U.S. FOOD & DRUG ADMINISTRATION

Standard Material Test Methods for Medical Device Development

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PERU Workshop on Medical Device Regulation and Standards: Policy and Technical Aspects

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Outline

- Why are standards important to CDRH?
- Material Test Methods Standards
- Developing ASTM standards: Write the method and then test it
  - MRI
  - Pitting Corrosion
  - Bone Cement

Why are Standards Important to CDRH?

- **Medical Device Amendments of 1976**
  - **FD&C Act section 514 (21 U.S. Code 360d.)**
- **CDRH was a leader in use of Standards**
- **Safe Medical Device Act of 1990**
  - **Promulgation of mandatory standards at the Agency's discretion**
- **FDA Modernization Act of 1997**
  - **Revised Section 514(c)**
  - **Added ability to formally recognize a standard, "all or in part"**
  - **Added the ability to accept a formal Declaration of Conformity**

US National Strategy

- **Passage of the National Technology Transfer and Advancement Act (NTTAA) of 1995**
- **Signed into law March 7, 1996**
- **Grew out DoD's experience of relying more on voluntary consensus standards and less on Military Specifications (MIL SPECs)**

NTTA Objective

- **National Technology Transfer and Advancement Act (NTTAA) P.L. 104 – 113**

- **…Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.**

- **…Federal agencies and departments shall consult [and "participate"] with voluntary, private sector, consensus standards bodies…**

OMB Circular A-119

- **Sets forth requirements for Agency participation in use & development of voluntary consensus standards**
- **Sets forth requirements for incorporation of standards into Agency regulations**
- **Goals:**
  - **Eliminate Government costs**
  - **Provide incentives that serve national needs**
  - **Encourage long-term growth for the US**
  - **Promote economic competition**

FDA & Standards

- **21 CFR 10.95, Participation in outside standard-setting activities**
- **FDA Policy regarding the development and use of standards with respect to international harmonization of regulatory requirements and guidelines, 60 FR 53078 (Oct. 11, 1995).**
- **FDA Staff Manual Guide (SMG, adopted March 2007)**

FDA SMG 9100.1

- Recognize by reference either in its entirety or in part standards developed by SDOs
- FDA will preferentially use internationally harmonized standards
- Guidances published by FDA will, wherever appropriate, reference standards
- FDA encourages sponsors of product applications and manufactures to cite standards
- FDA incorporates voluntary consensus standards
- We have partnered with ASTM for many years to develop consensus standards

Why are Standards Important to CDRH?

- **Standards help us accomplish our mission & attain our vision**
- **Mission – to protect and promote the public health**
  - **to assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products**
- **Vision – to assure that patients have access to high-quality, safe, and effective medical devices of public health importance**
- **Standards are developed with input from CDRH, Industry, Government**
  - **Leveraging knowledge of all stakeholders**
- **Allows everyone to use the same method**
  - **Efficient for Industry and CDRH reviewers**

Committee F04 Structure

- **F04.01 Division I - Resources**
- **F04.02 Division II - Orthopaedic Devices**
- **F04.03 Division III - Medical/Surgical Devices**
- **F04.04 Division IV - TEMPs**
- **F04.05 Division V - Computer Assisted Orthopaedic Surgical Systems**

Committee F04 Structure

- **F04.01: Division I on Resources - Terry Woods**
- **F04.11 on Polymeric Materials - Jon Moseley/Steve Kurtz**
- **F04.12 on Metallurgical Materials - Rod McMillan**
- **F04.13 on Ceramic Materials - Gary Fischman**
- **F04.15 on Material Test Methods - Terry Woods**
- **F04.16 on Biocompatibility - Anita Sawyer**

F04.15 Material Test Methods

- **Approximately 50 standards**
  - **5-10 under development**
- **Covering testing of materials (not specific devices)**
  - **Corrosion**
  - **MRI safety & compatibility**
  - **Cleanliness**
  - **UHMWPE & PAEK mechanical testing**
  - **Nitinol test methods**
  - **Bone Cement**
  - **Absorbable Polymers**
  - **Coatings**
  - **Biomechanics load measurement**
  - **Hydrogel mechanical testing**

Types of Standards

- **Guide —a compendium of information or series of options that does not recommend a specific course of action.**
  - **Increases awareness of information and approaches in a given subject area.**
- **Practice —a definitive set of instructions for performing one or more specific operations that does not produce a test result.**
  - **Examples include: application, assessment, cleaning, collection, decontamination, inspection, installation, preparation, sampling, screening, and training.**
- **Terminology standard —a document comprising definitions of terms; explanations of symbols, abbreviations, or acronyms.**

