Acceptable Media for Electronic Product User Manuals

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 20, 2024.

Document originally issued on: March 18, 2010

For questions about this document contact Office of Health Technology 8 (OHT8): Office of Radiological Health at RadHealth@fda.hhs.gov.



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

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number FDA-2020-D-0957. 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 email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number GUI00001710 and complete title of the guidance in the request.

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Contains Nonbinding Recommendations

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

1. Introduction

FDA has developed this guidance document to clarify that manufacturers can provide user manuals accompanying electronic products in either paper or electronic form. This is done to recognize that electronic media are now being widely used to provide instruction, while at the same time reducing paper consumption, increasing accessibility and providing rapid means for editing and updating content.

In general, FDA's guidance documents 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.

2. User Manuals

The Code of Federal Regulations (CFR) Title 21 Part 1002.3 states in part: "The Director… of the Center for Devices and Radiological Health… may require a manufacturer of a radiation emitting electronic product to provide to the ultimate purchaser…performance data and other technical data related to safety of the product…" These data are typically contained in user manuals that accompany electronic products and historically the media for these manuals has been printed paper. Specific performance standards in 21 CFR Parts 1020.20(c)(4)(i), 1020.30(h), 1020.40(c)(9), 1030.10(c)(4), 1040.10(h), and 1040.20(e) also contain requirements for providing instructions to users of electronic products. For example, 21 CFR 1020.30(h) and1040.10(h) specify information manufacturers must provide to users of diagnostic x-ray and laser products respectively.

With the availability of electronic information storage and display technology, many commercial product manuals are being provided electronically. Electronic documentation saves storage space, reduces paper consumption, increases accessibility, and provides rapid means for editing and updating of content.

For these reasons, manufacturers can provide the required user information in PDF format. Manufacturers may provide the required information as a web site download, on a compact disc (CD) or on other storage media in common use (*e.g.,* USB external drive), so long as it is made available directly to the purchaser of the product. If the product purchaser is unable to access the electronic version provided, the manufacturer must make the required documentation available in hard copy (*e.g.*, printed paper) at no additional cost. The manuals in whatever form provided should be in the English language.

3. Impact on Required Reports

Radiation safety reports (including user manuals) required by 21 CFR 1002.10 through 1002.13 may be submitted to FDA in one of the following ways:

1) All Radiation Safety reports may be submitted to CDRH by email to the RadHealthCustomerService@fda.hhs.gov mailbox. This includes all report types, such as product reports, annual reports, and supplemental reports of all types, and all communications such as notifications of defect/failure to comply, corrective action plan (CAP) proposals, and accidental radiation occurrences (AROs). Reports should be submitted in PDF format, or packaged by the eSubmitter packaging procedures, and attached to your email. eSubmissions no longer need to be transferred to a physical medium and mailed to the CDRH Document Control Center. An eSubmitter user does not need to acquire an FDA Electronic Submissions Gateway account.

2) Electronically using FDA's eSubmitter software which can be downloaded at no cost from https://www.fda.gov/industry/fda-esubmitter. Documents prepared using eSubmitter may be sent directly to CDRH via FDA's Electronic Submissions Gateway (ESG).

3) On CD using FDA's eSubmitter software. Documents prepared using eSubmitter may be loaded on a CD and mailed to CDRH for processing, or

4) In hard copy, paper documentation may be mailed to the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Note: If electronic versions of user manuals are submitted, the required radiation safety report should also be submitted electronically.