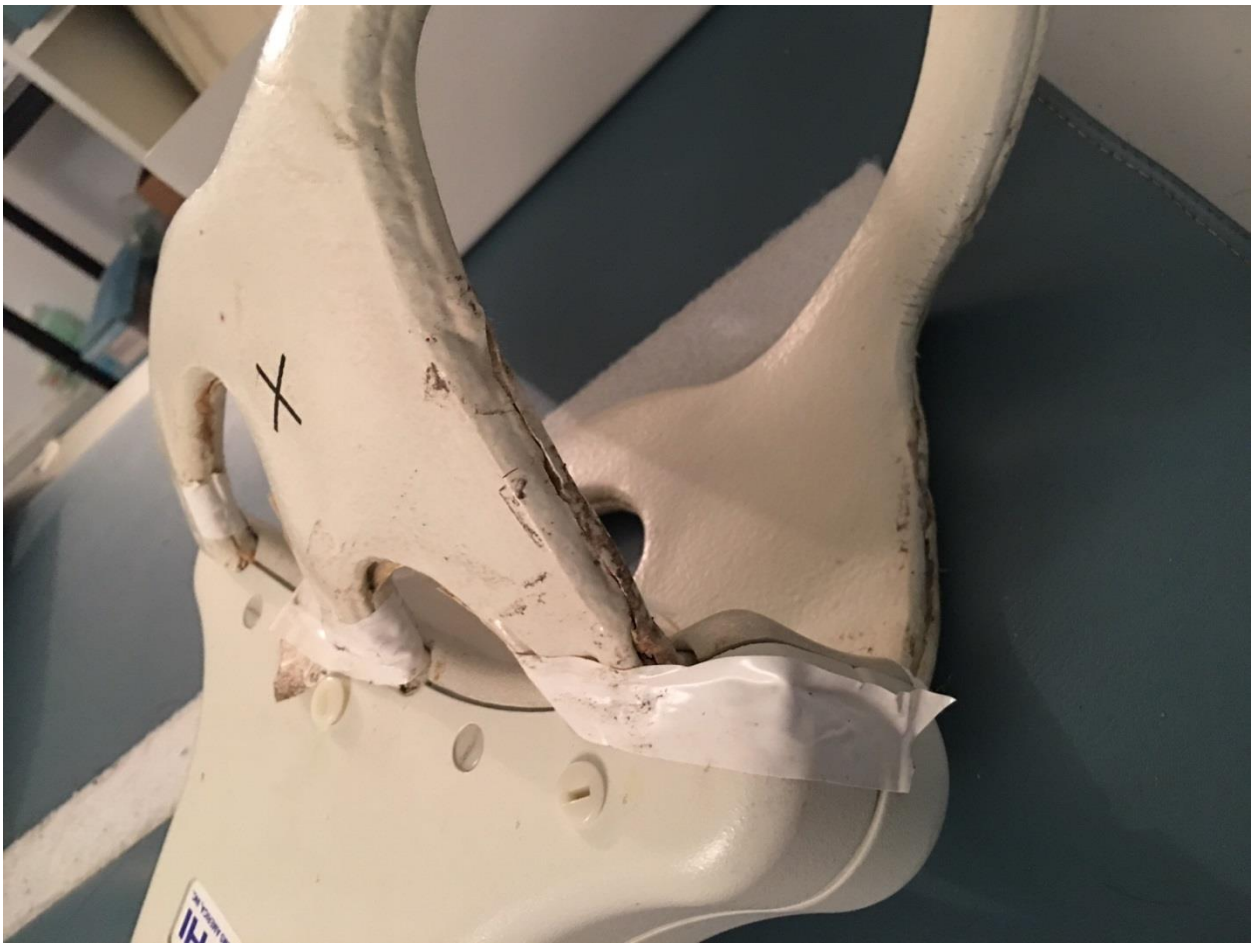
Overhead Counterpoise System held together with zip ties. This product suspends power injectors, often over patients while they are getting scanned. If these zip ties broke, the power injector could fall onto the patient, causing serious injury.



Aluminum Foil Used for Shielding

A third-party servicer used aluminum foil to shield some of an MRI system's cables in the scan room. This can present safety and electrical issues when used within the MRI filter panel that contains high voltage.

Shoulder Coil Serviced with Tape
This MRI shoulder coil was found damaged with several attempted repairs using a white tape. The use of tape would prevent proper cleaning of the coil and could have resulted in the coil failing to perform as specified.

