EXHIBIT 27

by Conor Hale | May 17, 2018 1:59pm

...ncy will work to promote quality management principles, strengthen cybersecurity practices, and foster quality assessments. (The Innovation Institute)

The FDA said it could not find reason to impose new regulations on the servicing of medical devices, whether performed by original equipment manufacturers (OEMs), hospital systems or third-party providers.

Instead, the agency found that many OEMs and third parties provided high-quality, safe and effective servicing, such as refurbishing and reselling more durable equipment including imaging machines, automated external defibrillators, endoscopes and ventilators.

"We believe the currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing of medical devices, including by third party servicers, that would justify imposing additional/different burdensome regulatory requirements at this time," the FDA said in its report.

Instead of pursuing formal regulatory action, the agency will work to promote quality management principles, strengthen cybersecurity practices, foster quality assessments and clarify the difference between servicing and remanufacturing—that is, making changes to a device's performance or specifications, instead of simply returning it to service.

The FDA also floated the idea of creating a public-private forum to address any challenges in the field.

Stakeholders, including manufacturers, have raised concerns about the quality of servicing and repairs, including the use of inferior replacement parts, inadequately trained personnel and poor documentation. Others have cited difficulty accessing servicing manuals, technical specifications and proper training.

"If there is sufficient interest and broad willingness to participate by all stakeholder groups, we would facilitate the creation of such a community," the FDA said.

The Medical Imaging and Technology Alliance **strongly supported** the FDA's decision to promote quality management principles but urged Congress to pass legislation that would require third-party services to register with the FDA and report adverse events.

"To ensure patient safety, the FDA needs to know who is servicing all medical devices so that if adverse events occur, the agency is alerted and can take appropriate action," said Patrick Hope, MITA's executive director.

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MedTech

Olympus to boost respiratory portfolio with $340M Veran buyout

by Conor Hale
Dec 7, 2020 7:52am

About the Author

Conor Hale

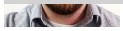

EXHIBIT 28

GUIDANCE DOCUMENT

Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems - Guidance for Industry and FDA Staff

SEPTEMBER 2003

Final

Docket Number:

FDA-2020-D-0957 (https://www.regulations.gov/docket?D=FDA-2020-D-0957)

Issued by:

(/regulatory-information/search-fda-guidance-documents/information-disclosure-manufacturers-assemblers-diagnostic-x-ray-systems-guidance-industry-and-fda)
Center for Devices and Radiological Health

Document issued on: September 5, 2003

PDF Printer Version
(42 KB) (/media/76019/download)

This document supersedes: "Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems" issued on April 2, 2001

For questions regarding this document contact Sean Boyd at 301-796-5895 or sean.boyd@fda.hhs.gov (mailto:sean.boyd@fda.hhs.gov)

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Diagnostic Devices Branch
Division of Enforcement B
Office of Compliance

Preface

Public Comment:

Written comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room

1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/RegulatoryInformation/Dockets/Comments/default.htm (http://www.fda.gov/RegulatoryInformation/Dockets/Comments/default.htm). Please identify your comments with the docket number listed in the notice of availability that publishes in the *Federal Register* announcing the availability of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov (mailto:CDRH-Guidance@fda.hhs.gov) to receive a copy of the guidance. Please use the document number (2619) to identify the guidance you are requesting.

Contains Nonbinding Recommendations

Guidance for Industry and FDA Staff

Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This document provides guidance to assemblers and manufacturers of diagnostic x-ray systems regarding the disclosure of specifications for assembly, installation, adjustment, and testing (AIAT). The guidance clarifies the scope and terms of the information disclosure provision and explains how affected parties should view cost and software issues. This revision further clarifies that manufacturers should provide, upon request, AIAT information for each certified component used for the controlled production of x-rays.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues (/media/109942/download)" document.

SUMMARY:

Manufacturers of diagnostic x-ray systems are subject to information disclosure obligations so that assemblers or other interested parties may obtain, upon request, information regarding the assembly, installation, adjustment, and testing (AIAT) of an x-ray system to ensure it meets federal performance standards. (21 Code of Federal Regulations sec. 1020.30(g) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1020.30)) The AIAT information should be provided at a cost not to exceed the cost of publication and distribution. The information helps to ensure compliance with performance standards that are intended to reduce unnecessary x-ray exposure to the patient and operator. With the evolution of new technology for x-ray systems and related major components, the Food and Drug Administration (FDA) has received new questions about the scope of the information disclosure obligation for manufacturers, and whether computerization of that information affects the disclosure provision and how to calculate its cost.

Background

FDA protects the public health from unnecessary exposure to electronic product radiation by, among other things, requiring that electronic products meet performance standards. (Section 532 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ii)) Federal regulations regarding the disclosure of AIAT information protect the public health by preventing unnecessary exposure to x-rays from diagnostic x-ray systems. This disclosure obligation

became effective on August 1, 1974. (38 Federal Register 15444) During that time, AIAT documentation for operational activities has evolved from the use of written manuals to computer software programs.

Assembly of Components

Assembly procedures can affect whether a diagnostic x-ray system complies with federal performance standards. Accordingly, the manufacturing process is not complete until the assembler has installed the component(s) into an x-ray system. The standard defines "manufacturer" to include "assembler." This means that the component manufacturer can only certify to a component's ability to function in compliance with the standard when the system is properly assembled and installed according to the manufacturer's instructions. A manufacturer's labeled certification of a component, coupled with adequate and complete assembly, installation, adjustment, and testing (AIAT) instructions, should provide the assembler with all of the information necessary to ensure the products will comply with applicable performance standards when assembled, installed, adjusted and tested, as directed by the instructions. Delivering a diagnostic x-ray system fully assembled does not relieve manufacturers of their obligations under 21 CFR 1020.30(g (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1020.30)) to provide assemblers and others with AIAT materials.