Types of Standards

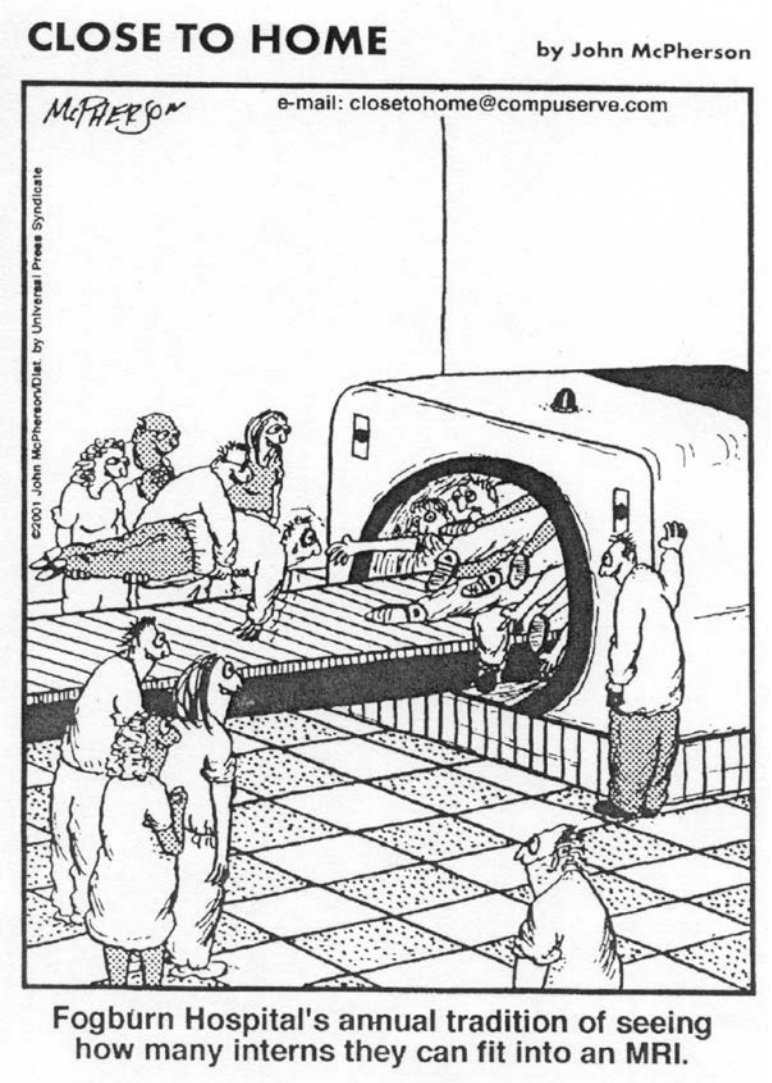
- **Specification —an explicit set of requirements to be satisfied by a material, product, system, or service.**
  - **Examples: requirements for physical, mechanical, or chemical properties, & safety, quality, or performance criteria. It identifies the test methods for determining whether each of the requirements is satisfied.**
- **Test method —a definitive procedure that produces a test result.**
  - **Examples: identification, measurement, and evaluation of one or more qualities, characteristics, or properties. A precision and bias statement shall be reported at the end of a test method.**

Developing ASTM Standards

- Write the method and then test it
- Interlaboratory studies – round robin testing
  - Testing the test method
  - Assessing within and between lab variability
- Examples
  - MRI
  - Pitting Corrosion
  - Bone Cement