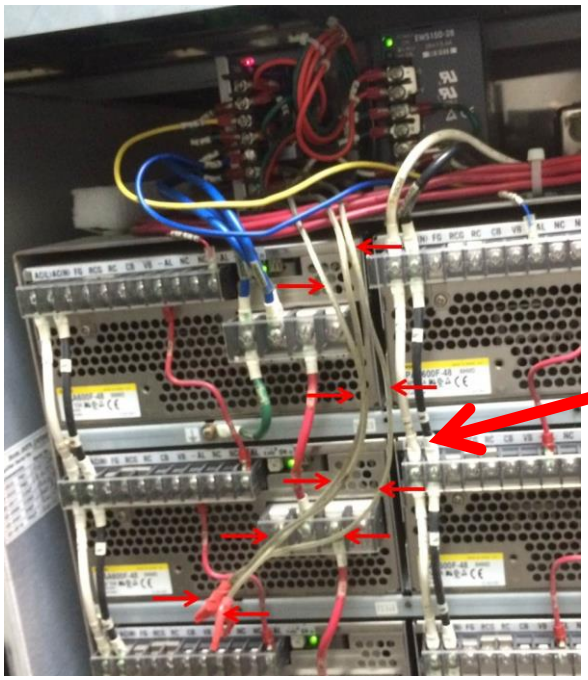


Improper Part in an Angiographic Power Injector System
A third-party service vendor inappropriately replaced an OEM steel pin with a simple wood screw to hold a syringe turret in place.

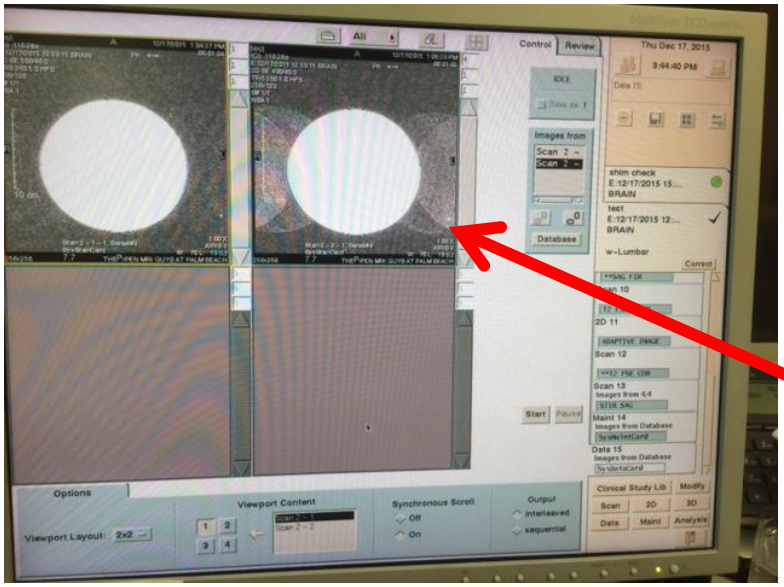
Angiographic power injectors can inject fluid at pressures of up to 1200 psi. If this wood screw were to fail during a procedure, the turret could break free, potentially causing the turret and connected syringe to act as dangerous projectiles. Additionally, this improper part could cause vibrations during the injection, thereby leading to issues such as delay of procedure and diagnosis due to unexpected equipment behavior.

Improper Servicing of an MRI System

This 0.3T permanent magnet MRI had ghosting on multiple images as a result of improper wiring. The healthcare provider had been experiencing machine downtime due to the inability to properly scan patients. Poor image quality could have resulted in misdiagnosis or need for repeat scans. Rewiring a device with non-qualified parts could have resulted in electrocution or fire.



Speaker wire connecting power supply to unknown points and terminated with wire nuts