Installation of Components

The component manufacturer should also provide AIAT instructions that describe how to install the assembled components so the unit meets applicable performance standards. For example, in order to install components properly as part of a system, the assembler needs to fix and align the relationship between the x-ray source and the related components of the diagnostic system. This activity involves adjustment and testing to ensure compliance with performance standards. If the assembler follows the AIAT instructions and the certified component does not meet the performance standard, the component manufacturer should, at no cost to the user, repair or replace the violative component(s), or refund the cost of the component.

Legal Responsibility

Manufacturers and assemblers each bear legal responsibility for their roles in the manufacture and commerce of products subject to section 1020.30. (See sections 535(e) and 538 of the act (21 U.S.C. 360ll(e), 360oo).) As a practical matter, close cooperation between the manufacturer and the assembler furthers the interests of both parties by controlling legal liability for noncompliant or defective x-ray equipment.

Guidance

The manufacturer can certify that the components or system manufactured meet the applicable federal performance standard only when they are assembled, installed, adjusted, and tested according to instructions. The assembler certifies that the system and its components were assembled, installed, adjusted, and tested according to the manufacturer's instructions. Reliable certification, then, depends upon the manufacturer's providing adequate and complete instructions to the assembler.

An x-ray system is an assemblage of components for the controlled production of x-rays. The information disclosure obligation applies to each individually certified component produced by a manufacturer and is independent of the manufacturer's decision to deliver a fully assembled x-ray system or subsystem. The regulation establishes that manufacturers of certified components should provide to assemblers and others, upon request, AIAT information for the certified components of a diagnostic x-ray system. (21 CFR 1020.30(a)(1)) This means that AIAT information should exist for each certified component produced by a manufacturer and be available to others upon request.

Explanation of Terms

The agency would like to explain the meaning of four terms that comprise AIAT to help manufacturers and assemblers establish clear expectations about what information is subject to disclosure.

Assembly: To fit together the parts or pieces of a component or system.

Discussion: New x-ray components and accessories are shipped to a final destination in various boxes and crates. These components must be unpacked and properly assembled before the unit can be used to make x-rays. The typical major component of a diagnostic x-ray system cannot simply be removed from the box and used by the operator. For example, various parts, such as printed circuit boards and switches, may require assembly into the control console of an x-ray control unit in a medical facility. Assembly also includes the re-assembly of components that were not replaced but must be re-connected to the new component. Correct electrical and hardware connections with all of the equipment must be made before using the system. Such connections are considered assembly. Complete assembly instructions in written form or software programs that automate the assembly process should be disclosed to the assembler to the extent they are part of the assembly procedures.

Software programs may incorporate information that does not relate to assembly or re-assembly activities. Such programs are not subject to disclosure. For example, the console's central processing unit may include unrevealed, protected software programs that create a log of assembly activities related to computer operations. Should the manufacturer wish to check the assembly history on a particular system, this log would provide information, independent of the assembler's report, about when activities occurred and perhaps about the identity of the replaced components. This information does not fall within the scope of the AIAT disclosure

requirements. However, the incorporation of non-AIAT information or software does not change obligation of the manufacturer to release the required AIAT information. It is incumbent upon the manufacturer to provide adequate AIAT information to the assembler.

It is important to note that the term "assembly" and "installation" should not be used interchangeably. The term "installation" includes other activity not covered in the assembly activity.

Installation: To set up for use by verifying that proper assembly and adjustments were made to assure compliance with federal performance specifications.

Discussion: The unit should not be used on humans until the installation is completed in accordance with the manufacturer's instructions, including any additional adjustments and testing needed to verify compliance with performance specifications. For example, to complete the installation of an x-ray system, the assembler combines (or assembles) the various certified components, e.g., tube housing assembly, beam-limiting device, and x-ray control, into an interdependent operating system. The assembler should be sure that the components work in coordination with each other and do not cause any of the interdependent components to operate outside of the equipment manufacturer's specified tolerances or outside of applicable federal performance specifications, which are detailed in the regulations. (21 CFR 1020.30 - 1020.33)

The manufacturer's documentation or software programs provide information on how the major components should be configured to meet applicable federal performance standards. However, a manufacturer may also have software programs that operate with specifications that are narrower than federal performance standards, which they use for internal quality assurance purposes. In addition, the firm may have developed a particular sequencing of installation that operates in conjunction with system accessories that do not directly or indirectly impact electronic radiation emissions specifications. This information does not fall within the scope of AIAT disclosure requirements.

Adjustment: To bring various component parts up to a true or more effective relative position for performance purposes.

Discussion: Adjustment covers activities performed on various components to make sure they work as a system within applicable federal performance standards. For example, adjustments to the electrical circuitry are often needed to ensure the system does not operate outside of its performance specifications. Calibration of the equipment's operational parameters is achieved by adjusting the electrical or mechanical features of the component.

The manufacturer's documentation or software that provides adjustment information also serves a critical function so assemblers can ensure the component(s) will comply with the applicable performance standards. Adjustment information would include any relevant calibration references. However, the manufacturer may have incorporated a proprietary

software program that continuously monitors the performance of the system and alerts the manufacturer if the system may need adjustment in the future, even though it is currently operating within the performance standard. This information does not fall within the scope of AIAT disclosure requirements.

