The Role of Voluntary Consensus Standards in Regulatory Frameworks

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FDA U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health
Division of Standards and Conformity Assessment

Topics

- Value of Consensus Standards
- FDA/CDRH Division of Standards and Conformity Assessment
- Standards for Regulator Use: Putting Standards to Work
- CDRH's Standards Recognition Program
- Question and Answer Session

VALUE OF CONSENSUS STANDARDS

US Government Authorities

Congress	National Technology Transfer Advancement Act	Federal agencies and departments shall use technical standards … developed or adopted by voluntary consensus standards bodies…to carry out policy objectives or activities
Executive Branch	OMB Circular A-119	Federal agencies will use voluntary consensus standards in lieu of government unique standards wherever appropriate
FDA Regulations	21CFR 10.95	60 FR 53078
FDA Staff Manual Guide	SMG 9100.1	FDA will preferentially use international standards where appropriate and when not in conflict with existing regulations

FDA/CDRH
DIVISION OF STANDARDS AND CONFORMITY ASSESSMENT (DSCA)

CDRH By the Numbers

~2000
EMPLOYEES

18k
Medical Device Manufacturers

183k
Medical Devices
On the U.S. Market

22k/year
Premarket Submissions
including supplements and amendments

570k
Proprietary Brands

25k
Medical Device Facilities Worldwide

1.4 MILLION/year
Reports on medical device adverse events and malfunctions

DSCA By the Numbers

~400
CDRH staff engaged in standards development

18
DSCA staff

300+
Years of standards experience in DSCA

~36
Standards development organizations we work with

2
Lists of recognized standards we update yearly

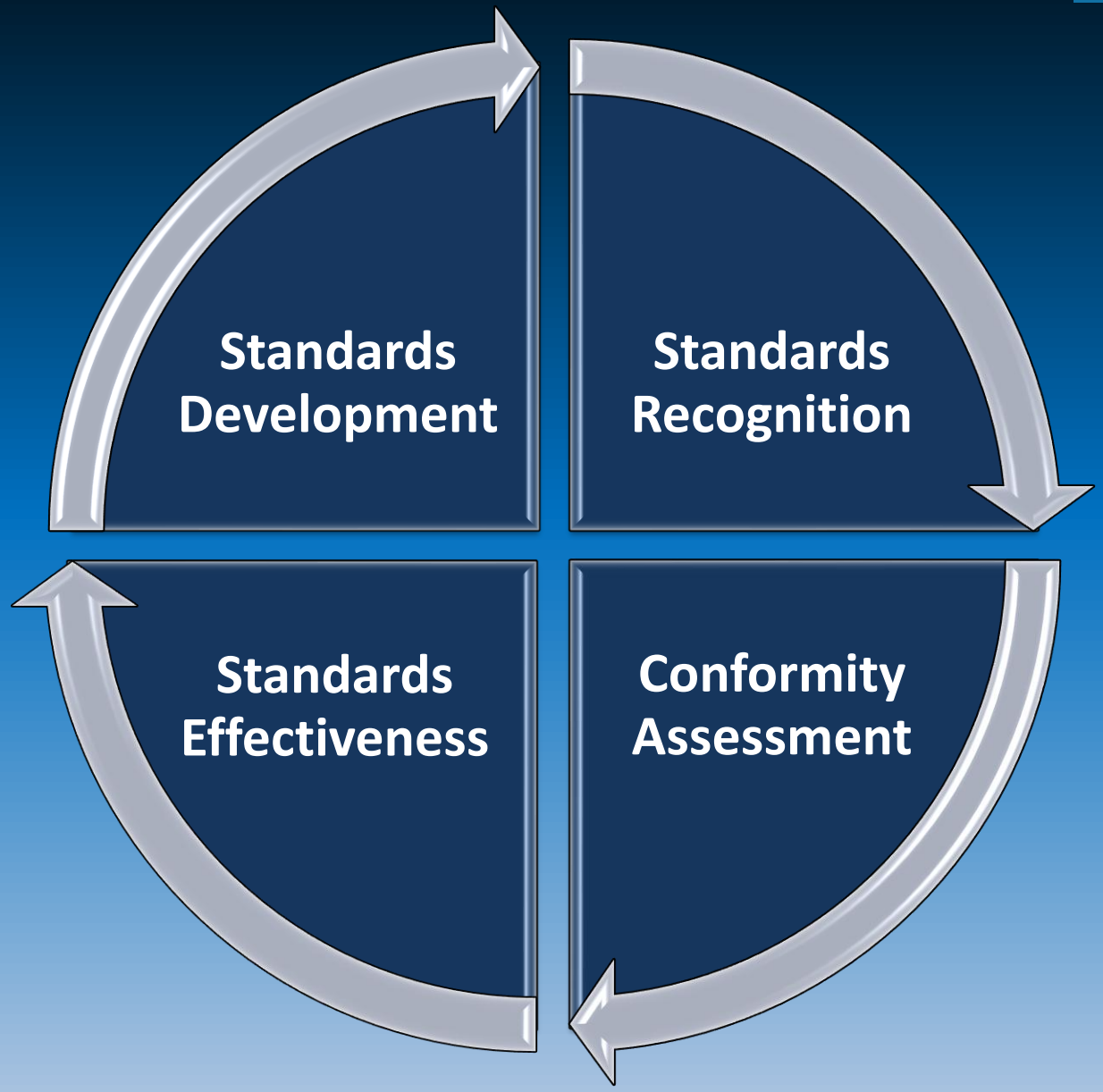
7
Number of standards cited in an average 510(k)