Example of ghosting on medical images

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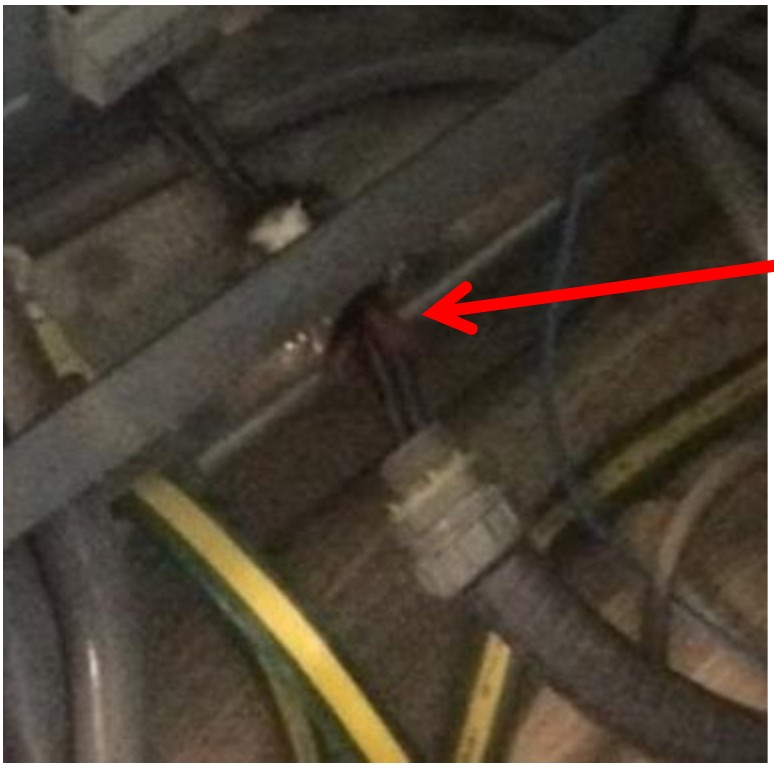
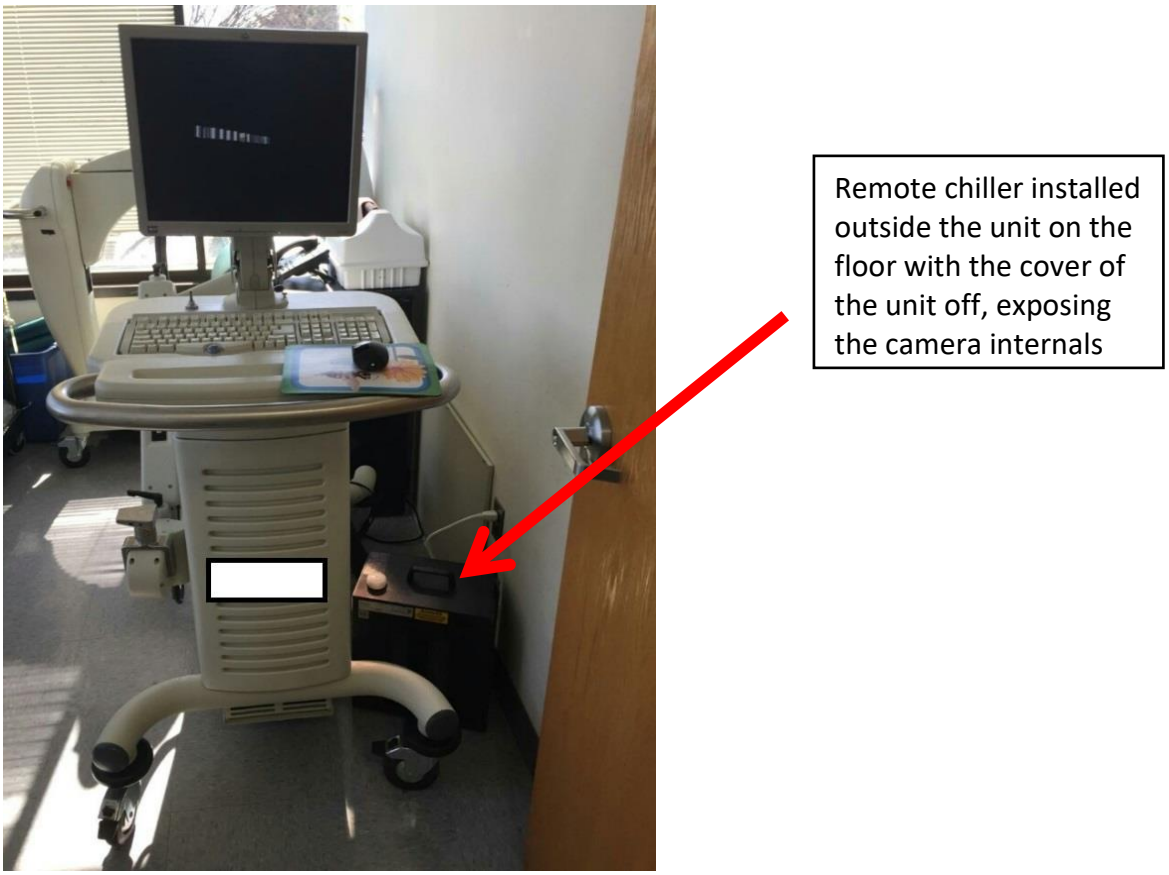


