How to Use Consensus Standards in Premarket Submissions

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Value of Consensus Standards

Enhance regulatory science
Promote quality
Improve patient access

Science-based least burdensome regulatory approach
Learning Objectives

• Explain how to use standards in device submissions
• Describe how declarations of conformity (DOC) improve device review
• Identify when you need supplemental documentation
• Discuss *Helpful Tips* for using standards and DOCs in submissions
How to Use Consensus Standards in Device Submissions
Use of Consensus Standards

- Voluntary
- Only mandatory if cited in regulation
  - Example: 21 CFR 801 cites ASTM D3492
- In any type of submission
- With a DOC (recognized standards only), “General Use” (any standards, recognized or not) or both
How to Cite Standards-Cover Sheet

Form FDA 3514 Cover Sheet* Section J

- Examples Section
- Entries for Utilization of Standards

* Download Form FDA 3514 “CDRH Premarket Review Submission Cover Sheet” at: www.fda.gov/media/72421/download
## How to Cite Standards-Cover Sheet

### Entries for Utilization of Standards

<table>
<thead>
<tr>
<th>Recognition Number</th>
<th>Declaration of Conformity or General Use</th>
<th>Standards Development Organization (SDO), Designation Number-Year, and Title</th>
<th>Location</th>
</tr>
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<tbody>
<tr>
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To add another row for Section J, please click on the button to the right. May be repeated as needed. (To remove a particular row, please click on the “X” button at the beginning of the row.)

Add Row/Standard
Form 3514 Cover Sheet
Section J: Recognition Number

Recognized Consensus Standards database
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
## How to Cite Standards-Cover Sheet

### Form 3514 Cover Sheet

#### Section J: Declaration of Conformity or General Use

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>X</td>
<td>8-185 Declaration of Conformity</td>
<td>ASTM F451-08, standard specification for acrylic bone cement</td>
<td>Section 3, p. 15</td>
</tr>
<tr>
<td>2</td>
<td>3-44 General Use</td>
<td>AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers</td>
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Add Row/Standard
# How to Cite Standards-Cover Sheet

## Form 3514 Cover Sheet

### Section J: Standard

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Add Row/Standard
How to Cite Standards-Cover Sheet

Form 3514 Cover Sheet
Section J: Location
(In Submission)

### Examples

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Declaration of Conformity (DOC)
What is a DOC?

• Attestation that device conforms with cited FDA-recognized standard
  – All normative requirements are met
  – All testing has been conducted
  – Testing is on finished device or final finished device

• If submitter declares conformity with a recognized standard, a DOC accompanies the submission

→ Use of DOC with a recognized standard generally reduces documentation needed in a submission
Elements of a DOC

- Name and address of applicant/sponsor responsible for DOC
- Product/device identification
- Statement of conformity
- List of standards to which DOC applies
- FDA recognition number for each standard

Elements of a DOC, cont’d

• Date and place of issuance of DOC
• Signature, printed name, and function of applicant/sponsor responsible for DOC
• Any limitation on validity of DOC (e.g., how long declaration is valid, what was tested, or concessions made about testing outcomes)
• Supplemental documentation per ISO 17050-2 or equivalent

Elements of a DOC

- Responsible Party
- Product/Device Identification
- Statement of Conformity
- Limitations on Validity of DOC
- Signature

Example Declaration of Conformity (DOC)

Note: This example is intended to illustrate elements of the Declaration of Conformity per FDA’s guidance "Voluntary Consensus Standards in Premarket Submissions for Medical Devices."

Responsible Party
Name of entity responsible for DOC.
Address of entity responsible for DOC.

Product/Device Identification
All identifying information for the product/device including (e.g., product code(s), device marking(s), model number(s), etc.)

Statement of Conformity
☐ The test results demonstrate that the device is in conformity with the standard(s) listed below:1
- Title of Standard:
- FDA Recognition #: (e.g., 19-A)
- Options Selected:
  ☐ Standard included no options
  ☐ Standard included options

- Testing Laboratory Name: (e.g., Testing Laboratories, Inc.)
- Testing Locations(s): (e.g., 1234 Example Road, Silver Spring, MD 20999)
- Testing Date(s): (e.g., Sept 1, 2020 - Sept 15, 2020)
- Supplemental Documentation: Refer to Section 7.C. of this guidance for specific requirements.

☐ Supplementary documentation is not included.
☐ Supplementary documentation is included at the following location within the submission, and I have checked that there are no differences regarding protocol and data between the tests conducted and the supplemental documentation: (e.g., Appendix A of this premarket submission)

1 See section 114(b)(6)(E)(i) of the FD&C Act, cited in Section IV.A.(3)(b) of FDA’s guidance "Voluntary Consensus Standards in Premarket Submissions for Medical Devices."

Limitations on Validity of DOC

Description of any limitation on the validity of the DOC (e.g., how long the declaration is valid, what was tested, or conclusions made about the testing outcomes

Signature
Printed name:
Function within entity responsible for DOC.

Signature Date
Responsible Party and Product/Device Identification

Example Declaration of Conformity (DOC)

Note: This example is intended to illustrate elements of the Declaration of Conformity per FDA’s guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices that the device manufacturer submits as part of their premarket submission.

Responsible Party
Name of entity responsible for DOC:
Address of entity responsible for DOC: ________________________________

Product/Device Identification

All identifying information for the product/device including (e.g., product code(s), device marketing name(s), model number(s), etc.).
Statement of Conformity

☐ The test results demonstrate that the device is in conformity with the standard(s) listed below¹:

- Title of Standard:
- FDA Recognition #: (e.g., 19-4)
- Options Selected
  - Standard included no options
  - Standard included options

List of options selected in standard (e.g., clause 5.3 permits modified test conditions if ambient temperature cannot be maintained).