Testing: A critical examination, observation, or evaluation of such conditions or operations through procedures provided by the manufacturer that will prove the unit meets specifications.

Discussion: The regulations define the performance requirements for diagnostic radiographic exposure reproducibility such that the coefficient of variation of radiation exposures shall not exceed 0.05. (21 CFR §1020.31(b)(1)) A test method for determining compliance with this performance standard is identified in the regulations. (21 CFR §1020.31(b)(2)) A test of x-ray equipment should produce data to verify the proper operation or performance of the x-ray system or component. For example, information on how to test for radiation leakage or proper beam alignment is important when the assembler needs to use a special technique due to the special design of the component or when the beam alignment procedures are so complex that a computer program is needed.

The manufacturer's documentation or basic software programs provide critical information about testing for applicable federal performance standards that correspond to the manufacturer's AIAT specifications. However, the manufacturer may have additional enhanced software programs, with privileged access codes, that conduct the required tests more quickly to save time. The enhanced software programs may operate in conjunction with other proprietary accessories or functions, such as a daily test trend analysis that is relayed to the manufacturer in order to schedule advanced service calls. This helps the user avoid any interruption in the clinical use of the system. Such proprietary functions may increase the value of the system to the user, but the accessories and the software programs used in conjunction with these functions do not fall within the scope of AIAT for purposes of meeting applicable federal performance standards, provided they are not required by the AIAT instructions.

Manufacturers should provide all informational materials needed for assembly, installation, adjustment, and testing, as described above, regardless of the format in which those materials exist. Manufacturers may provide assemblers and other members of the public hard copies of instructional software, as long as the package made generally available contains adequate, complete, and useable instructions for assembly, installation, adjustment, and testing.

Software

Some manufacturers bundle AIAT information covered by 1020.30(g) with other types of proprietary software; in some instances the proprietary software cannot be deleted from the bundled information. Nothing in section 1020.30 prohibits bundling software information or programs; however, the practice does not relieve manufacturers of their responsibilities under

the performance standard to provide AIAT documentation or the AIAT software at cost. Manufacturers who bundle their AIAT software with other software may comply with 1020.30(g) by providing the entire bundle at the cost of the AIAT software. Alternatively, the manufacturer may, by parceling the software domains, provide only the AIAT software to assemblers and others. Manufacturers may also satisfy the performance standard by providing printed materials, or by any other means that result in the provision of adequate, complete, and useable instructional materials.

Cost

Manufacturers may recover from assemblers and others the "cost" of providing required instructional materials. Manufacturers should, in negotiation with purchasers, assemblers, and others, determine the dollar amount for any instructional package. Although private parties can and should set the exact price for materials provided under subsection (g), the performance standard establishes limits on what costs manufacturers may recover in determining that price.

The agency has explained that manufacturers may charge for the cost of producing each additional package or unit of instructions. The charge can incorporate factors such as the cost of paper, labor, use of a copying machine, or other costs associated with each package the manufacturer provides under the performance standard. This principle should govern the calculation of the costs for all information subject to disclosure, whether printed, encoded in software, or any other format. For software, recoverable charges equivalent to printed materials would include such factors as the cost of the technical labor of producing such additional package or unit, computer disks, and packaging materials used to produce each additional unit of software. Using a reasonable set of factors should govern the calculation of the costs for any materials that are provided.

Although the question concerning cost has arisen primarily in the context of disclosing AIAT information, the same principle should also apply to the cost of disclosure of safety and technical information to the user of diagnostic x-ray systems or computed tomography equipment. In any scenario involving AIAT information disclosure, the factors that constitute a recoverable cost should not create a profit or loss for the manufacturer.

Closing Summary

The public health need to provide AIAT information to assemblers and users since the Radiation Control for Health and Safety Act was passed in 1968 has not changed. If the information is not available, the public may be exposed to unnecessary radiation hazards from electronic products. Without this information, FDA, manufacturers, assemblers, users, and consumers could not make reasonable determinations or decisions associated with the safe and effective use of diagnostic x-ray systems and computed tomography components and systems in their health care.

For further information regarding compliance with the information disclosure requirements for diagnostic x-ray systems and their major component systems, please contact Sean Boyd at 301-796-5895 or sean.boyd@fda.hhs.gov (mailto:sean.boyd@fda.hhs.gov)

Submit Comments

Submit Comments Online (https://www.regulations.gov/docket?D=FDA-2020-D-0957)

You can submit online or written comments on any guidance at any time (see 21 CFR 10.115(g)(5))

If unable to submit comments online, please mail written comments to:

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

All written comments should be identified with this document's docket number: FDA-2020-D-0957 (https://www.regulations.gov/docket?D=FDA-2020-D-0957).

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EXHIBIT 29

UNITED STATES COPYRIGHT OFFICE

SECTION 1201 RULEMAKING:
Seventh Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention

INTRODUCTION AND RECOMMENDED REGULATORY LANGUAGE

OCTOBER 2018

I. Introduction

Enacted in 1998 as part of the Digital Millennium Copyright Act ("DMCA"), section 1201 of Title 17 plays a critical role in fostering the dissemination and enjoyment of creative works online. In adopting section 1201, Congress recognized that the development of the online marketplace for copyrighted works required a legal framework that adequately addressed the harm of internet piracy and encouraged copyright owners to make their works available to the public in emerging digital formats.[1] Section 1201 accordingly affords copyright owners important legal protections against those who circumvent technological measures used to prevent unauthorized access to their works. Many have credited section 1201 as a key factor in the growth of the vast array of content delivery platforms available to consumers today, which offer more lawful options to access expressive material than ever existed previously.[2]