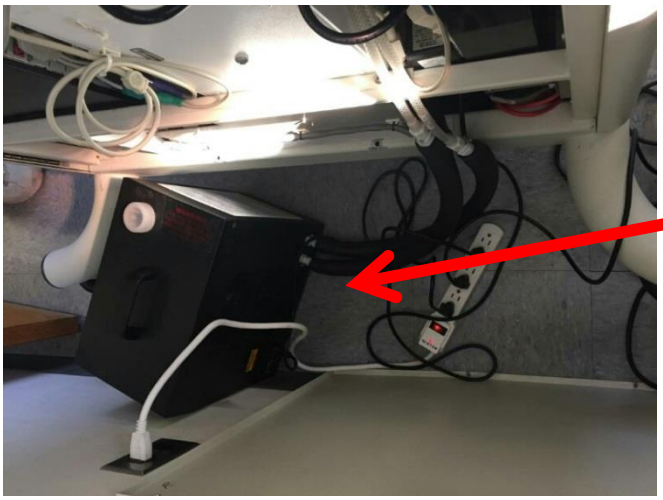
The primary power supply cables lacked strain relief and protection from abrasion

Improper Servicing of a Nuclear Medicine Camera
This nuclear medicine camera had numerous masked adjacent pixels in the detector which could obscure any heart defects in the image. Further, the cooling unit was improperly connected to external power, bypassing the system's isolated power and grounding system, potentially compromising patient safety and device performance.

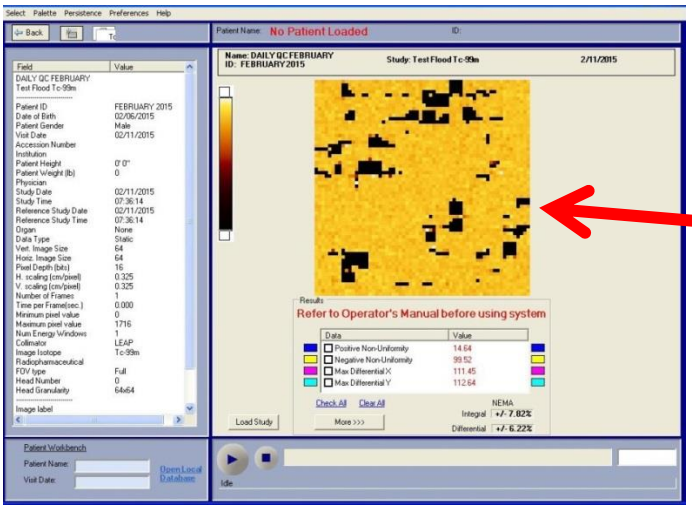
When adjacent pixels are removed, a portion of the imaging detector is lost, meaning parts of the heart might not be imaged and a defect could go undetected.

The improper power connection of the cooling system violated the manufacturer's power and grounding isolation scheme, creating risks of fire and electrocution

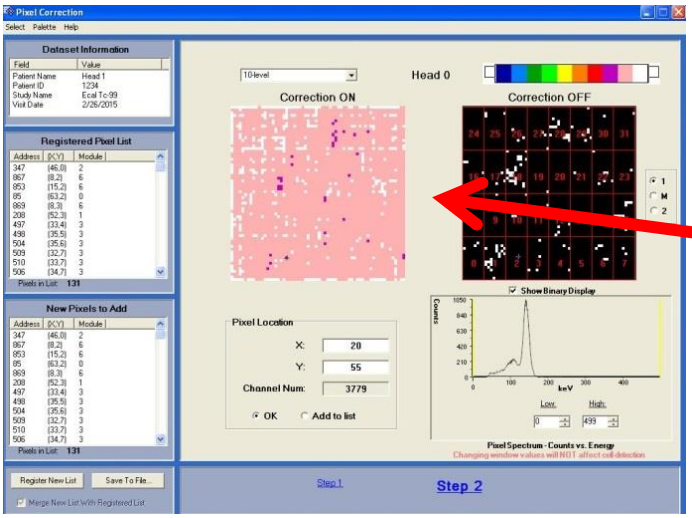




Remote chiller installed outside the unit on the floor with the cover of the unit off, exposing the camera internals