600
Standards development organization technical committees we contribute expertise to

Division of Standards and Conformity Assessment

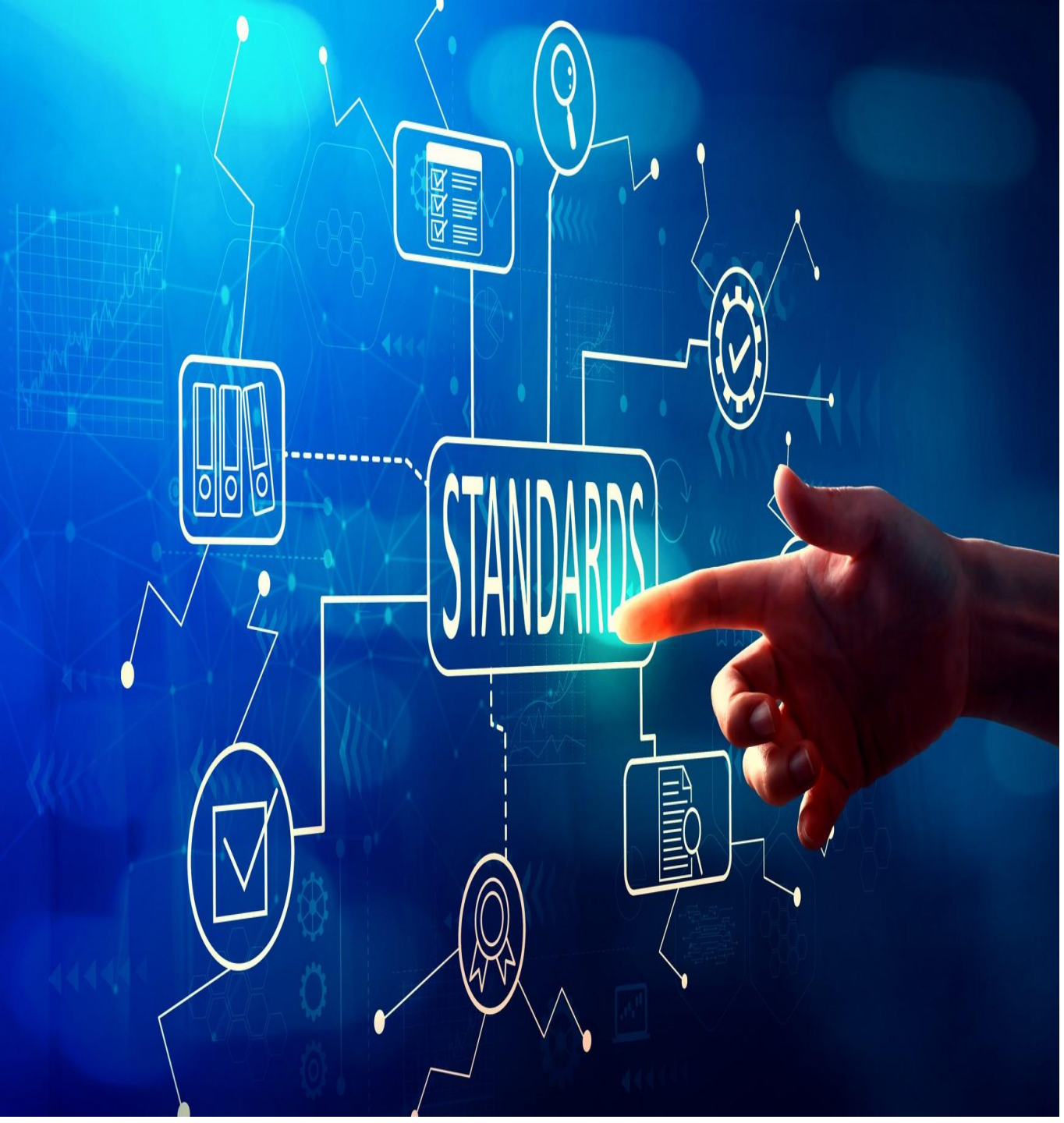
DSCA Mission

Drive the development, recognition, and appropriate use of regulatory-ready standards for medical devices throughout their lifecycles



DSCA Goals

Optimize	Increase	Enhance	Support	Practice	Improve
Optimize standards for regulatory use	Increase the appropriate use of FDA-recognized standards across the total product life cycle of devices	Enhance conformity assessment in device review	Support international harmonization through standards	Practice leadership to demonstrate the promise of standards in policymaking, regulatory science and device review priorities	Improve cross-cutting DSCA programs



Optimizing Standards for Regulatory Use

- Initiative for SDO Technical Committees and US mirror committees to make standards more regulatory-ready
  - AAMI White Paper on Regulatory Ready Standards – published
  - F3766-25 ASTM Guide for Content and Format of Test Report Summaries for Medical and Surgical Materials and Device Standards – published
  - Draft AAMI White Paper: Bridging the Conformity Assessment Gap Through Enhanced Collaboration

STANDARDS FOR REGULATORY USE: PUTTING STANDARDS TO WORK

Reminder: Regulatory Options to Market Medical Devices

Submission Type	Classification	Statutory Threshold
510(k) (Premarket Notification)	Class I, II	Substantial Equivalence (SE)
De Novo	Class I, II	Reasonable Assurance of Safety and Effectiveness through Special Controls
PMA (Premarket Approval)	Class III	Reasonable Assurance of Safety and Effectiveness

Reminder: FDA Review Process

Key elements of a device submission:

- Administrative content requirements
- Indications for Use / Intended Use
- Device Description
- Discussion of Technological Characteristics
- Product Labeling
- **Performance Testing**
  - **Recognized consensus standards are frequently used**
- Discussion of how the statutory threshold is met

Why Consensus Standards?

- Participation by all stakeholders in standards development including - *especially* - regulators