In adopting these new protections, however, Congress also recognized the need to ensure that legitimate uses of copyrighted works not be inhibited unnecessarily. The triennial section 1201 rulemaking is a key part of the statutory scheme, striking a balance between copyright and digital technologies. Every three years, the Librarian of Congress, upon the recommendation of the Register of Copyrights, determines whether the prohibition on circumvention is having, or is likely to have, an adverse effect on users' ability to make noninfringing uses of a particular class of copyrighted works.[3] Upon such a determination, the Librarian may adopt a temporary exemption waiving the prohibition for such users for the ensuing three-year period.[4]

The rulemaking occurs through a formal public process administered by the Register of Copyrights, who consults with the National Telecommunications and Information Administration of the Department of Commerce ("NTIA"). The first rulemaking was completed in 2000, and subsequent rulemakings have taken place every three years since then.

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[1] *See* U.S. COPYRIGHT OFFICE, SECTION 1201 OF TITLE 17 9–10 (2017), https://www.copyright.gov/policy/1201/section-1201-full-report.pdf ("Section 1201 Report").

[2] *See, e.g.*, *Chapter 12 of Title 17: Hearing Before the Subcomm. on Courts, Intellectual Prop. & the Internet of the H. Comm. on the Judiciary*, 113th Cong. 2 (2014) (statement of Rep. Tom Marino, Vice-Chairman, Subcomm. on Courts, Intellectual Prop. & the Internet) ("The digital economy has enabled wide distribution of movies, music, eBooks and other digital content. Chapter 12 seems to have a lot to do with [that] economic growth . . . ."); *id.* at 3 (statement of Rep. Jerrold Nadler, Ranking Member, Subcomm. on Courts, Intellectual Prop. & the Internet) ("Section 1201 has proven to be extremely helpful to creators because it has helped creators to have the confidence to provide video content over the internet despite the risk of piracy.").

[3] 17 U.S.C. § 1201(a)(1)(C).

[4] *Id*. § 1201(a)(1)(D).

Revised Rulemaking Procedures

For this seventh triennial proceeding, following a comprehensive policy study,[5] the Copyright Office implemented new streamlining procedures to facilitate the renewal of previously adopted exemptions to which there is no meaningful opposition. This process proved successful, allowing stakeholders to seek renewal of noncontroversial exemptions—some of which had been repeatedly granted over multiple rulemakings—without the need to provide wholly new evidentiary showings in support. For example, in 2015, the American Foundation for the Blind participated in three rounds of comments and sent two affiliates to a hearing regarding an unopposed exemption to facilitate assistive technology for e-books. This time, the same exemption was renewed through a brief four-paragraph statement.

In fact, the Office did not receive meaningful opposition to renewal of any of the exemptions granted in the 2015 rulemaking, which enabled the Acting Register to announce her intention to recommend readoption of those exemptions at the early stages of this proceeding. This in turn allowed participants to concentrate their energies on new proposals, including requested expansions of existing exemptions. Indeed, the significant number of petitions received in this cycle indicates that stakeholders now are able to devote resources to a broad range of additional issues.

The Acting Register expects that the streamlining process likewise will benefit the records in future proceedings. In this regard, the new procedures underscore the importance of ensuring that exemption proposals are supported by sufficient evidence, as the same record can now be relied upon in multiple subsequent proceedings. At the same time, the process gives opponents the opportunity to demonstrate that the factual or legal grounds supporting an exemption in a prior cycle have changed to the point that the renewal petition should be considered as part of the full rulemaking process. The Acting Register continues to believe that a legislative change providing for presumptive renewal of existing exemptions would introduce even greater efficiencies by eliminating the need for parties to petition for, and the Office to consider, readoption of uncontested exemptions.[6] Nevertheless, the streamlining procedures appear to have accomplished their goal of reducing unnecessary burdens on both participants and the Office.

Policy Considerations

This proceeding involves many of the same proposed uses of copyrighted works that the Office has frequently considered in prior rulemakings. Several exemption petitions seek

[5] *See* Section 1201 Report at 141.

[6] *See id*. at 141; *The Register's Perspective on Copyright Review: Hearing Before the H. Comm. on the Judiciary*, 114th Cong. 27 (2015) (statement of Maria A. Pallante, Register of Copyrights and Dir., U.S. Copyright Office).

to access traditional forms of expressive content for purposes such as teaching and facilitating use by persons with disabilities—activities that Congress undoubtedly had in mind when it created the triennial review process and that have long been a focus of the rulemaking. This cycle also saw an increased focus on ensuring that preservation activities undertaken by libraries, archives, and museums can reach a wide and increasing range of digital works, including computer software and video games.

At the same time, the landscape for the seventh section 1201 rulemaking differs in important ways from that of its inception in 1998, and even from 2008. A significant portion of the exemption proposals received in this cycle reflect a new consumer reality resulting from the growing pervasiveness of the Internet of Things. Like the 2015 rulemaking, this proceeding saw numerous requests to access copyrighted software contained in consumer products and other devices and systems. Proponents of these exemptions do not wish to access such software for its creative content, but instead are seeking to study, repair, or modify the functionality of the device or system itself. In the written comments and public hearings, many of these stakeholders expressed frustration at the notion that copyright should prevent owners of devices from repairing, tinkering with, or otherwise exercising control over their own property. In the words of one individual, "[i]t's my own damn car, I paid for it, I should be able to repair it or have the person of my choice do it for me."[7]