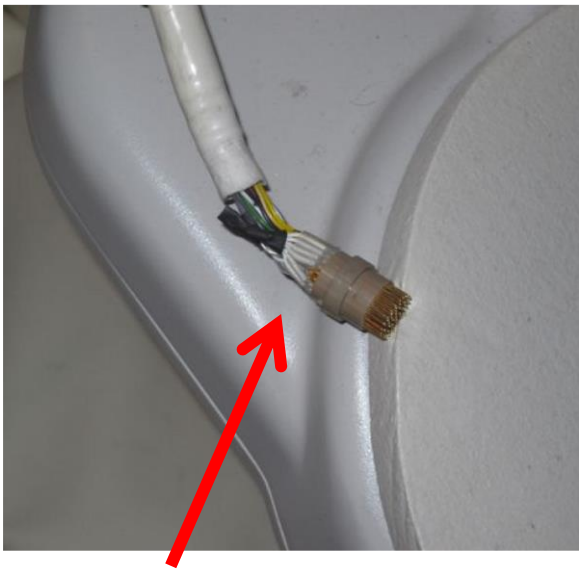
Masked pixels



Masked pixels

Improper Repair of an MRI Coil
In a 0.3T permanent magnet MRI RF coil, the signal cable had been pulled out of a connector housing and was repaired with zip ties and plastic tubing. This could have resulted in:
Misdiagnosis or need for additional scans due to lost signal or imaging artifacts
Electrical arcing, resulting in electrocution or burns

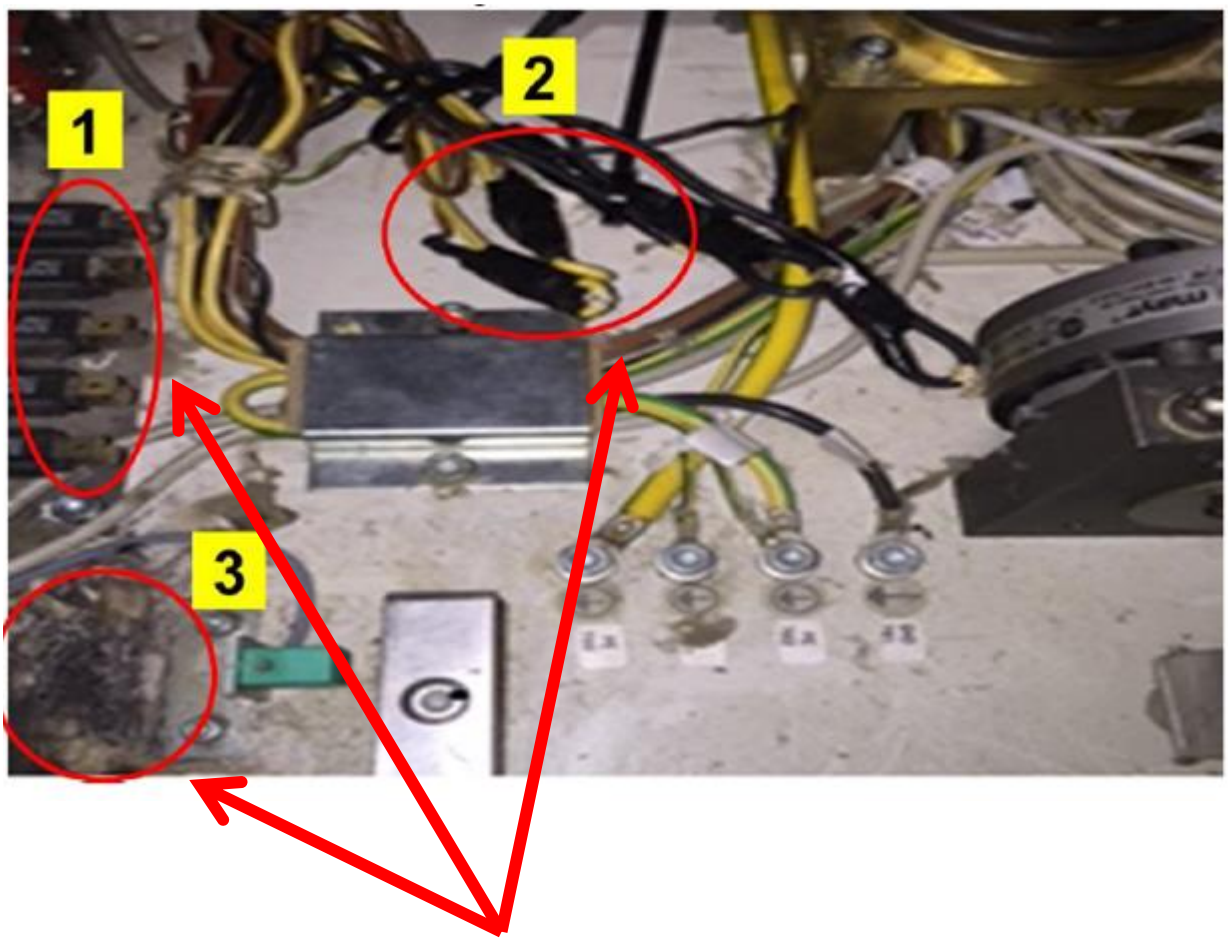
Coil with plastic tubing and zip ties used to cover damaged cable



Example of failed coil that was hidden using zip ties and plastic tubing

Improper Servicing of a CT Scanner

A facility reported to the OEM that it had been having issues with a CT table, workstation, and tube for approximately six months. An OEM service engineer identified table cabling connections that were modified to be non-standard, exposed wiring, non-OEM fuses installed, improperly exposed and non-OEM soldering connections, cable connections routed and repaired using electrical tape, bent table bolt, and defective transmit cable. Excessive oil was also found in the device, creating risk for fire or other kind of device failure.