MRI Example

- **MRI is an invaluable imaging tool**
- **There are some safety issues**



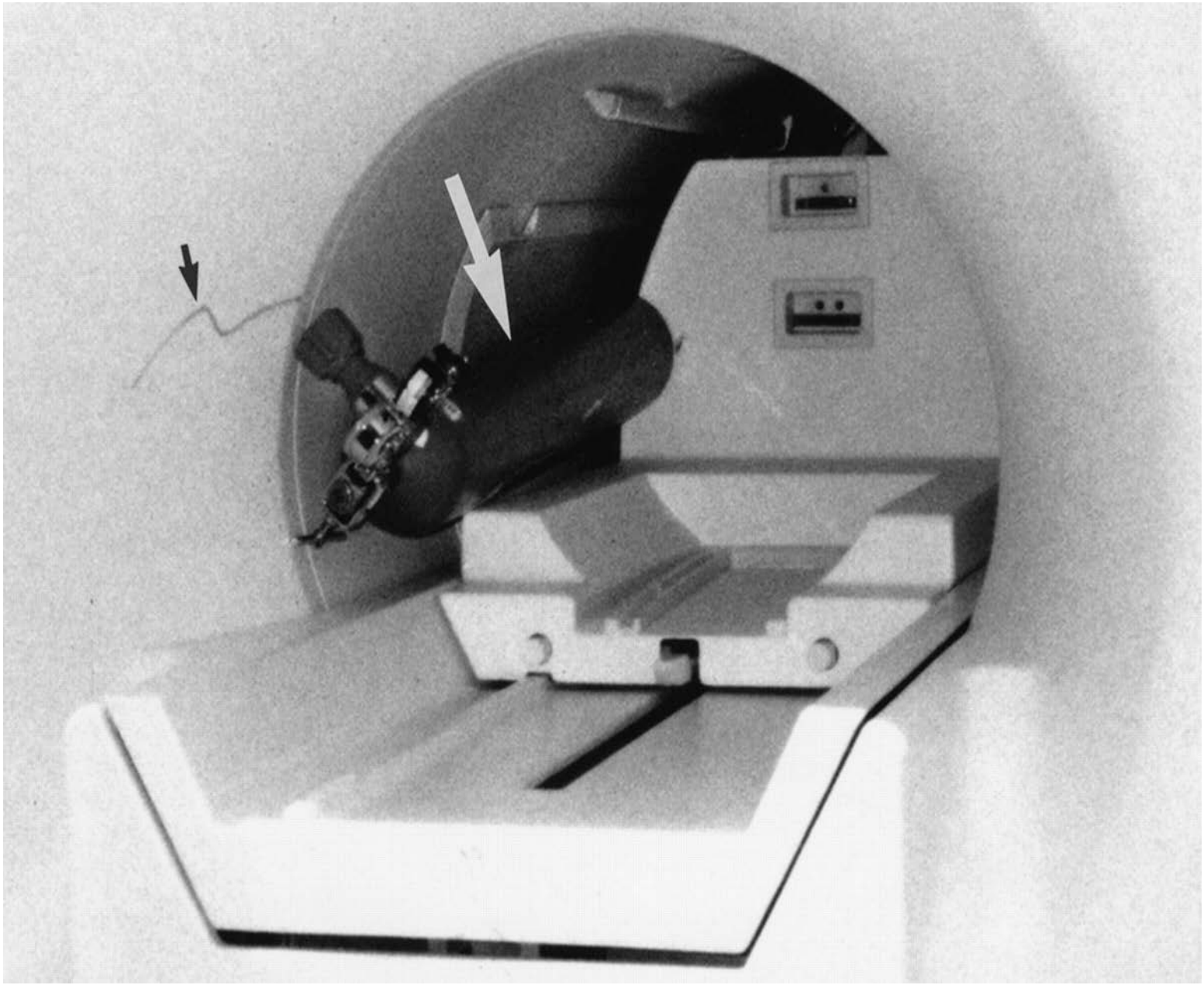
Introduction

- First MRI scanners approved in 1984
- Safety Concerns produced by
  - Large Static Field and Spatial Gradients, dB/dx

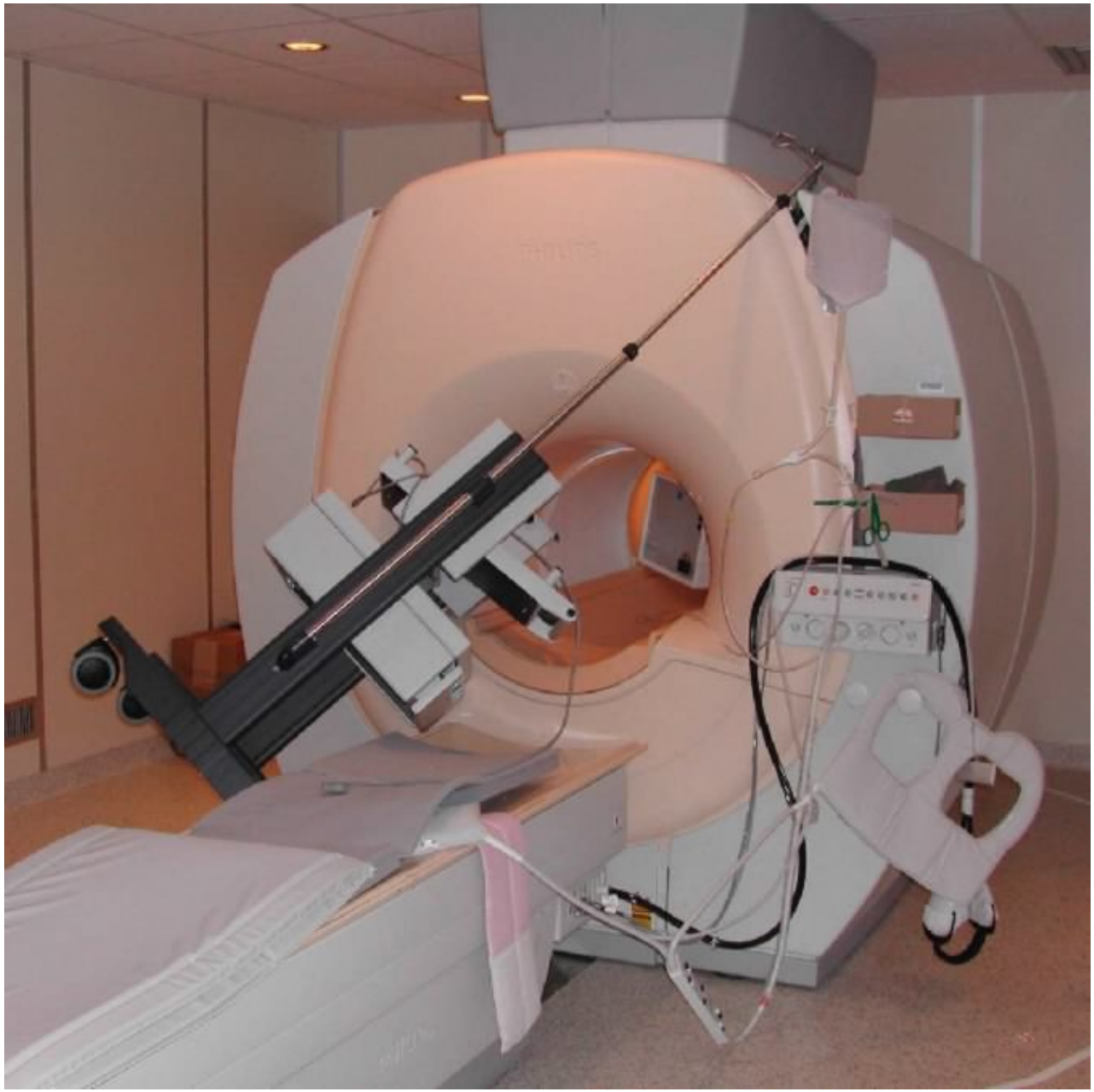
    Current clinical scanners: 3T, > 1500 gauss/cm

