



# WHO SHOULD ATTEND?

Manufacturers, health care practitioners and regulatory professionals concerned about the cleaning, disinfection or sterilization of reusable medical devices will not want to miss this conference. It is geared to medical device manufacturing professionals including those in product design, research/development, regulatory affairs, and sterility assurance; managers and users of medical devices such as clinical and biomedical engineers and technicians, nurses, physicians, regulatory personnel and infection control professionals.

# DAY ONE

April 9, 1996

7:30-8:30 am

Registration and Continental Breakfast

8:30-8:45 am

Introduction and Welcome

Virginia Chamberlain, PhD

8:45-9:50 am

## GENERAL OVERVIEW

Principles of Sterilization and Disinfection

Jan Schultz, RN, MSN

Review of Hospital Infections Associated with Device Reprocessing

William R. Jarvis, MD

Adverse Events: Experience from the FDA's Medical Device Reporting, Product Problem Reporting and MedWatch Programs

Sharon Dillard, MS

9:50-10:10 am: BREAK

10:10-11:10 am

## GENERAL OVERVIEW OF REPROCESSING

Co-Chairs: Zoe Aler, RN, Charlie Hancock and Jack Scoville

Common Hospital Cleaning/Decontamination Agents and Procedures

Betty Strickland, RN

Understanding Chemical Disinfection

Susan Springthorpe, PhD

Sterilization

Patrick McCormick, PhD

11:10-12:15 pm

## THE CLINICAL PERSPECTIVE: REPROCESSING PROBLEMS AND SOLUTIONS

Co-Chairs: Marimargaret Reichert, RN, MA and Frank Stout, DDS

The Reprocessing of Endoscopes

Phyllis Sanford, LPN, CGN

The Reprocessing of Dental Devices

Irene Stavros

The Perioperative Environment

Marimargaret Reichert, RN, MA

12:15-1:15 pm LUNCHEON

1:15-3:00 pm

## STANDARDS, REGULATIONS AND GUIDELINES

Co-Chairs: Darlene McLeod, RN, MSN, CNOR, and Tim Ulatowski

FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities

Tim Ulatowski

FDA Good Manufacturing Practices (GMP) Requirements

Kimberly Trautman

National and International Standards and Resources

Bill Young

Perspectives from the Joint Commission on the Accreditation of Healthcare

Organizations: Association of Operating Room Nurses and Association for

Professionals in Infection Control and Epidemiology

Fran Koch, RN, MSN, CNOR and

Bill Rutala, PhD, MPH

3:00-3:15 pm: BREAK

3:15-4:30 pm

## DESIGN CONSIDERATIONS

Co-Chairs: Alden Kay and Barry Page

Use-Related, Physical and Total System Design Considerations

Steven Sosnowski

Materials Compatibility

Henry Hum, PhD

Rebuilding/Refurbishing Devices

Judith Hoyer

4:30-5:00 pm: SUMMATION

# HOW WILL I BENEFIT?

Participants will gain new insight into the principles of sterilization and disinfection; reprocessing techniques; hospital infections associated with reprocessed devices; standards, regulations and guidelines; design considerations; clinicians' expectations of device manufacturers; and the future of device reprocessing. Interactive breakout sessions will address reprocessing issues related to specific types of medical devices including endoscopes, dental devices, imaging and non-critical devices, orthopedic devices, cardiovascular devices and micro-instrumentation.

# DAY TWO

April 10, 1996

7:30-8:30 am

Registration and Continental Breakfast

8:30-9:45 am

## **MANUFACTURERS' RESPONSIBILITIES**

Co-Chairs: Bill Young and Bob Reich

Validation of Washing Procedures

Jim Whitbourne

Validation of Disinfection Procedures

Carolyn Kinsley

Validation of Sterilization Procedures

Phil Schneider

Regulatory Responsibility

Bill Young

9:45-10:00 am BREAK

10:00-12:00 noon

## **CONCURRENT BREAKOUT SESSIONS**

Endoscopes

Facilitators: Tim Ulatowski and Phyllis

Sanford, LPN, CGN

Dental Devices

Facilitators: Jack Scoville and Charlie

Hancock

Imaging and Non-Critical Devices

Facilitators: Jan Schultz, RN, MSN and

Virginia Chamberlain, PhD

Orthopedic Devices

Facilitators: Darlene McLeod, RN, MSN,

CNOR and Barry Page

Cardiovascular Devices

Facilitators: Marimargaret Reichert, RN,

MA and Bill Young

Micro-Instrumentation (including ENT and

Ophthalmology)