1. The bank of black fuses is not connected to cables, per OEM design and manufacturing specifications
2. Cables have been field repaired with fuses taped to the cable
3. Grease identified in cabling area

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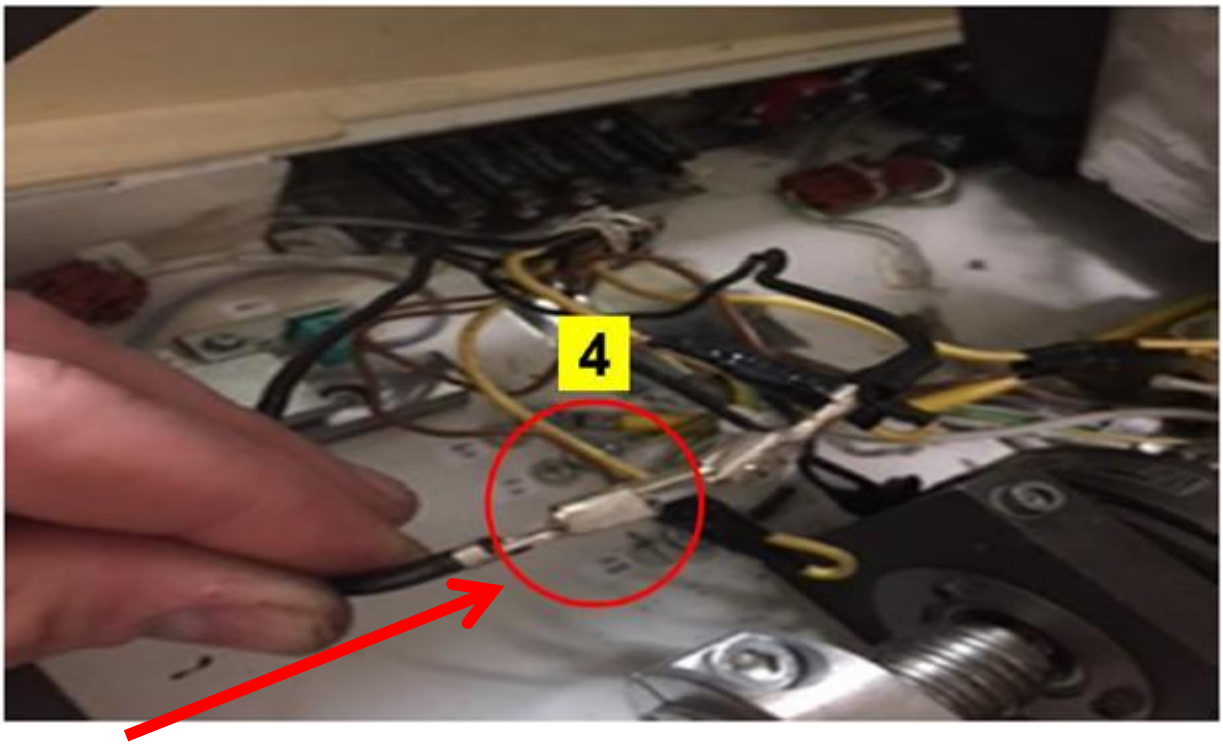
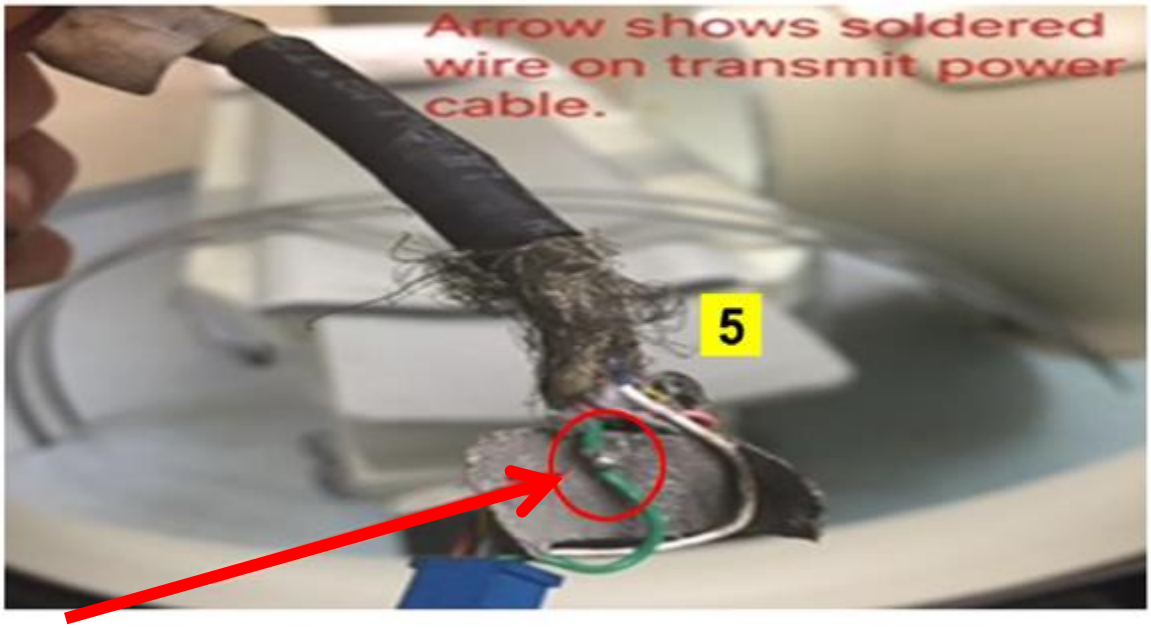