    >50,000 times Earth's magnetic field
  - Pulsed RF fields 128 MHz for 3T scanner

    used to elicit MR signal from tissue



Chaljub, et. al. AJR:177, July 2001



www.fda.gov

http://www.simplyphysics.com/flying_objects.html

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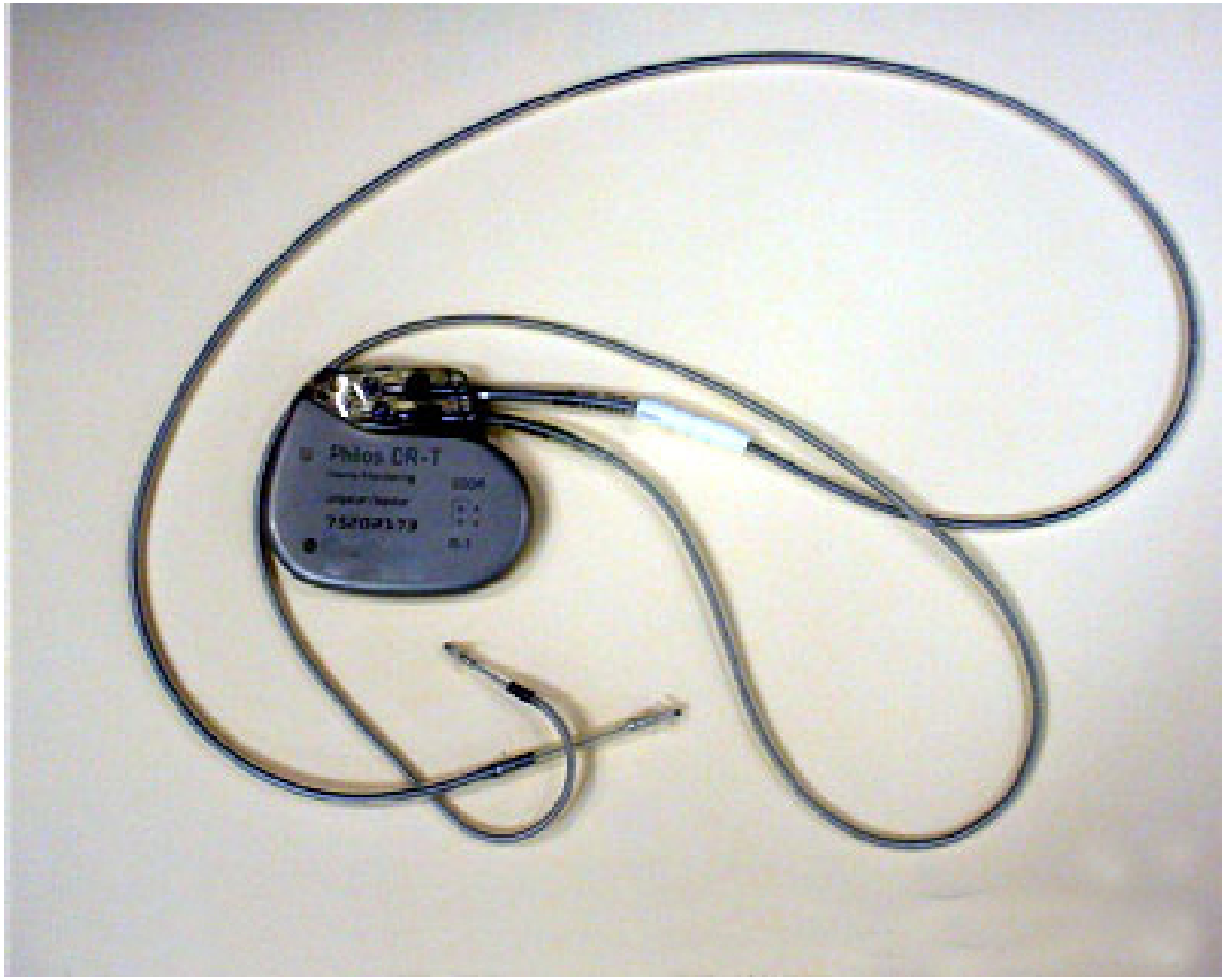
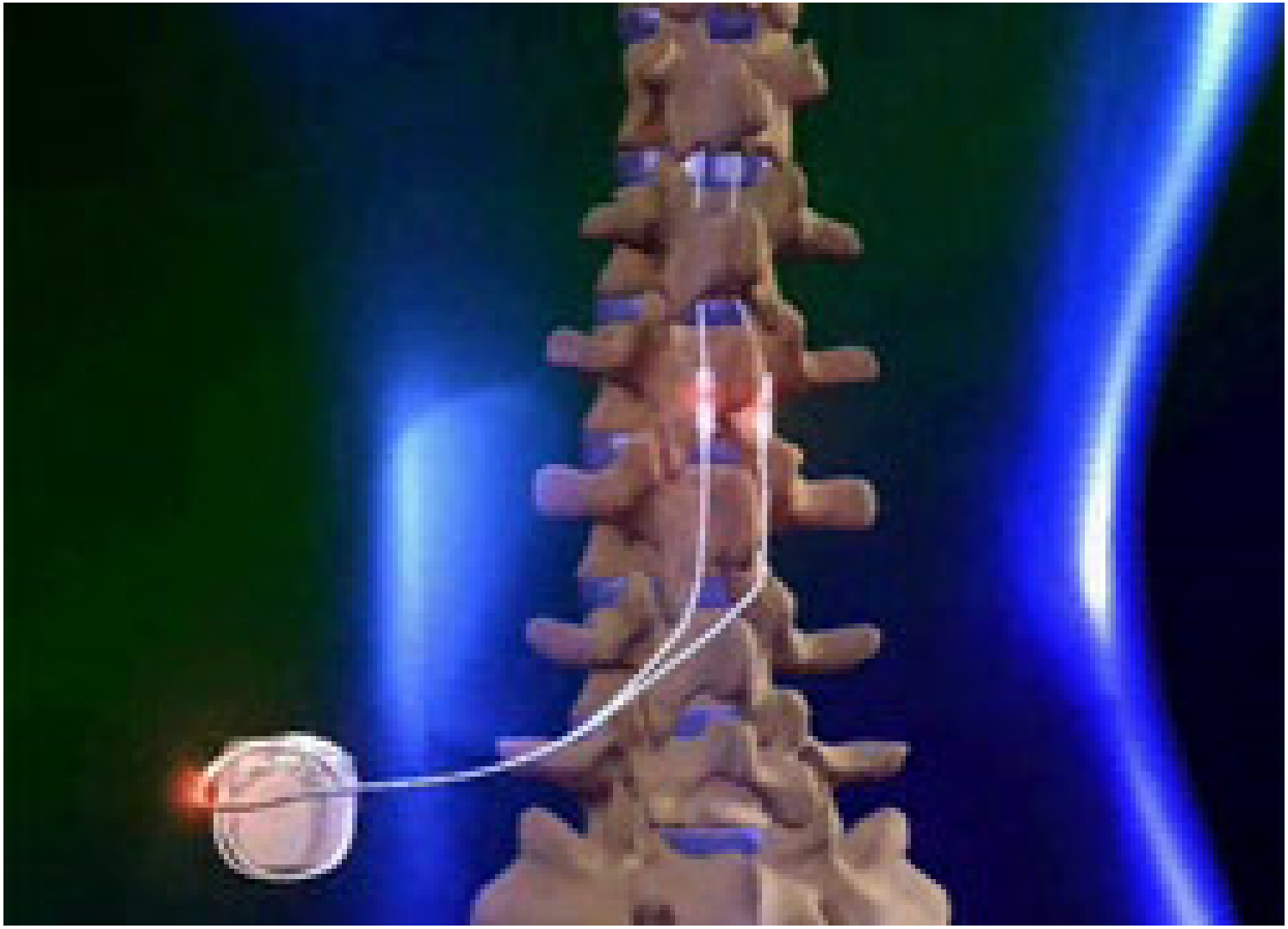
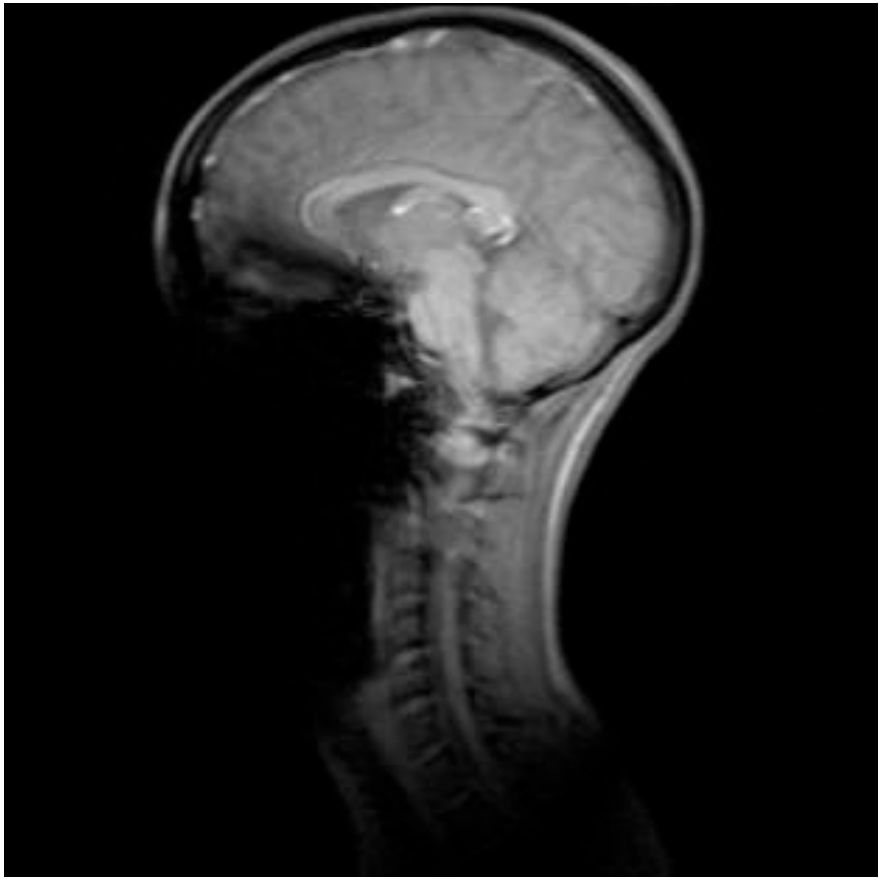


