

A Workshop on

Measurement Methods for Evaluation of the Reliability of Active Implantable Medical Devices

October 3–4, 2005

**Lecture Room B
Administration Building, Building 101
National Institute of Standards and Technology
Gaithersburg, MD 20899**

Conference Chairperson

**William F. Regnault
U.S. Food and Drug Administration**

Conference Co-chairperson

**Elizabeth S. Drexler
Materials Reliability Division
National Institute of Standards and Technology**

Conference Co-chairperson

**John A. Tesk
Biomedical Materials and Devices Consulting**

Sponsored by:

**US Food and Drug Administration (FDA) <http://www.fda.gov/>
Center for Devices and Radiological Health <http://www.fda.gov/cdrh/>
National Institute of Standards and Technology (NIST) <http://www.nist.gov/>
Materials Science & Engineering Laboratory <http://www.msel.nist.gov/>
Materials Reliability Division <http://www.boulder.nist.gov/div853/>
Polymers Division <http://polymers.msel.nist.gov/>
Manufacturing Engineering Laboratory <http://www.mel.nist.gov/>**

**With cooperation of: The American Society for Testing and Materials International (ASTM)
<http://www.astm.org/>**

**Pre-registration is required, on-site registration is not available.
To pre-register go to: https://rproxy.nist.gov/CRS/conf_ext.cfm?conf_id=1485**

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Agenda

October 3, Day 1

8:00 AM Registration & Continental Breakfast
8:55 AM **Introductions, Moderator, John A. Tesk**
9:00 AM Welcome to the Workshop, NIST & the FDA Rich Kayser NIST
9:10 AM NIST & Biomaterials Lori Henderson NIST
9:20 AM Introduction to the Workshop Issues William F. Regnault FDA

Plenary Sessions I, II & III Moderator, William F. Regnault, FDA

9:35 AM **Plenary Session I**
9:35 AM Patient Perceptions leading to Explantation James Kane FDA
10:00 AM Post-Market Regulation of Medical Devices Betty Collins FDA
10:25 AM GMP Regulations and Standards Jan Welch FDA
10:45 AM **BREAK**
11:00 AM **Plenary Session II** – Designing for Intended Use and Reliability Ali Mosleh U MD
11:30 AM **Plenary Session III** – MIL-STDS and Consensus Standards – Their Utility and their
Inference for Device Reliability
11:30 AM What Standards are Needed? Celeste Null Intel
12:00 AM Issues Surrounding the Use of Standards and Test Methods Open Discussion

12:30 PM **Lunch**, NIST Cafeteria

Working Sessions I & II Moderator, Elizabeth S. Drexler, NIST

1:30 PM **Working Session I**–Plausible Mechanisms for Failure: Mechanisms inside the Can
Session Chair: Jack Martinez NIST
1:30 PM Chip-level Design: Developments, Failure Mechanisms and Reliability Testing
Ken Rodbell IBM
1:50 PM Package-level Design: Developments, Failure Mechanisms and Reliability Testing
Robert Munroe (Retired) Motorola
2:10 PM Residual Gas Content and Ionic Content Bob Thomas (Retired) Rome AFB
2:30 PM Answers for Advice that the Workshop Seeks (see Session Chair's Guide)
3:30 PM **BREAK**
3:45 PM **Working Session II** – Plausible Mechanisms for Failure: Mechanisms Outside the Can
Session Chair: Michael Schen NIST
3:45 PM Corrosion Issues Robert Baboian RB Corrosion Service
4:05 PM Impact, Trauma, and Vibration Issues Dominick Hammerer Med-El
4:25 PM Answers for Advice that the Workshop Seeks (see Session Chair's Guide)
5:25 PM End of Day 1

OCTOBER 4, DAY 2

- 7:45 AM Registration & Continental Breakfast
- 8:45 AM **Working Sessions III & IV** Moderators; Elizabeth Drexler, NIST & John Tesk
Working Session III- Measurements for Accelerated Reliability Testing of Packages
Session Chair: Stan Purwin Johns Hopkins University Applied Physics Laboratory
- 8:45AM What are the Proper Accelerators for Predicting the Reliability of Active Implantable Medical Devices? Michael G. Pecht U MD
- 9:05 AM Answers for Advice that the Workshop Seeks (see Session Chair's Guide)
- 10:05 AM **BREAK**
- 10:20 AM **Working Session IV Medical System Concerns- Manufacturers' Perspectives**
Session Chair: Keith McLain Advanced Bionics Inc.
- 10:20 AM Medical System Concerns – A Device Manufacturer's Perspective David Erhart Medtronic
- 10:40 AM Self-Imposed Standards and Requirements for Demonstrating Safety and Reliability: A Device Manufacturer's Perspective Edmond Capcelea Cochlear Corporation
- 11:00 AM Answers for Advice that the Workshop Seeks (see Session Chair's Guide)
- 12:00 PM **Lunch**, NIST Cafeteria
- 1:00 PM **Drafting of Workshop Sessions I, II, III & IV Summaries**
(Dining Room B: *Session I, J. Martinez*, K. Rodbell, R. Munroe, B. Thomas;
Session II, M. Schen, R. Baboian, D. Hammerer)
(Room A149, Bldg 224, Polymers: *Session III, S. Purwin*, M. Pecht;
Session IV, K. McLain, D. Erhart, E. Capcelea)
- 1:00 PM **Working Session V, Reliability Issues for Future Devices**
Session Chair: John Suehle Moderator, Elizabeth Drexler NIST

(Session V is open to all except the previous session chairs and presenters from their sessions who wish to work with their session chairs on developing Summary Recommendations)

- 02:15 PM **Conclusion and Summary Recommendations** Moderator, W. F. Regnault, FDA
Who is to do what?
Where is the work to be done?
How is the work to be accomplished?

Is there a need for a follow-up workshop or symposium?

3:00 PM: **End of Workshop**

Planning Committee

- William F. Regnault,..... Center for Devices and Radiological Health, FDA &
Guest Researcher, NIST
- Elizabeth S. Drexler,..... Materials Reliability Division, NIST
- John A. Tesk,..... Consultant &
Guest Researcher, NIST
- Michael Schen,..... Advanced Technology Program, NIST

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- Tonya Icenogle,..... Center for Devices and Radiological Health, FDA &
Guest Researcher, NIST
- Tithi Dutta Roy,..... Postdoctoral Fellow, Biomaterials Group, Polymers Division