Technical Publications

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1.0 PURPOSE

This document defines the requirements for the development and maintenance of instructions for use (IFUs) and their localized versions created by or for Abbott. This SOP applies to the Technical Writing and Localization functions.

This document applies to IFUs (both printed and electronic) as well as to the localization of software user interfaces, label content, voice recordings, and SMS content. Marketing materials, training materials, and label creation are outside the scope of this document.

2.0 REFERENCES

2.1 Applicable Documents

Number	Title
86942	Content Development WI
86943	Output WI
86941	Release WI
86962	Electronic Instructions for Use WI

Number	Title
87728	Instructions for Use Responsibilites Matrix
87778	Instructions for Use Requirements Matrix
90161994	Supplemental Labeling Process WI

2.2 External References

Number	Title
FDA 21 CFR Part 801	US Code of Federal Regulations - Medical Device Labeling
FDA 21 CFR Part 812	US Code of Federal Regulations - Investigational Device Exemptions
N/A	FDA Guidance on Medical Device Patient Labeling
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
IEC/TR 60878:2015	Graphical symbols for electrical equipment in medical devices
IEC 60417:2002	Graphical symbols for use on equipment
ISO 15223-1:2012	Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. General Requirements
EN ISO 15223-1:2012	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN 45502-1:2015, Section 28 (Accompanying Documentation)	Implants for surgery. Active implantable medical devices. General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-1:2003, Section 28 (Accompanying Documentation)	Active implantable medical devices. Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardia pacemakers)
EN 45502-2-2:2008, Section 28 (Accompanying Documentation)	Active implantable medical devices. Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)
ISO 14708-1:2014, Section 28 (Accompanying Documentation)	Implants for surgery. Active implantable medical devices. General requirements for safety, marking and for information to be provided by the manufacturer
ISO 14708-2:2012, Section 28 (Accompanying Documentation)	Implants for surgery. Active implantable medical devices – Part 2: Cardiac Pacemakers
ISO 14708-3:2008, Section 28 (Accompanying Documentation)	Implants for surgery. Active implantable medical devices - Part 3 - Implantable neurostimulators

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Number	Title
ISO 14708-6:2010, Section 28 (Accompanying Documentation)	Implants for Surgery. Active implantable medical devices- Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
No 207/2012	Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices

3.0 RESPONSIBILITIES

Function or Title	Responsibility
Technical Publications	Owns this procedure and is responsible for ensuring that it is maintained and followed.

4.0 DEFINITIONS

Term	Definition
eIFU	Electronic instructions for use, either in English or translated
ICR	In-country review; the process of reviewing localized content by an Abbott employee living in-country where the language is the primary language spoken, a native speaker of the language, and a subject-matter expert in the information being reviewed. If an Abbott employee is not available then the reviewer must fit the criteria and can be a distributor, physician, clinician, etc.
IFU	Instructions for use, either in English or translated
Localization	The practice of customizing a product to accommodate the language, cultural, and legal differences of a foreign market or country, including translation
PLM	Product Lifecycle Management (document control system)
SMS	Short message service; a text messaging service component of most telephone, World Wide Web, and mobile telephony systems

5.0 FLOW CHART

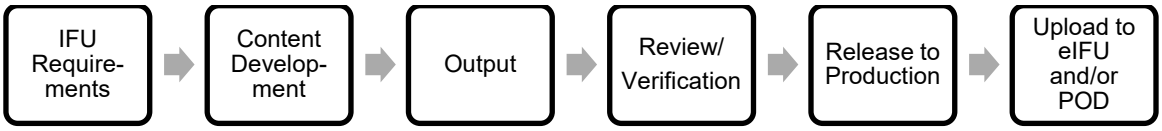

Figure 1: Technical Publications Workflow

6.0 REQUIREMENTS

6.1 Content Development

The Technical Publications Content Development Work Instruction defines the steps required to develop and maintain IFUs.

IFUs shall meet all applicable requirements, standards and regulations as determined by Quality Management and Regulatory Affairs.

IFU content that communicates product risks, proper use, product traceability, notifications, or warnings shall be traceable to product design or risk analysis and management documents (e.g., uFMEA).

87778, Instruction for Use Requirements Matrix, lists requirements for accompanying documents. All “Minimum Requirements” shall be met for all IFUs. The “Requirement When Applicable” in 87778 shall be determined by design input, requirements, risk analysis, or risk management, and by designated subject matter experts on a product-by-product basis. Additional IFU content may be required to fulfill a business or other need.