Facilitators: Zoe Aler, RN and Gary

Graham, PhD

12:00-1:00 pm LUNCHEON

1:00-2:00 pm

## **POSTER PRESENTATIONS**

Co-Chairs: Vicki Hitchins, PhD,

Jan Schultz, RN, MSN, Sharon Dillard, MS,

and Gary Graham, PhD

2:00-3:00 pm

## **REPORTS OF BREAKOUT SESSIONS**

3:00-3:15 pm BREAK

3:15-4:45 pm

## **THE FUTURE OF DEVICE REPROCESSING**

Co-Chairs: Virginia Chamberlain, PhD and

Ofelia Tablan, MD

Changes in Hospital Practice

Michelle Alfa, PhD, SCM (CCM)

Single-use Versus Reusable Devices

Rita McCormick, RN

Epidemiological Future-New Concerns About

Infections

Ofelia Tablan, MD

Changes in the Science of Sterilization and

Disinfection

Bob Morrissey, PhD

Regulatory Future-U.S. and Europe

Virginia Chamberlain, PhD and

Eammon Hoxey, PhD

4:45-5:00 pm

## **CLOSING PANEL/SUMMATION**

## **POSTER SESSIONS**

A limited number of scientific and technical poster presentations addressing the science of reprocessing reusable medical devices will be featured on the second day of the conference. Poster presentations will be selected from abstracts submitted prior to February 15, 1996. For additional information on the poster presentations contact Candace Kane at 703/525-4890, ext. 256.

## HOTEL

The conference hotel, Washington Hilton and Towers, 1919 Connecticut Avenue, N.W., Washington, DC is offering a special group rate of \$145 single and \$165 double guaranteed for AAMI registrants through March 15, 1996. To reserve a room, call hotel reservations at 202/797-5820 or fax your request to 202/797-5755. The main number at the hotel is 202/483-3000. When making your reservation, please identify yourself as an AAMI attendee.

## TRAVEL

Washington, DC, is served by National and Dulles International Airports, a newly renovated AMTRAK station, and a clean and efficient Metrorail system. The Washington Hilton is a few blocks from the Dupont Circle stop on the Washington Metrorail red line. For airline reservations and exclusive discounts for AAMI registrants call Connections, AAMI's official travel agency at 703/519-1700. When calling, please identify yourself as an AAMI attendee.