Several of these proposals seek to extend exemptions granted in the last rulemaking to a broader range of products. For example, security researchers currently authorized to circumvent technological measures in consumer devices, vehicles, and medical devices petition to apply that exemption to software-enabled devices generally. Similarly, other petitioners seek to broaden the current exemption for repair and modification of motor vehicles to encompass other devices ranging from smartphones to home appliances to consumables. In considering these proposals, the Office again notes that many of these activities seem to "have little to do with the consumption of creative content or the core concerns of copyright."[8] It should be emphasized, however, that section 1201 does not permit the Acting Register to recommend, or the Librarian to grant, exemptions on that basis alone. They may do so only where specific evidence demonstrates that the statute

[7] DeVolve Class 7 Reply. Comments received in this rulemaking are available at http://copyright.gov/1201/2018. References to these comments in this Recommendation are by party name (abbreviated where appropriate), followed by class number and "Initial," "Opp'n," or "Reply" for comments submitted in the first, second, or third round, respectively.

[8] REGISTER OF COPYRIGHTS, SECTION 1201 RULEMAKING: SIXTH TRIENNIAL PROCEEDING TO DETERMINE EXEMPTIONS TO THE PROHIBITION ON CIRCUMVENTION, RECOMMENDATION OF THE REGISTER OF COPYRIGHTS 2 (2015). References to the Register's Recommendations in prior rulemakings are cited by the year of publication followed by "Recommendation" (*e.g.*, "2015 Recommendation"). Prior Recommendations are available on the Copyright Office website at https://www.copyright.gov/1201/.

is causing, or is likely to cause, an adverse impact on noninfringing uses of copyrighted works. Moreover, the Acting Register's ability to consider broad exemptions in these categories, encompassing wide and varied assortments of devices, is limited by the statutory rulemaking standard, which restricts the inquiry to "particular class[es] of copyrighted works" for which there is evidence of adverse effects.[9]

It is also important to acknowledge the significant countervailing interests that could be implicated by overbroad exemptions. Copyright owners participating in this proceeding emphasized the substantial investments they have made in distributing their creative works through subscription streaming services and other protected ways to lawfully access music, movies, games, books, and more. These platforms provide a critical revenue source for modern artists and authors, and are supplanting more traditional avenues for users to access a wide variety of cultural works. And they all rely on ensuring that the devices and formats used to access this content remain secure and are not used to facilitate infringement. Confronting a very real history of massive piracy of music, movies, and other creative works, rightsholders have concerns over what they characterize as a perfunctory dismissal of serious infringement risks and the blurring of important nuances in the copyright law.

Given these competing policy interests, as well as the inherent constraints of the rulemaking process, the Acting Register recently has advised Congress that many of these issues would be appropriate subjects for legislation. Specifically, in its 2017 Section 1201 Report, the Office recommended that Congress consider expanding the permanent exemption under section 1201(j) permitting circumvention for purposes of security testing.[10] Additionally, the Office recommended congressional consideration of new permanent exemptions for diagnosis, repair, and maintenance of software-enabled devices,[11] and for unlocking of wireless devices.[12] While the Acting Register has attempted to appropriately balance stakeholder interests to the extent permitted under the regulatory framework, legislative review would enable Congress and interested parties to address these issues in a more comprehensive manner.

This rulemaking also echoes the 2015 proceeding in that some proposed exemptions potentially involve activities subject to legal or regulatory regimes outside of copyright. In 2015, the Environmental Protection Agency, the Department of Transportation, and the Food and Drug Administration expressed concerns over the impact that the proposed exemptions for security research and vehicle modification could have on health and safety matters within their jurisdictions. While recognizing that such

[9] 17 U.S.C. § 1201(a)(1)(C).

[10] Section 1201 Report at 71–80.

[11] *Id*. at 88–95.

[12] *Id*. at 97–99.

concerns did not directly implicate copyright, the Register concluded that they were sufficiently serious that other agencies should have the opportunity to prepare for any potential impacts. Therefore, the Register recommended, and the Librarian implemented, a one-year delay in the effective date of those exemptions.[13] Subsequently, however, the Office noted that it did not anticipate the need for future delays now that those agencies have had time to respond, and that going forward it "will generally decline to consider health, safety, and environmental concerns" as part of the rulemaking.[14] Consistent with those statements, the Acting Register in this proceeding did not accord significant weight to such considerations, despite the urging of some participants. While the Acting Register certainly appreciates the seriousness of these issues, they generally are best addressed through other legal frameworks and by agencies with expertise in those areas. Indeed, in contrast to 2015, only one additional federal agency submitted comments in this proceeding, and that agency—the U.S. Department of Justice's Computer Crime and Intellectual Property Section ("CCIPS")—agrees with this view.

Finally, this proceeding again raises the question of whether, or to what extent, third parties, such as independent automobile repair shops, may provide assistance to persons entitled to exercise an exemption. In 2015 the Register declined requests to recommend an exemption for circumvention "on behalf of the owner" of a motor vehicle, finding that such assistance could run afoul of the prohibition on trafficking in circumvention "service[s]" under section 1201(a)(2) and (b). The anti-trafficking provisions provide vital protections to copyright owners, and Congress did not authorize the Librarian to grant exemptions from them. In this proceeding, proponents of the vehicle repair exemption again request provision for third-party assistance, arguing that limiting the exemption to individual owners threatens to render it effectively meaningless for those who lack the technical knowledge to access and manipulate increasingly complex embedded computer systems. The Acting Register is sympathetic to these concerns and has attempted to draft the exemption language in a manner that accommodates such assistance to the extent it does not implicate the anti-trafficking provisions. As the Office has recently noted, however, the scope of those provisions is uncertain,[15] and it is beyond the scope of the rulemaking for the Acting Register to opine on that issue. The Office continues to believe that legislation permitting third-party assistance in appropriate circumstances would benefit stakeholders and provide valuable clarity to the overall statutory scheme.[16]

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[13] *See* 2015 Recommendation at 3.