- FDA-recognized standards have FDA's confidence that conformity will support device claims
- Using recognized standards with a declaration of conformity generally reduces documentation needed in the submission
- Fewer Additional Information questions
- Reduce burdens on manufacturers by harmonizing expectations across jurisdictions

CDRH’S STANDARDS RECOGNITION PROGRAM

FDA's Standards Recognition Program

'Recognition': FDA's formal identification of a standard after determining that it is appropriate for manufacturers to declare conformance (with a declaration of conformity) to meet relevant requirements

- We may recognize all, part, or none of the standard
- We publish the decision rationale
- We regularly update the Recognized Consensus Standards Database
- We may withdraw recognized standards, as appropriate, generally to accommodate new versions

FDA Recognized Consensus Standards Database

Searchable by:

- Standards Development Organization (SDO)
- Designation number
- FDA recognition number
- Keywords
- Inclusion in ASCA
- Product code
- And more…

Supplementary Information Sheets (SIS) include:

- Recognition number
- Date of entry into Recognized Consensus Standards Database
- SDO and designation number
- US identical adoption (if applicable)
- Scope of standard
- Extent of recognition
- Included in ASCA?
- Rationale for recognition or partial recognition
- Transition period (if any)
- Examples of applicable device product codes
- Relevant guidance documents or other publications
- Relevant FDA Specialty Task Group (STG)
- Name of contact person

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Part B: Supplementary Information Sheet (SIS)

FR Recognition List Number 057 **Date of Entry** 12/20/2021

FR Recognition Number 8-571

Standard

ASTM F2052-21
Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

Scope/Abstract

1.1 This test method covers the measurement of the magnetically induced displacement force produced by static magnetic field gradients (spatial field gradient) on medical devices and the comparison of that force to the weight of the medical device.