- Testing Laboratory Name: (e.g., Testing Laboratory ABC)
- Testing Location(s): (e.g., 1234 Example Road, Silver Spring, MD 20993)
- Testing Date(s): (e.g., Sep 1, 2020 – Sep 15, 2020)
- Supplemental Documentation (Refer to Section V.C. of this guidance for specific recommendations):
  - Supplementary documentation is not included
  - Supplementary documentation is included at the following location within the submission, and I have checked that there are no differences regarding protocol and data between the testing conducted and the supplemental documentation: (e.g., Appendix A of this premarket submission)

¹ See section 514(c)(3)(A)(i) of the FD&C Act, cited in Section IV.A.3(f) of FDA’s guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Device.
Limitations on Validity of DOC and Signature

<Repeat for each standard in DOC>

Limitations on Validity of DOC

Description of any limitation on the validity of the DOC (e.g., how long the declaration is valid, what was tested, or concessions made about the testing outcomes)

Signature

Printed name: ________________________________
Function within entity responsible for DOC:

Signature ________________________________ Date
“General Use” of Standards

• May cite any consensus standard
• Should include complete test reports
• Considerations:
  – If modifications not referenced or permitted in standard, should include complete test reports
  – When in doubt, ask FDA review team!
Supplemental Documentation
## Supplemental Documentation

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<td>Complete Test Report</td>
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*Notes*:
- **Included** indicates that the test method is included in the test report.
- **Not Included** indicates that the test method is not included in the test report.
- **Yes** indicates that supplemental documentation is needed.
- **No** indicates that supplemental documentation is not needed.
- **Complete Test Report** indicates that a complete test report is needed.
## Supplemental Documentation

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Supplemental Documentation

• Supplemental documentation is needed when:
  – Standard has neither test method nor prespecified acceptance criteria
  – Deviations or adaptations have been made to recognized standard

• Provide complete test report as supplemental documentation

• Note: If elect “General Use”, additional documentation may be needed
ANSI/AAMI HE75:2009(R)28
Not FDA-recognized: Section 9: Usability testing

<table>
<thead>
<tr>
<th>Section</th>
<th>Contents</th>
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<tbody>
<tr>
<td>1</td>
<td>Conclusion</td>
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<tr>
<td>2</td>
<td>Descriptions of intended device users, uses, use environments, and training</td>
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<tr>
<td>3</td>
<td>Description of device user interface</td>
</tr>
<tr>
<td>4</td>
<td>Summary of known use problems</td>
</tr>
<tr>
<td>5</td>
<td>Analysis of hazards and risks associated with use of device</td>
</tr>
<tr>
<td>6</td>
<td>Summary of preliminary analyses and evaluations</td>
</tr>
<tr>
<td>7</td>
<td>Description of categorization of critical tasks</td>
</tr>
<tr>
<td>8</td>
<td>Details of human factors validation testing</td>
</tr>
</tbody>
</table>

FDA Guidance: Applying Human Factors & Usability Engineering to Medical Devices
When Supplemental Documentation is **NOT** Needed

- Design standard is cited
- Standard includes both:
  - test method and
  - pre-specified performance limit

INTERNATIONAL STANDARD
ISO
17665-1
Sterilization of health care products — Moist heat —
Part 1:
Requirements for the development, validation and routine control of a sterilization process for medical devices
Helpful Tips for Using Standards in a Submission
What to Avoid

• Inappropriate use of consensus standards
  – Not applicable to your device or intended use
  – Not knowing Extent of Recognition (complete or partial)

• Inappropriate use of a declaration of conformity
  – Citing non-recognized standards (such as older, previous versions)
  – Deviations from recognized standards
  – Using DOCs without appropriate supplemental documentation
What to Avoid

• Assuming that use of consensus standards satisfies ALL submission questions

• Not checking relevant regulation/guidance for additional requirements

• FDA Form 3654: Standards Data Report for 510(k)s; no longer available!
Summary

• How to use standards in device submissions
• How DOCs improve device review
• Use of supplemental documentation
• Helpful tips for using standards and DOCs in submissions
Resources

- Standards & Conformity Assessment Program (S-CAP)
  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/

- FDA Recognized Consensus Standards Database
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

- Device Advice: Comprehensive Regulatory Assistance
  www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance

- CDRH Learn: How to Study and Market Your Device: Standards
  www.fda.gov/training-and-continuing-education/cdrh-learn#collapseTwo
Guidances

• Appropriate Use of Voluntary Consensus Standards in Premarket Submission for Medical Devices

• Recognition and Withdrawal of Voluntary Consensus Standards

Contact: CDRHStandardsStaff@fda.hhs.gov
Industry Education:
Three Resources for You

1. CDRH Learn: Multi-Media Industry Education
   - Over 200 modules
   - Videos, audio recordings, power point presentations, software-based “how to” modules
   - Mobile-friendly: access CDRH Learn on your portable devices
   [www.fda.gov/CDRHLearn](http://www.fda.gov/CDRHLearn)

2. Device Advice: Text-Based Education
   - Comprehensive regulatory information on premarket and postmarket topics
   [www.fda.gov/DeviceAdvice](http://www.fda.gov/DeviceAdvice)

3. Division of Industry and Consumer Education (DICE)
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: [www.fda.gov/DICE](http://www.fda.gov/DICE)
Your Call to Action

• Put standards to work
  – Use FDA-recognized standards in your submissions

• Make sure your documentation is complete
  – Know when you need DOCs and supplement documentation

• Participate in standards development!