4. Non-qualified fuse, with field repair to reform connector to fit around non-qualified



5. Transmit wire connection repaired previously and taped and visible and exposed at joint of green wire

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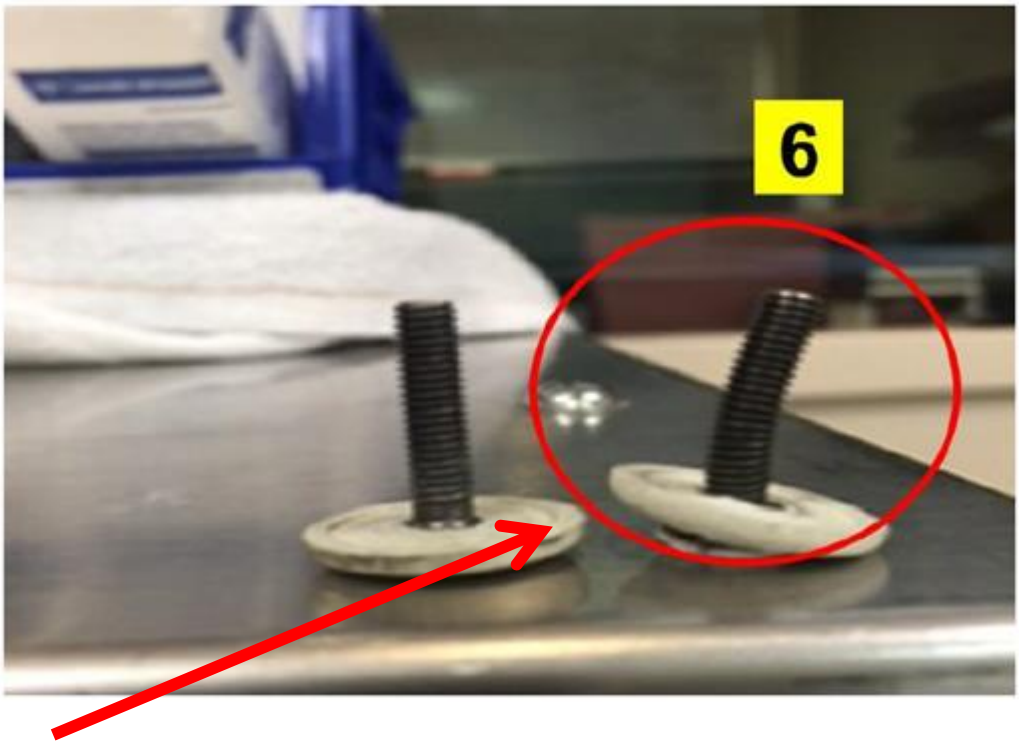
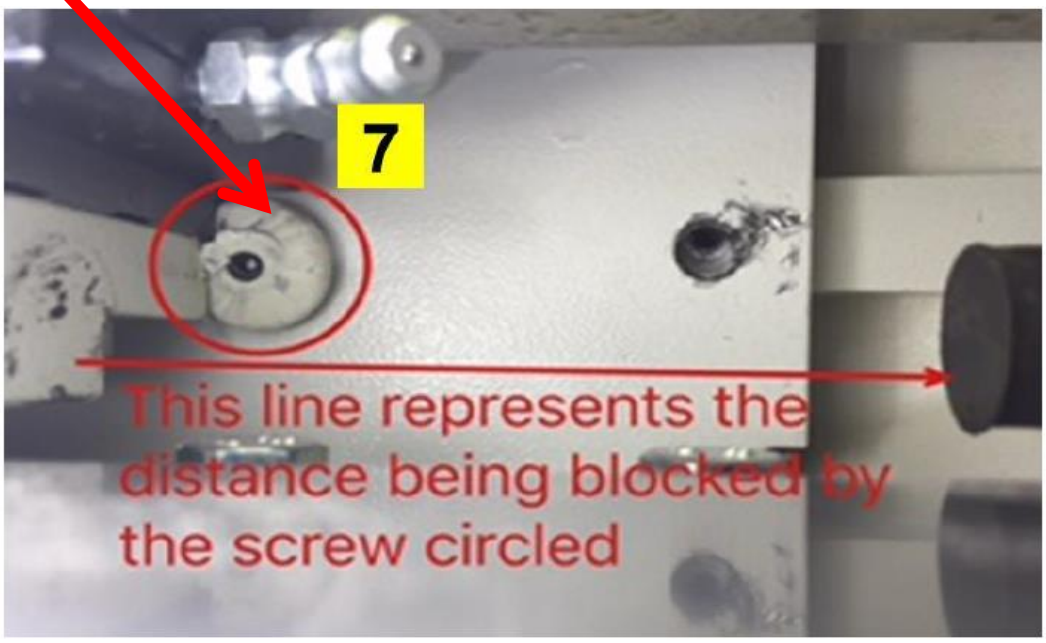