1.2 This test method does not address other possible safety issues which include, but are not limited to: issues of magnetically induced torque, radiofrequency (RF) heating, induced heating, acoustic noise, interaction among devices, and the functionality of the device and the magnetic resonance (MR) system.

1.3 This test method is intended for devices that can be suspended from a string. Devices which cannot be suspended from a string are not covered by this test method. The weight of the string from which the device is suspended during the test must be less than 1% of the weight of the tested device.

1.4 This test method shall be carried out in a horizontal bore MR system with a static magnetic field oriented horizontally and parallel to the MR system bore.

Extent of Recognition

Complete standard

Rationale for Recognition

This standard is relevant to medical devices and is recognized on its scientific and technical merit and/or because it supports existing regulatory policies.

Relevant FDA Guidance and/or Supportive Publications*

Guidance for Industry and Food and Drug Administration Staff: Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, Issued May 2021

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices - Guidance for Industry and Food and Drug Administration Staff, issued September 2018.

FDA Technical Contact

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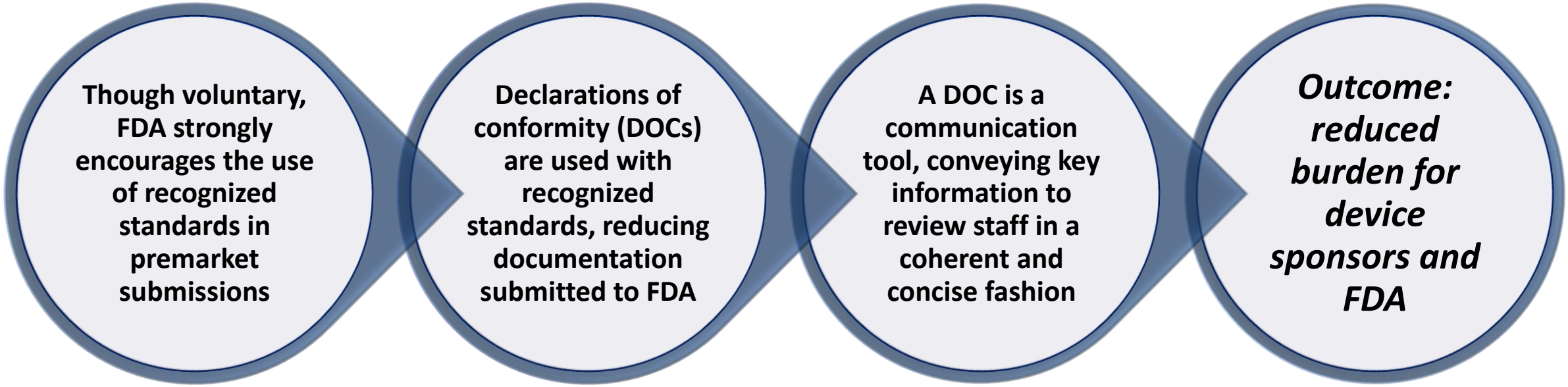
ASTM F2052-21

Standard Test Method for Measurement of Magnetically Induced Displacement Force

- Note extent of recognition
- Note rationale for recognition
- Note other relevant documents
- Note FDA contacts