## SPEAKERS & PROGRAM ADVISORY COMMITTEE

- \*Zoe Aler, RN, Processing Manager, Union Memorial Hospital; Baltimore, MD
- \*Michelle Alfa, PhD, SCM (CCM), Clinical Microbiologist, Assistant Director, Department of Microbiology, St. Boniface General Hospital; Winnipeg, Manitoba, Canada
- \*Ann Baldwin, Health Industry Manufacturers Association; Washington, D.C.
- \*Carl Bruch, PhD, Consultant; Hudson, WI
- \*Ross Caputo, PhD, President, Abtox, Inc.; Mundelein, IL
- \*Virginia Chamberlain, PhD, Senior Quality Systems Associate, Biometric Research Institute, Inc.; Arlington, VA
- \*Sharon Dillard, MS, Office of Surveillance and Biometrics, Center for Devices and Radiological Health (CDRH), US Food and Drug Administration (FDA); Rockville, MD
- \*Michael Glade, MD, Representative, American Medical Association; Chicago, Illinois
- \*Anne Dixon, Joint Commission on the Accreditation of Healthcare Organizations; Oak Brook Terrace, IL
- \*Steve Goldstine, DDS, PhD, R&D, Medical Instrument Division, Olympus America, Inc.; Melville, NY
- \*Barbara Goodman, RN, CNOR, James L. Kerman Hospital; Baltimore, MD
- \*Gary Graham, PhD, Vice President, Abtox, Inc.; Cary, NC
- \*Charlie Hancock, Senior Manager, Regulatory Compliance, MDT, Rochester, NY
- \*Vicki Hitchins, PhD, Center for Devices and Radiological Health (CDRH), US Food and Drug Administration (FDA); Rockville, MD
- \*Eammon Hoxey, PhD, Device Technology and Safety, Medical Devices Agency, Department of Health; London, United Kingdom
- \*Judith Hoyer, Director of New Business, Source Scientific, Inc.; Garden Grove, CA
- \*Henry Hui, PhD, Principal Research Scientist, Advance Sterilization Products, Division of Johnson & Johnson Medical; Irvine, CA
- \*William Jarvis, MD, Chief Investigation and Prevention Branch, Hospital Infections Program, Centers for Disease Control and Prevention; Atlanta, GA
- \*Alden Kay, Intramed Laboratories, Baxter Vascular Systems Division; San Diego, CA
- \*Carolyn Kinsley, Manager of Sterilization Sciences, Becton Dickinson Division; Franklin Lakes, NJ
- \*Anne Kobs, Associate Director, Joint Commission on the Accreditation of Healthcare Organizations; Oak Brook Terrace, IL
- \*Fran Koch, RN, MSN, CNOR, Patient Care Director, Operating Rooms, Presbyterian Hospital of Dallas; Dallas, TX
- \*Rita McCormick, RN, Senior Infection Control Practitioner, University of Wisconsin Hospital and Clinic; Madison, WI
- \*Paul Malchesky, Steris Corporation; Mentor, OH
- Patrick McCormick, PhD, Senior R&D Manager, MDT Biologic Co.; Rochester, NY
- \*Darlene McLeod, RN, MSN, CNOR, Clinical Specialist, Mt. Vernon Hospital; Alexandria, VA
- \*Candace McManus, Center for Devices and Radiological Health (CDRH), US Food and Drug Administration (FDA); Rockville, MD
- \*Chris Miller, DDS, Department of Oral Microbiology, Indiana University School of Dentistry; Indianapolis, IN
- Bob Morrissey, PhD, Corporate Director, Sterilization Science and Technology, Johnson & Johnson; New Brunswick, NJ
- \*Barry Page, Consultant; Garner, NC
- \*Bob Reich, President, Pharmaceutical Systems, Inc.; Mundelein, IL
- \*Marimargaret Reichert, RN, MA, Reichert Consulting; Olmsted Falls, OH
- Bill Rutala, PhD, MPH, Director, The University of North Carolina Hospitals Epidemiology, Occupational Health, and Safety Program; Chapel Hill, NC
- Phyllis Sanford, LPN, CGN, Sanford-Koenig and Associates, Medical Practice and Facility Planners; Cockeysville, MD
- Phil Schneider, Senior Specialist, Sterilization Products, 3M Healthcare; St. Paul, MN
- \*Jan Schultz, RN, MSN, Vice President, Professional Services, AMSCO International; Pittsburgh, PA
- \*Jack Scoville, Director, Regulatory Affairs, Cottrell, Ltd.; Englewood, CO
- Steven Sosnowski, Vice President, Research and Development, Baxter/Intramed Laboratories; San Diego, CA
- Susan Springthorpe, PhD, Research Associate, Department of Microbiology and Immunology, University of Ottawa; Ottawa, Ontario
- Irene Stavros, Registered Dental Hygienist; Miami, FL
- \*Frank Stout, DDS, University of Florida, College of Dentistry; Gainesville, FL
- Betty Strickland, RN, Materials Manager, Memorial Hospital System of Houston; Houston, TX
- \*Ofelia Tablan, MD, Medical Epidemiologist, Investigation and Prevention Branch, Hospital Infections Program, Centers for Disease Control and Prevention; Atlanta, GA
- Kimberly Trautman, Acting Chief, Cardiovascular Branch, Office of Compliance, US Food and Drug Administration (FDA); Rockville, MD
- \*Tim Ulatowski, Acting Director, Division of Dental Infection Control and General Hospital Devices, Office of Device Evaluation, US Food and Drug Administration (FDA); Rockville, MD
- Jim Whitbourne, President, Sterilization Technical Services; Rush, NY
- \*Thelma Wilcott, Manager, Corporate Sterilization Services, Becton Dickinson; Franklin Lakes, NJ
- \*Bill Young, Vice President, Sterility Assurance, Baxter Healthcare Corporation; Round Lake, IL

indicates program advisory committee members




**Designing, Testing &  
Labeling Reusable Medical  
Devices for Reprocessing in  
Healthcare Facilities**

**April 9-10, 1996  
Washington, DC**

**SIGN ME UP!**

Space is Limited. Register Early!

**Register in advance—it's faster and easier.**

-  Call 1-800/332-2264 or 703/525-4890, ext. 260 to register with a credit card.
-  Fax completed registration form and payment to 703/276-0793.
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AAMI, PO Box 2942, Merrifield, VA 22116-2942.

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**Registration Fees**

- Members of AAMI, HIMA, MDMA, APIC, AMA, AORN, Soc. for Biomaterials. .... \$475
- Registration **PLUS** AAMI Individual Membership: ..... \$615
- Non-member: ..... \$625
- FDA/Government Employees: ..... \$140

Subtotal	\$ _____
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**Payment Method**

- Payment enclosed (check or money order in U.S. dollars payable to AAMI)
- Bill me (a \$25 billing fee will be added. Purchase Order required)
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Photocopy form for multiple registrations. All registrations must be prepaid by credit card or check prior to the conference. All refunds will have a \$50 fee deducted. All refund requests **MUST** be in writing. **No refunds within two weeks of the conference date**

While contributions or gifts to AAMI are not tax deductible as charitable contributions for federal income tax purposes, they may be tax deductible under other provisions of the Internal Revenue Code.

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**AAMI**

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