The following inputs are used to create and update IFUs: predicate versions of IFUs, specifications, reports, risk management files, information from subject-matter experts, and customer requirements.

The content of English-language IFUs shall be reviewed for accuracy and completeness by Abbott subject-matter experts.

90161994, Supplemental Labeling Process WI, defines the process by which IFUs that are not included on a product bill of material are associated with the appropriate products using the ZLSD manual table in SAP.

6.1.1 Localization

Localization of English-language content shall be performed by approved vendors with an internal system for review and editing. Vendors shall be subject to supplier quality management procedures. Online translation tools shall not be used.

Once localization is completed, an additional review shall be performed by a designate of Abbott knowledgeable in the clinical use of the device or system and proficient in the given language. Revisions requested during this review shall be considered and, if applicable, incorporated into the localized content. The vendor shall ensure and certify in writing that the localization is a complete and accurate representation of the English-language content.

ICR shall determine the appropriate localized terminology for commonly used terms and phrases specific to the clinical use of the device or system.

6.1.1.1 Vendor Management Activities

The vendors’ SOPs shall be reviewed annually to ensure adherence to localization requirements.

The glossary, style guide, and translation memory files shall be managed by the vendors and shall be collected by Abbott quarterly.

Translation errors shall be monitored to ensure translation quality.

6.1.1.2 Instructions for Use

English-language IFUs are written by technical writers within Technical Publications and localization is managed by the localization team within Technical Publications.

Technical Publications shall be responsible for the release and maintenance of English and localized IFUs.

6.1.1.3 Software Interface

English-language software user-interface content shall be provided by software development and localization shall be managed by the localization team within Technical Publications.

Linguistic contextual testing of localized software user interfaces shall be conducted in conjunction with software development and design quality engineering.

Software development shall be responsible for the incorporation and release of localized software user-interface content.

6.1.1.4 Labels

English-language product labels shall be provided by the Abbott labeling group and localization shall be managed by the localization team within Technical Publications.

The Abbott labeling group shall be responsible for the incorporation and release of localized product labels.

6.1.1.5 Voice Recordings

English-language script for voice recording shall be provided by software development. Localization and recording shall be managed by the localization team within Technical Publications.

Linguistic contextual testing of localized voice recordings shall be conducted in conjunction with software development and design quality engineering.

Software development shall be responsible for the incorporation and release of localized voice recordings.

6.1.1.6 SMS Content

English-language SMS content shall be provided by software development and localization shall be managed by the localization team within Technical Publications.

Linguistic contextual testing of localized SMS content shall be conducted in conjunction with software development and design quality engineering.

Software development shall be responsible for the incorporation and release of localized SMS content.

6.2 Output

The Technical Publications Output Work Instruction defines the steps required to output IFUs in the required formats.

Output of IFUs may include print, PDF, HTML, or other formats as required. IFU page size and format are determined by device package size, sterilization process, and distribution plans.

Output requirements for device-based help shall be determined in conjunction with software development.

6.3 Release

The Technical Publications Release Work Instruction defines the steps required to release IFUs to pre-production or production.

IFUs shall be approved and released through the PLM system of record for the product.

Anyone releasing IFUs to production shall be trained in the appropriate PLM system of record.

If verification/validation of an IFU is required, it shall be released at either a pre-production or production level. A pre-production or production release may be required prior to regulatory submission, depending on project needs.

6.4 Electronic Instructions for Use (eIFU)

The Electronic Instructions for Use Work Instruction defines the steps required to upload and review electronic IFUs.

Abbott may provide IFUs electronically on the web, on portable electronic media, or as onscreen help. Electronic IFUs allow for the removal of the printed IFUs from the product package. For geographies where an eIFU is not accepted, a paper copy is packaged with the product.

For product having an eIFU placed on a website, Abbott provides a generic insert.

The insert shall be localized and contain the following information:

- Website address and URL: manuals.sjm.com for Saint Jude Medical-branded IFUs or medical.abbott/manuals for Abbott-branded IFUs.
- Adobe Acrobat Reader instructions for viewing, printing, or downloading
- Instructions for requesting a paper copy of the IFU
- Company branding

The latest version of an eIFU will be maintained on the eIFU website for the following device types and expiration terms:

- Non-implantable devices with an expiration date: at least two years after the expiration date of the last device manufactured
- Implantables and devices without an expiration date: at least fifteen years after the last device was manufactured