Using FDA-Recognized Standards

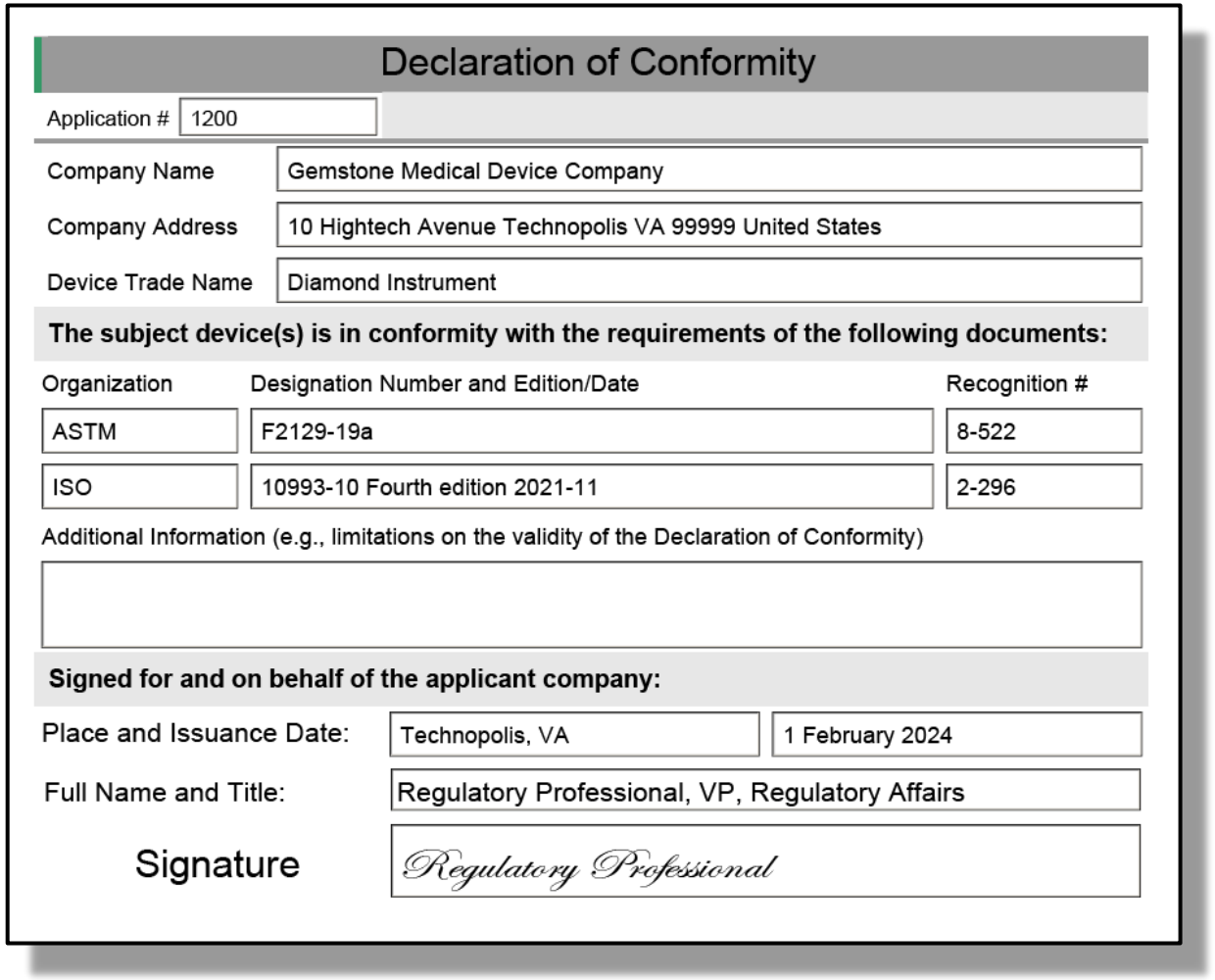


Using Consensus Standards

- Voluntary
  - Only mandatory if cited in regulation ('incorporated by reference')
- In any type of premarket submission
- With a DOC (recognized standards only) or 'General Use' (any standards, recognized or not)

What is a Declaration of Conformity (DOC)?