[14] Section 1201 Report at 125–26.

[15] *See id*. at 56–59.

[16] *See id*. at 59–61.

Summary of Recommendations

The Librarian has previously adopted six sets of exemptions under section 1201 based upon prior Recommendations of the Register.[17] In this seventh triennial proceeding, as discussed more fully below, the Acting Register recommends that the Librarian adopt another set of exemptions covering the following types of uses:

- Excerpts of motion pictures (including television programs and videos) for criticism and comment:
    - For educational uses,
        - By college and university or K-12 faculty and students
        - By faculty of massive open online courses ("MOOCs")
        - By educators and participants in digital and literacy programs offered by libraries, museums and other nonprofits
    - For nonfiction multimedia e-books
    - For uses in documentary films and other films where the use is in parody or for a biographical or historically significant nature
    - For uses in noncommercial videos
- Motion pictures (including television programs and videos), for the provision of captioning and/or audio description by disability services offices or similar units at educational institutions for students with disabilities
- Literary works distributed electronically (*i.e.*, e-books), for use with assistive technologies for persons who are blind, visually impaired or have print disabilities
- Literary works consisting of compilations of data generated by implanted medical devices and corresponding personal monitoring systems
- Computer programs that operate the following types of devices, to allow connection of a new or used device to an alternative wireless network ("unlocking"):

[17] Each of these Final Rules and the Register's Recommendations can be found at http://www.copyright.gov/1201.

  - Cellphones
  - Tablets
  - Mobile hotspots
  - Wearable devices (*e.g.*, smartwatches)
- Computer programs that operate the following types of devices, to allow the device to interoperate with or to remove software applications ("jailbreaking"):
  - Smartphones
  - Tablets and other all-purpose mobile computing devices
  - Smart TVs
  - Voice assistant devices
- Computer programs that control motorized land vehicles, including farm equipment, for purposes of diagnosis, repair, or modification of the vehicle, including to access diagnostic data
- Computer programs that control smartphones, home appliances, or home systems, for diagnosis, maintenance, or repair of the device or system
- Computer programs for purposes of good-faith security research
- Computer programs other than video games, for the preservation of computer programs and computer program-dependent materials by libraries, archives, and museums
- Video games for which outside server support has been discontinued, to allow individual play by gamers and preservation of games by libraries, archives, and museums (as well as necessary jailbreaking of console computer code for preservation uses only), and preservation of discontinued video games that never required server support
- Computer programs that operate 3D printers, to allow use of alternative feedstock

The Register declines to recommend the following requested exemptions:

- Audiovisual works, for broad-based space-shifting and format-shifting (declined due to lack of legal and factual support for exemption)

- Audiovisual works protected by HDCP/HDMI, for non-infringing uses (declined due to lack of legal and factual support for exemption)
- Access to avionics data (declined due to lack of factual support that access controls were protecting copyrighted works)

APPENDIX RECOMMENDED REGULATORY LANGUAGE

Recommended Regulatory Language

(a) *General.* This section prescribes the classes of copyrighted works for which the Librarian of Congress has determined, pursuant to 17 U.S.C. 1201(a)(1)(C) and (D), that noninfringing uses by persons who are users of such works are, or are likely to be, adversely affected. The prohibition against circumvention of technological measures that control access to copyrighted works set forth in 17 U.S.C. 1201(a)(1)(A) shall not apply to such users of the prescribed classes of copyrighted works.

(b) *Classes of copyrighted works.* Pursuant to the authority set forth in 17 U.S.C. 1201(a)(1)(C) and (D), and upon the recommendation of the Register of Copyrights, the Librarian has determined that the prohibition against circumvention of technological measures that effectively control access to copyrighted works set forth in 17 U.S.C. 1201(a)(1)(A) shall not apply to persons who engage in noninfringing uses of the following classes of copyrighted works:

> (1) Motion pictures (including television shows and videos), as defined in 17 U.S.C. 101, where the motion picture is lawfully made and acquired on a DVD protected by the Content Scramble System, on a Blu-ray disc protected by the Advanced Access Content System, or via a digital transmission protected by a technological measure, and the person engaging in circumvention under paragraph (b)(1)(i) and (b)(1)(ii)(A) and (B) of this section reasonably believes that non-circumventing alternatives are unable to produce the required level of high-quality content, or the circumvention is undertaken using screen-capture technology that appears to be offered to the public as enabling the reproduction of motion pictures after content has been lawfully acquired and decrypted, where circumvention is undertaken solely in order to make use of short portions of the motion pictures in the following instances:
>
> > (i) For the purpose of criticism or comment:
> >
> > > (A) For use in documentary filmmaking, or other films where the motion picture clip is used in parody or for its biographical or historically significant nature;
> > >
> > > (B) For use in noncommercial videos (including videos produced for a paid commission if the commissioning entity's use is noncommercial); or
> > >
> > > (C) For use in nonfiction multimedia e-books.