http://academic.evergreen.edu/l/lavie19/project02/images/dual-lead.jpg



http://www.accucarepainmedicine.com/video.htm



Patient without braces

Patient with full set of braces

http://www.shc.uiowa.edu/cohrcd/artifact.htm

3D gradient echo image of knee with implanted metal screw

3D fast spin echo sequence image of knee with implanted metal screw

http://www.shc.uiowa.edu/cohrcd/artifact.htm

Standards for Implants and Other Medical Devices

- FDA asks for information demonstrating MR safety for finished devices
- Needed test methods did not exist
- In 1997, FDA requested ASTM International consider developing MR safety/compatibility standards

Standards for Implants and Other Medical Devices

- **ASTM task group F04.15.11 on MR Safety and Compatibility of Materials and Medical Devices**
  - **Completed 5 standards addressing the principal issues that produce safety concerns for implants and other devices in the MR environment**

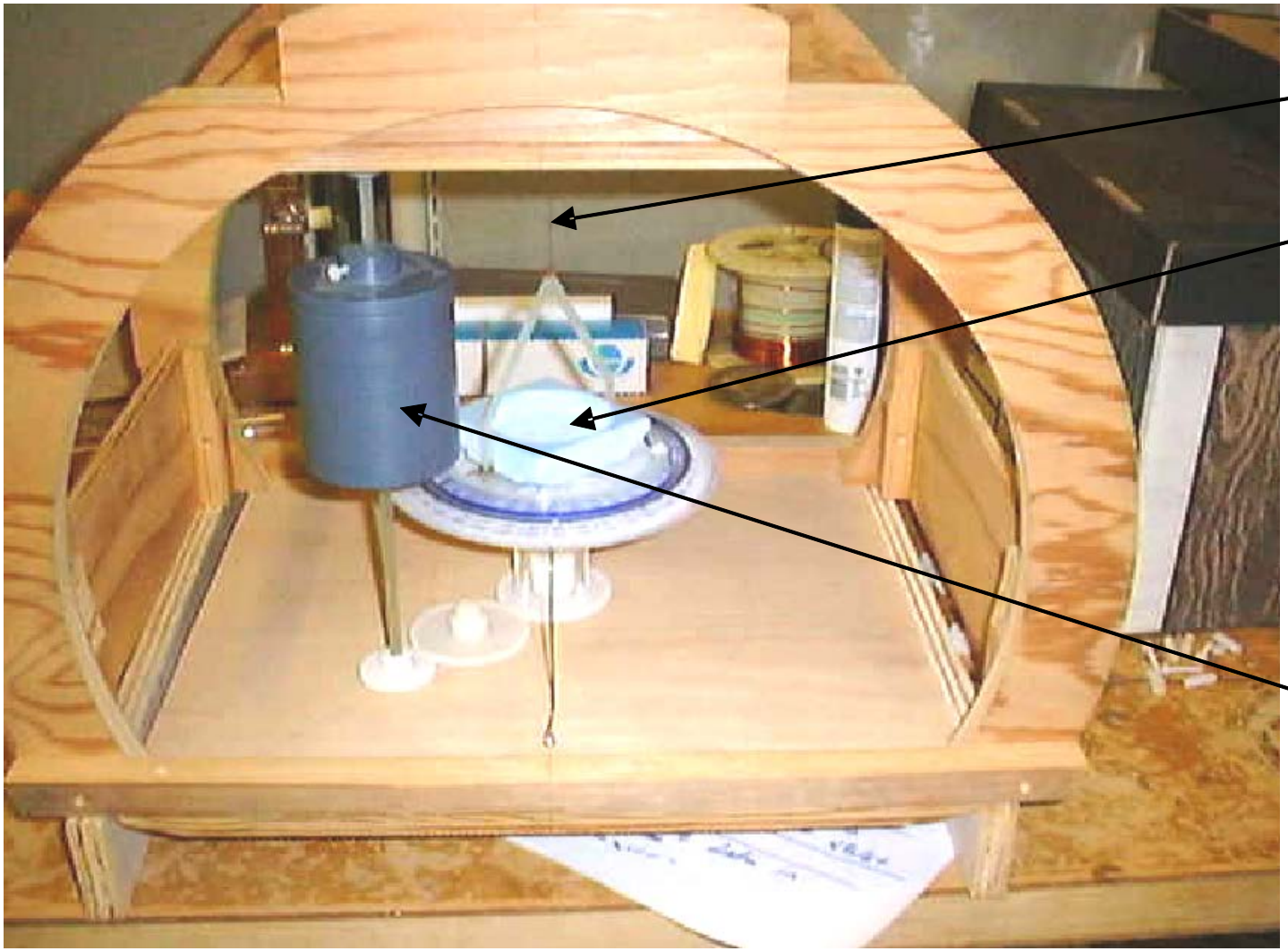
ASTM MR Test Methods

- **ASTM F2052 for Measurement of *Magnetically Induced Displacement Force* on Medical Devices in the MR Environment**
- **ASTM F2119 for Evaluation of *MR Image Artifacts* from Passive Implants**
- **ASTM F2182 for Measurement of Measurement of *Radio Frequency Induced Heating* Near Passive Implants During MRI**
- **ASTM F2213 for Measurement of *Magnetically Induced Torque* on Medical Devices in the MR Environment**
- **ASTM F2503 Standard Practice for *Marking Medical Devices and Other Items for Safety* in the Magnetic Resonance Environment**