6. Bent screw found, preventing table from full range of horizontal motion

7. OEM service engineer identified horizontal travel distance blocked by bent screw



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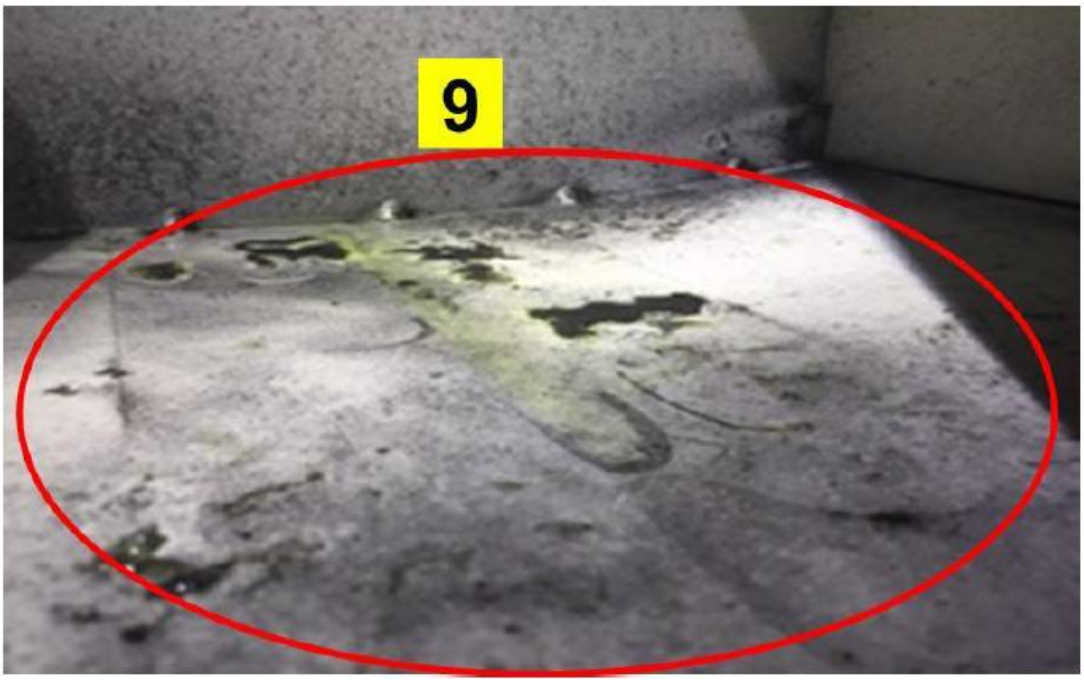
8. Excessive oil identified



9. Oil and debris identified in back corners of gantry