- Attestation that the device conforms with the cited FDA-recognized standard
  - All normative requirements are met
  - All testing has been conducted
- If the manufacturer declares conformity with a recognized standard, a DOC and any associated supporting documentation accompanies the submission
- DOCs generally reduce the documentation needed to be included – ***and reviewed*** - in a submission
- eSTAR makes this easy



Declaration of Conformity

Application #	1200
Company Name	Gemstone Medical Device Company
Company Address	10 Hightech Avenue Technopolis VA 99999 United States
Device Trade Name	Diamond Instrument

The subject device(s) is in conformity with the requirements of the following documents:

Organization	Designation Number and Edition/Date	Recognition #
ASTM	F2129-19a	8-522
ISO	10993-10 Fourth edition 2021-11	2-296

Additional Information (e.g., limitations on the validity of the Declaration of Conformity)

Signed for and on behalf of the applicant company:

Place and Issuance Date:	Technopolis, VA	1 February 2024
Full Name and Title:	Regulatory Professional, VP, Regulatory Affairs	
Signature	*Regulatory Professional*	

Above image is a DOC from eSTAR

Supporting Documentation

- Information that supports the declaration of conformity
- Needed when:
  - Standard does not feature test methods or acceptance criteria
  - Standard allows choices, e.g., for methods or criteria
- The ultimate goal: a standard that clearly outlines expectations for manufacturers and regulators

DOC Supporting Documentation

If the standard has:		This supporting documentation is needed:			
Test Method	Acceptance Criteria	Test Methods/ Protocols	Acceptance Criteria	Summary Results*	Complete Test Report
No	No	X	X	X	X
No	Yes	X		X	
Yes	No		X	X	
Yes	Yes				

*Note: There may be instances in which FDA needs additional information even if methods and criteria are included.

‘General Use’ of Standards

Choose ‘General Use’ when citing:

- Non-recognized standards
- A recognized standard without submitting a DOC (not recommended)
- A recognized standard where deviations have been made to the methodology

**** Complete test reports should be submitted - *and will be reviewed* - for ‘General Use’ ****

Summary:

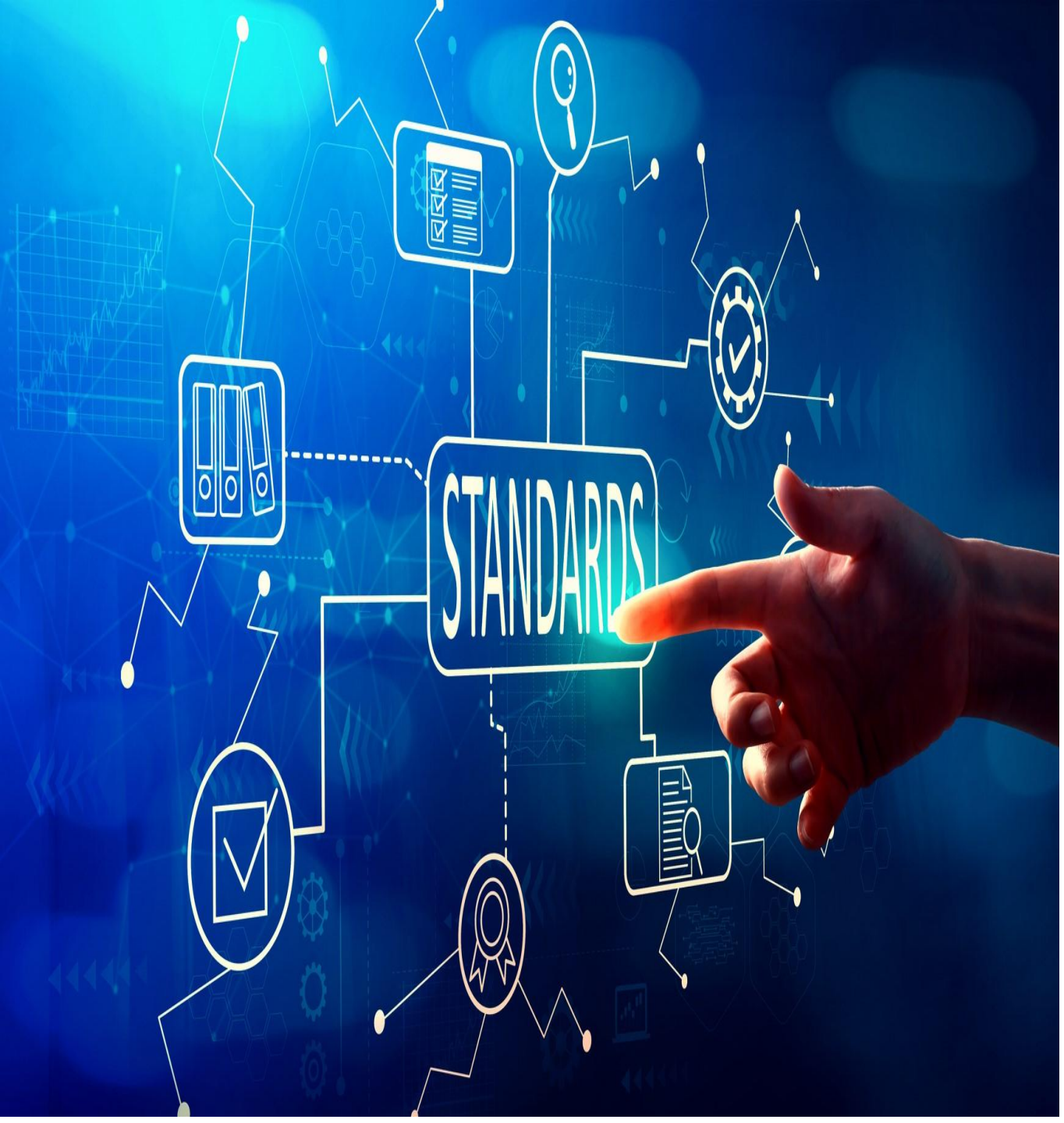
Using standards in submissions

- Submission cites standards used
  - Recognized standards with DOC and associated supporting documentation
  - General use (Always with a complete test report)
    - Recognized standard with or without modifications
    - Non-recognized standard with complete test report

Summary:

Putting Standards to Work

- Ultimate Goal: Reduce burden in getting safe and effective devices to patients
- Standards leverage expertise of entire medical device community
- Standards support global harmonization
- CDRH strongly encourages use of standards in submissions
- Formal recognition programs are not the only way regulators can use standards



Future

- Optimizing Standards for Regulatory Purposes Initiative
  - Improving test method and report content in standards
- Standards-driven international harmonization
- Capacity-building with international consensus standards
- Fewer ‘national’ standards

Greater reliance upon consensus standards to reduce burden and enhance quality

QUESTION AND ANSWER SESSION

RESOURCES

Industry Updates and Education

1. **CDRH New**
   - Sign up at: https://www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-email-lists
2. **CDRH Learn: Multi-Media Industry Education**
   - Videos, audio recordings, power point presentations, software-based "how to" modules
   - www.fda.gov/CDRHLearn
3. **Device Advice: Text-Based Education**
   - Comprehensive regulatory information on premarket and postmarket topics
   - www.fda.gov/DeviceAdvice
4. **Division of Industry and Consumer Education (DICE)**
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100
   - Web: www.fda.gov/DICE
5. **eSTAR Program**
   - https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program?utm_medium=email&utm_source=govdelivery

FDA Standards Resources

- **Division of Standards and Conformity Assessment**
  www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#intro

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

- **Email us at: CDRHStandardsStaff@fda.hhs.gov**

Relevant Guidances

- **Recognition and Withdrawal of Voluntary Consensus Standards guidance**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards
- **Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices guidance**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices
- **Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff**
  https://www.fda.gov/media/113230/download

ASCA Resources

- **ASCA web page**
  www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca
- **ASCA program guidance**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program
- **ASCA Standards-specific guidances**
  - **Basic Safety and Essential Performance standards-specific guidance:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and
  - **Biocompatibility standards-specific guidance:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme
- **Ask ASCA! ASCA@FDA.HHS.GOV**

ASCA Draft Guidances

- **Draft ASCA Program Guidance:**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-program

- **Draft ASCA Biocompatibility Guidance:**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme-0

- **Draft ASCA Basic Safety and EP Guidance:**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and-0

- **Docket for Commenting:**
  https://www.regulations.gov/docket/FDA-2019-D-3805/document

Additional Resources

- **ASCA-accredited TL List**
  https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/asca-accredited-testing-laboratories.cfm

- **Withdrawn ASCA TLs**
  https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/withdrawn-asca-testing-laboratories.cfm

- **Notifications on Data Integrity – Medical Devices**
  https://www.fda.gov/medical-devices/industry-medical-devices/notifications-data-integrity-medical-devices

- **MDUFA VI**
  https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/medical-device-user-fee-amendments-2028-mdufa-vi

FDA U.S. FOOD & DRUG + Devices
ADMINISTRATION