ASTM F2052 - Test Method for Displacement Force

- **Interlaboratory study in progress**

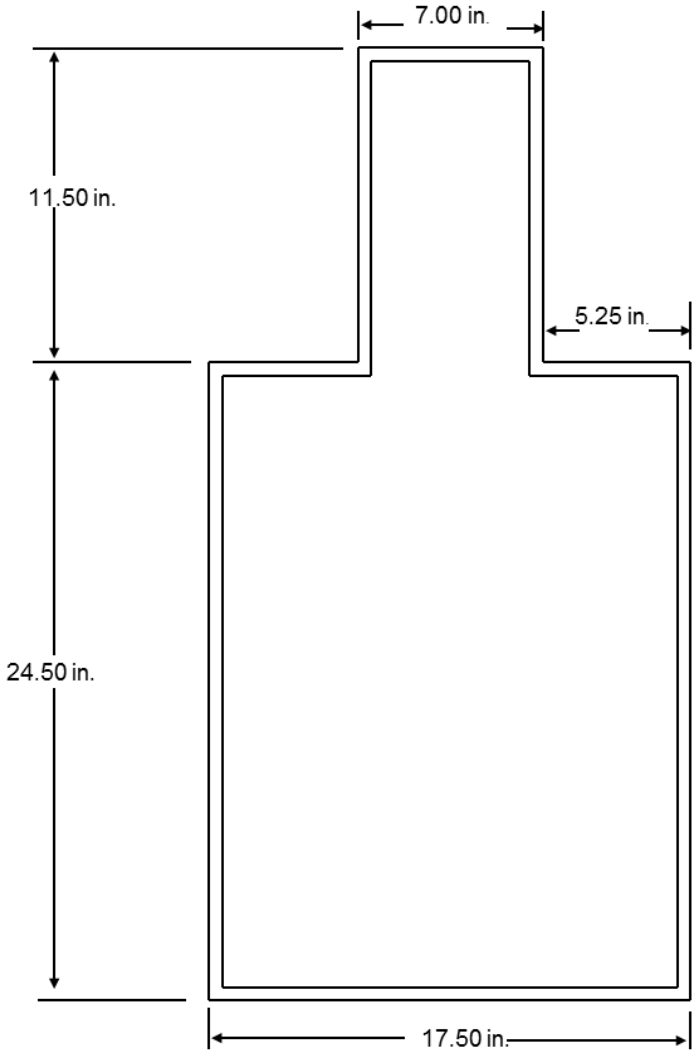
ASTM F2213 - Test Method for Torque



ASTM F2119 – Test Method for Image Artifact

- Defines standard sequences for determining artifact so the amount of artifact for different devices can be compared
- No acceptance criteria: Depending on region of interest, different amounts of artifact are acceptable
- In some cases, artifacts are desirable (biopsy needles, image guided surgery)

ASTM F2182 - Measurement of RF Induced Heating near Passive Implants



- **Place device in gelled saline phantom**
- **Subject to RF field and measure worst case temperature rise during scan**

ASTM F2503 - Practice for Marking Items for Safety in MRI

- **Intent:**
  - **TO PREVENT MR RELATED ACCIDENTS**
  - **To introduce terms and MR icons consistent with international safety signs**
- **MR Safe**

- **MR Conditional**

- **MR Unsafe**

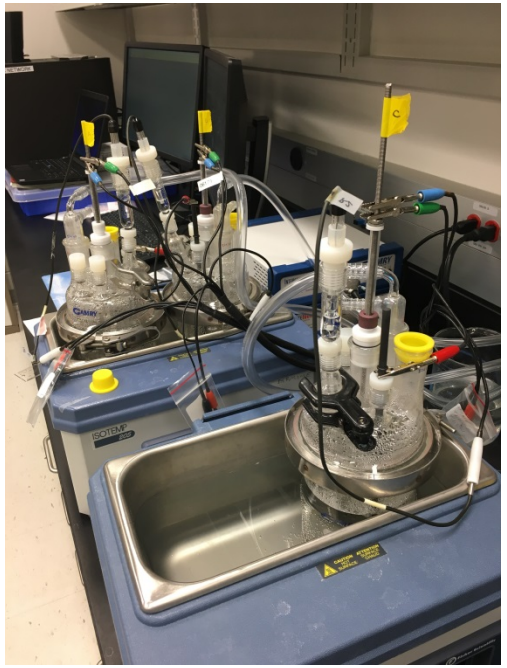
Pitting Corrosion Example

Implants are subject to corrosion

- **In the 1990s Nitinol use in implants was increasing**
- **CDRH labs noticed poor corrosion behavior for some devices**
- **No standardized test method existed**

Pitting Corrosion Example

- **Drafted test method for pitting corrosion of small implants**
- **Worked with industry & universities to develop & test the method**



Designation: F2129 – 15

Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices[1]

This standard is issued under the fixed designation F2129; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method assesses the corrosion susceptibility of

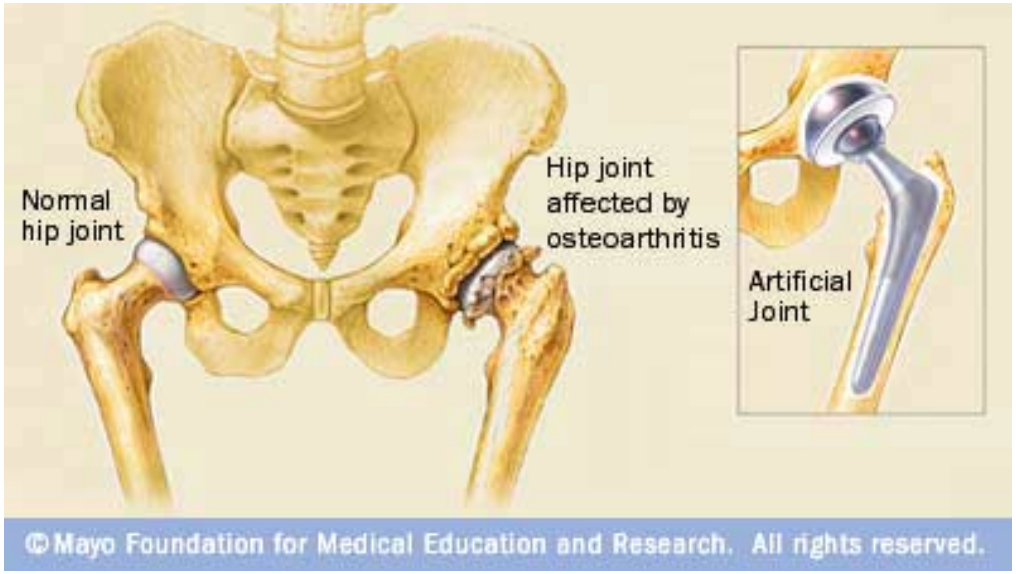
2. Referenced Documents

2.1 *ASTM Standards:*[2]

Bone Cement Example

What is Bone Cement?