(ii) For educational purposes:

(A) By college and university faculty and students or kindergarten through twelfth-grade (K-12) educators and students (where the K-12 student is circumventing under the direct supervision of an educator), including of accredited general educational development (GED) programs, for the purpose of criticism, comment, teaching, or scholarship;

(B) By faculty of massive open online courses (MOOCs) offered by accredited nonprofit educational institutions to officially enrolled students through online platforms (which platforms themselves may be operated for profit), in film studies or other courses requiring close analysis of film and media excerpts, for the purpose of criticism or comment, where the MOOC provider through the online platform limits transmissions to the extent technologically feasible to such officially enrolled students, institutes copyright policies and provides copyright informational materials to faculty, students, and relevant staff members, and applies technological measures that reasonably prevent unauthorized further dissemination of a work in accessible form to others or retention of the work for longer than the course session by recipients of a transmission through the platform, as contemplated by 17 U.S.C. 110(2); or

(C) By educators and participants in nonprofit digital and media literacy programs offered by libraries, museums, and other nonprofit entities with an educational mission, in the course of face-to-face instructional activities, for the purpose of criticism or comment, except that such users may only circumvent using screen-capture technology that appears to be offered to the public as enabling the reproduction of motion pictures after content has been lawfully acquired and decrypted.

(2)

(i) Motion pictures (including television shows and videos), as defined in 17 U.S.C. 101, where the motion picture is lawfully acquired on a DVD protected by the Content Scramble System, on a Blu-ray disc protected by the Advanced Access Content System, or via a digital transmission protected by a technological measure, where:

(A) Circumvention is undertaken by a disability services office or other unit of a kindergarten through twelfth-grade educational

institution, college, or university engaged in and/or responsible for the provision of accessibility services to students, for the purpose of adding captions and/or audio description to a motion picture to create an accessible version as a necessary accommodation for a student or students with disabilities under an applicable disability law, such as the Americans With Disabilities Act, the Individuals with Disabilities Education Act, or Section 504 of the Rehabilitation Act;

(B) The educational institution unit in paragraph (b)(2)(i)(A) of this section has, after a reasonable effort, determined that an accessible version cannot be obtained at a fair price or in a timely manner; and

(C) The accessible versions are provided to students or educators and stored by the educational institution in a manner intended to reasonably prevent unauthorized further dissemination of a work.

(ii) For purposes of this paragraph(b)(2), "audio description" means an oral narration that provides an accurate rendering of the motion picture.

(3) Literary works, distributed electronically, that are protected by technological measures that either prevent the enabling of read-aloud functionality or interfere with screen readers or other applications or assistive technologies:

(i) When a copy of such a work is lawfully obtained by a blind or other person with a disability, as such a person is defined in 17 U.S.C. 121; provided, however, that the rights owner is remunerated, as appropriate, for the price of the mainstream copy of the work as made available to the general public through customary channels; or

(ii) When such work is a nondramatic literary work, lawfully obtained and used by an authorized entity pursuant to 17 U.S.C. 121.

(4) Literary works consisting of compilations of data generated by medical devices that are wholly or partially implanted in the body or by their corresponding personal monitoring systems, where such circumvention is undertaken by a patient for the sole purpose of lawfully accessing the data generated by his or her own device or monitoring system and does not constitute a violation of applicable law, including without limitation the Health Insurance Portability and Accountability Act of 1996, the Computer Fraud and Abuse Act of 1986 or regulations of the Food and Drug Administration, and is accomplished through the passive monitoring of wireless transmissions that are already being produced by such device or monitoring system.

(5) Computer programs that enable the following types of lawfully acquired wireless devices to connect to a wireless telecommunications network, when circumvention is undertaken solely in order to connect to a wireless telecommunications network and such connection is authorized by the operator of such network:

(i) Wireless telephone handsets (i.e., cellphones);

(ii) All-purpose tablet computers;

(iii) Portable mobile connectivity devices, such as mobile hotspots, removable wireless broadband modems, and similar devices; and

(iv) Wearable wireless devices designed to be worn on the body, such as smartwatches or fitness devices.

(6) Computer programs that enable smartphones and portable all-purpose mobile computing devices to execute lawfully obtained software applications, where circumvention is accomplished for the sole purpose of enabling interoperability of such applications with computer programs on the smartphone or device, or to permit removal of software from the smartphone or device. For purposes of this paragraph (b)(6), a "portable all-purpose mobile computing device" is a device that is primarily designed to run a wide variety of programs rather than for consumption of a particular type of media content, is equipped with an operating system primarily designed for mobile use, and is intended to be carried or worn by an individual.

(7) Computer programs that enable smart televisions to execute lawfully obtained software applications, where circumvention is accomplished for the sole purpose of enabling interoperability of such applications with computer programs on the smart television.

(8) Computer programs that enable voice assistant devices to execute lawfully obtained software applications, where circumvention is accomplished for the sole purpose of enabling interoperability of such applications with computer programs on the device, or to permit removal of software from the device, and is not accomplished for the purpose of gaining unauthorized access to other copyrighted works. For purposes of this paragraph (b)(8), a "voice assistant device" is a device that is primarily designed to run a wide variety of programs rather than for consumption of a particular type of media content, is designed to take user input primarily by voice, and is designed to be installed in a home or office.

(9) Computer programs that are contained in and control the functioning of a lawfully acquired motorized land vehicle such as a personal automobile, commercial vehicle, or mechanized agricultural vehicle, except for programs accessed through a separate subscription service, when circumvention is a necessary step to allow the diagnosis, repair, or lawful modification of a vehicle function, where such circumvention does not constitute a violation of applicable law, including without limitation regulations promulgated by the Department of Transportation or the Environmental Protection Agency, and is not accomplished for the purpose of gaining unauthorized access to other copyrighted works.

(10) Computer programs that are contained in and control the functioning of a lawfully acquired smartphone or home appliance or home system, such as a refrigerator, thermostat, HVAC, or electrical system, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system, and is not accomplished for the purpose of gaining access to other copyrighted works. For purposes of this paragraph (b)(10):

(i) The "maintenance" of a device or system is the servicing of the device or system in order to make it work in accordance with its original specifications and any changes to those specifications authorized for that device or system; and

(ii) The "repair" of a device or system is the restoring of the device or system to the state of working in accordance with its original specifications and any changes to those specifications authorized for that device or system.

(11)

(i) Computer programs, where the circumvention is undertaken on a lawfully acquired device or machine on which the computer program operates, or is undertaken on a computer, computer system, or computer network on which the computer program operates with the authorization of the owner or operator of such computer, computer system, or computer network, solely for the purpose of good-faith security research and does not violate any applicable law, including without limitation the Computer Fraud and Abuse Act of 1986.

(ii) For purposes of this paragraph (b)(11), "good-faith security research" means accessing a computer program solely for purposes of good-faith testing, investigation, and/or correction of a security flaw or vulnerability, where such activity is carried out in an environment designed to avoid any harm to individuals or the public, and where the information derived from the activity is used primarily to promote the security or safety of the

class of devices or machines on which the computer program operates, or those who use such devices or machines, and is not used or maintained in a manner that facilitates copyright infringement.

(12)

(i) Video games in the form of computer programs embodied in physical or downloaded formats that have been lawfully acquired as complete games, when the copyright owner or its authorized representative has ceased to provide access to an external computer server necessary to facilitate an authentication process to enable gameplay, solely for the purpose of:

(A) Permitting access to the video game to allow copying and modification of the computer program to restore access to the game for personal, local gameplay on a personal computer or video game console; or

(B) Permitting access to the video game to allow copying and modification of the computer program to restore access to the game on a personal computer or video game console when necessary to allow preservation of the game in a playable form by an eligible library, archives, or museum, where such activities are carried out without any purpose of direct or indirect commercial advantage and the video game is not distributed or made available outside of the physical premises of the eligible library, archives, or museum.

(ii) Video games in the form of computer programs embodied in physical or downloaded formats that have been lawfully acquired as complete games, that do not require access to an external computer server for gameplay, and that are no longer reasonably available in the commercial marketplace, solely for the purpose of preservation of the game in a playable form by an eligible library, archives, or museum, where such activities are carried out without any purpose of direct or indirect commercial advantage and the video game is not distributed or made available outside of the physical premises of the eligible library, archives, or museum.

(iii) Computer programs used to operate video game consoles solely to the extent necessary for an eligible library, archives, or museum to engage in the preservation activities described in paragraph (b)(12)(i)(B) or (b)(12)(ii) of this section.

(iv) For purposes of this paragraph (b)(12), the following definitions shall apply:

(A) For purposes of paragraph (b)(12)(i)(A) and (b)(12)(ii) of this section, "complete games" means video games that can be played by users without accessing or reproducing copyrightable content stored or previously stored on an external computer server.

(B) For purposes of paragraph (b)(12)(i)(B) of this section, "complete games" means video games that meet the definition in paragraph (b)(12)(iv)(A) of this section, or that consist of both a copy of a game intended for a personal computer or video game console and a copy of the game's code that was stored or previously stored on an external computer server.

(C) "Ceased to provide access" means that the copyright owner or its authorized representative has either issued an affirmative statement indicating that external server support for the video game has ended and such support is in fact no longer available or, alternatively, server support has been discontinued for a period of at least six months; provided, however, that server support has not since been restored.

(D) "Local gameplay" means gameplay conducted on a personal computer or video game console, or locally connected personal computers or consoles, and not through an online service or facility.

(E) A library, archives, or museum is considered "eligible" when the collections of the library, archives, or museum are open to the public and/or are routinely made available to researchers who are not affiliated with the library, archives, or museum.

(13)

(i) Computer programs, except video games, that have been lawfully acquired and that are no longer reasonably available in the commercial marketplace, solely for the purpose of lawful preservation of a computer program, or of digital materials dependent upon a computer program as a condition of access, by an eligible library, archives, or museum, where such activities are carried out without any purpose of direct or indirect commercial advantage and the program is not distributed or made available outside of the physical premises of the eligible library, archives, or museum.

(ii) For purposes of the exemption in paragraph (b)(13)(i) of this section, a library, archives, or museum is considered "eligible" if—

(A) The collections of the library, archives, or museum are open to the public and/or are routinely made available to researchers who are not affiliated with the library, archives, or museum;

(B) The library, archives, or museum has a public service mission;

(C) The library, archives, or museum's trained staff or volunteers provide professional services normally associated with libraries, archives, or museums;

(D) The collections of the library, archives, or museum are composed of lawfully acquired and/or licensed materials; and

(E) The library, archives, or museum implements reasonable digital security measures as appropriate for the activities permitted by this paragraph (b)(13).

(14) Computer programs that operate 3D printers that employ microchip-reliant technological measures to limit the use of feedstock, when circumvention is accomplished solely for the purpose of using alternative feedstock and not for the purpose of accessing design software, design files, or proprietary data.

(c) *Persons who may initiate circumvention*. To the extent authorized under paragraph (b) of this section, the circumvention of a technological measure that restricts wireless telephone handsets or other wireless devices from connecting to a wireless telecommunications network may be initiated by the owner of any such handset or other device, by another person at the direction of the owner, or by a provider of a commercial mobile radio service or a commercial mobile data service at the direction of such owner or other person, solely in order to enable such owner or a family member of such owner to connect to a wireless telecommunications network, when such connection is authorized by the operator of such network.