- PMMA material used for over 50 years to fix joint implants to living bone
- ~750,000 hip & knee replacements/year



Fatigue Testing of Bone Cement

- **Fatigue failures happen**
- **No standard test**
- **We helped write a test method**
- **Participated in interlaboratory study to help test the test method**

Designation: F2118 – 14

Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials[1]

This standard is issued under the fixed designation F2118; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method describes test procedures for evaluating the constant amplitude, uniaxial, tension-compression uni-

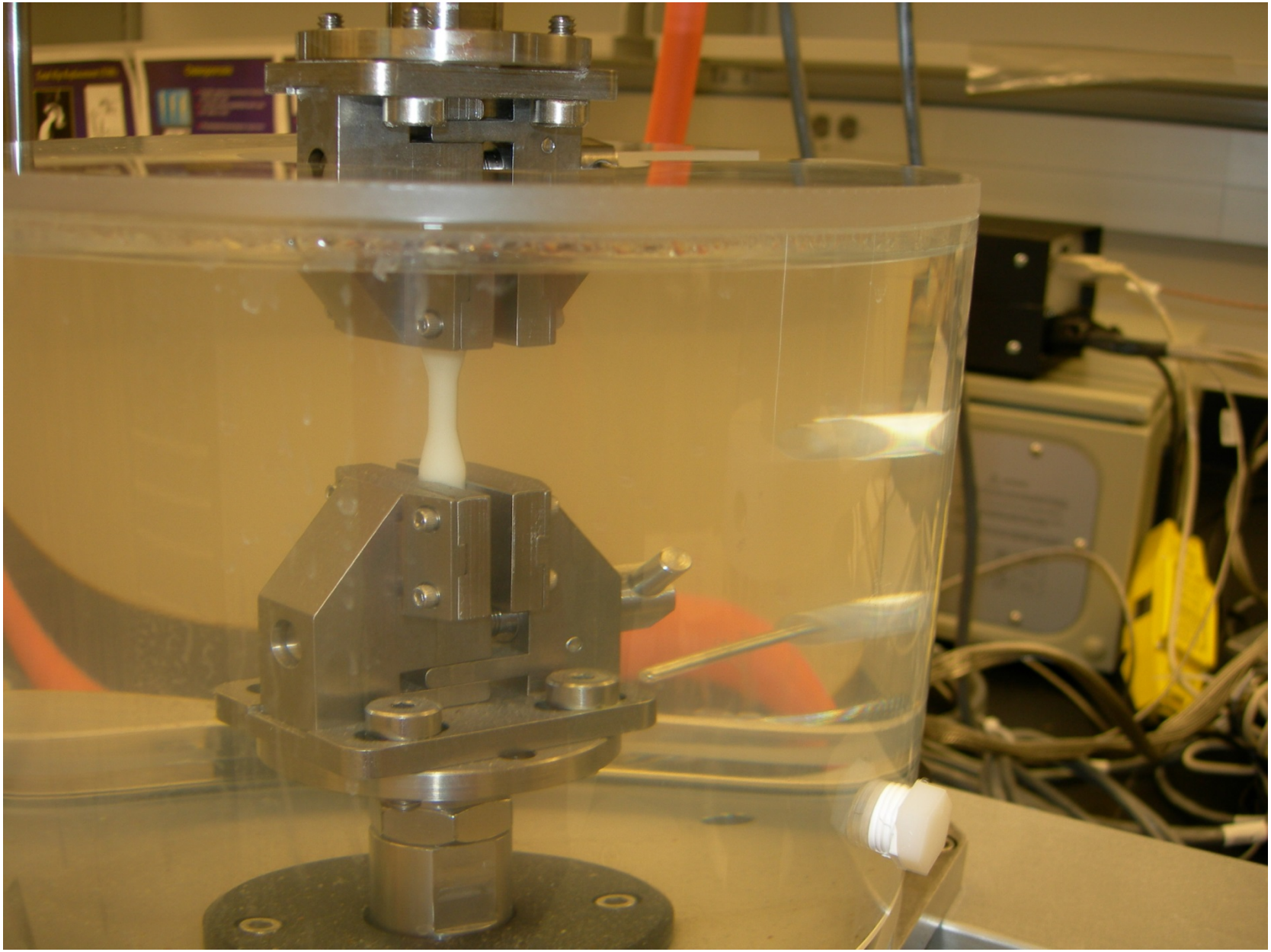
F451 Specification for Acrylic Bone Cement

2.2 *ISO Standard:*

ISO 16402 Flexural Fatigue Testing of Acrylic Resin Cements Used in Orthopedics[3]

Interlaboratory Study

- Make bone cement fatigue specimens
- Set up testing machine and fixtures
- Perform testing using the method

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Summary

- Why are standards important to CDRH?
- Material test methods standards
- Developing ASTM standards: Write the method and then test it
  - MRI
  - Pitting Corrosion
  - Bone Cement

Thank You!