

## Curriculum Vitae - Bruce H. Barkalow, Ph.D., PE, CCE

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### Educational Background:

<b>Ph.D.</b> Biomedical Engineering	University of Wyoming Laramie, Wyoming	1972
<b>M.S.</b> Physics	Michigan Technological University Houghton, Michigan	1967
<b>B.S.</b> Applied Physics	Michigan Technological University Houghton, Michigan	1964
Associate in Science	Grand Rapids Junior College Grand Rapids, Michigan	1962

### Licenses and Certification:

[Registered Engineer](#) – Michigan  
[Registered Electrical Engineer](#) – California  
[Registered Safety Engineer](#) (Medical Instrumentation) – California  
[Certified in Clinical Engineering](#) – Healthcare Technology Foundation

### Professional Experience:

**08/2012 to present:** [B. H. Barkalow & Associates, LLC](#), Newaygo, MI. **Senior Clinical Engineering Expert Consultant** for hospitals, medical device companies, legal firms, insurance carriers, Federal Food and Drug Administration (FDA), and other biomedical engineering consultants or firms. Work experience includes the performance of independent expert medical technology related accident or incident investigations in areas such as anesthesia, physiological monitoring, life support ventilation, defibrillators, pacemakers, hemodialysis, peritoneal dialysis, implanted orthopedic devices, infusion pump support, radiology, hospital electrical power distribution, fires, and burn injuries. More specifically for client hospitals, services include: performing consulting projects related to biomedical and clinical engineering program quality assurance; vendor maintenance service contract review; establishment of hospital based biomedical departments; contract management of biomedical engineering (BME) departments; biomedical engineering support to hospital architects for facility design or renovations; strategic medical technology and capital budget planning; medical equipment selection; custom medical instrumentation design or modification; provision or establishment of computerized medical device control programs for preventive maintenance and maintenance; assistance in biomedical technical labor contract negotiations; hospital advocacy for state law changes regarding technology; [The Joint Commission](#) (TJC) compliance reviews and pre-inspection surveys, TJC QA procedures related to medical technology; nursing education related to medical equipment safety and usage; electrical power distribution systems for electrically sensitive areas; medical gas delivery systems, dialysis systems; surgical laser technology programs; establishment of percutaneous transluminal angioplasty programs; selection, acquisition, and implementation of physiological monitoring systems; and assistance in hospital risk management as related to applied medical technology. Industrial client projects include product development, FDA GMP compliance, 510(k) submissions, interface to FDA to resolve issues, risk management, user training programs, and assistance in medical device market feasibility studies. Work for FDA has included expert review of FDA inspector 483 reports and consultation to FDA regarding contemplated action against medical device manufacturers. Experienced in fire investigations related to medical devices and in human burn injuries as caused by hot water or other sources. Worked in technical support of the Sutter Community Hospital Dialysis Unit for user training, maintenance and preventive maintenance for hemodialysis and peritoneal dialysis

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devices. Investigated four dialysis unit adverse outcomes and one for Joint Commission non-compliance. The events included issues of water treatment, disconnection, dialysate contamination, manufacturer FDA compliance, state standards for operation of the dialysis unit, system alarms and dialysis related patient monitors. Qualified as an expert and performed forensic, confidential investigations with reports and one deposition. Have studied principles of dialysis including semipermeable membrane technology.

**08/2014 – 12/31/14:** *Adjunct professor of Biomedical Engineering, Michigan Technological University, Houghton, MI.* Contracted to teach senior/graduate course, “Medical Devices.” One of three professors in a team.

**09/2006 to 05/2011:** *Michigan Instruments, Inc., Grand Rapids, MI. President.* Medical device manufacturer of an FDA Class III mechanical cardiopulmonary resuscitators and calibrated training/test lungs. Duties included overall management, and compliance with FDA Good Manufacturing Practices. Served as the person behalf of the company who is most responsible to the FDA.

**06/1986 to 08/2012:** *B. H. Barkalow, P.C., Newaygo, MI. President.* Provided biomedical engineering consulting services for hospitals, medical device companies, legal firms, insurance carriers, Federal Food and Drug Administration (FDA), and other biomedical engineering consultants or firms.

**01/1984 to 06/1986:** *Harvard Medical Center (HMC), Boston, MA. Biomedical Engineer Consultant.* Selected as the expert consultant biomedical engineer for HMC under a Federal program (JECOR) to work on assignment at King Faisal University (KFU), Eastern Province, Saudi Arabia. Established a comprehensive biomedical engineering support service and designed a degree program in Clinical Engineering for the College of Medicine and the associated 450-bed teaching hospital. Served as a liaison between KFU and HMC to transfer medical technology and resources to Saudi Arabia. In addition, served as the technical member of the Medical Research Advisory Committee to the Dean of the Medical College.

**03/1977 to 01/1984:** *Integral BioMedical Engineering, Inc., Sacramento, CA. President and Senior Biomedical Engineering Consultant.* Consulting firm serving primarily West Coast hospitals, clinics, physician groups, legal firms, universities, federal and state agencies. In addition to managing the consulting firm, technical assignments included: establishment of hospital biomedical departments; contract management of biomedical departments; medical equipment selection; custom instrumentation; contract programming; computerized medical device control programs for preventive maintenance and maintenance; incident investigations; biomedical technician contract negotiations; hospital advocacy for state law changes in California and Washington regarding technology; Joint Commission on Accreditation Healthcare Organization (JCAHO) compliance reviews; nursing education; legal investigations; expert opinions; medical computer design/analysis; database design and systems analysis for management information systems; and management consulting. Other projects included product development and medical device market/feasibility studies.

**09/1971 to 09/1977:** *Sutter Community Hospitals, Sacramento, CA. Department Head of Biomedical Engineering.* Originator of the present-day Sutter Hospital Biomedical Engineering program. Established one of the first hospital based biomedical engineering programs. The department provided clinical engineering support for a 650-bed acute-care hospital system (two separate tertiary care hospitals). All preventive maintenance and maintenance was provided for approximately 3000 medical devices including the hospital dialysis unit. Services also included medical equipment purchase advice, evaluation, implementation, maintenance, preventive maintenance, and user training. Department personnel participated in facilities planning and hospital computer applications. A clinical engineering internship program for M.S. biomedical engineering graduate students was established with California State University, Sacramento.

**09/1964-09/1965:** *Texas Instruments, Inc. Science Services Division, Dallas, TX. Engineer.* Advised technician crew - seismic data processing.

### Academic Experience:

**01/1992 to present:** *Michigan Technological University, Houghton, Michigan.* Adjunct professor in Biomedical Engineering. Professional Advisory Board Member to the Biomedical Engineering Program.

**01/1984 to 06/1986:** *Harvard University, Boston, Massachusetts.* Harvard University faculty member as a

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Biomedical Engineering consultant to establish a graduate biomedical engineering program for College of Medicine of the King Faisal University, Eastern Province, Saudi Arabia.

**09/1971 to 01/1984:** *California State University*, Sacramento, California. Adjunct professor in Bioengineering. Graduate level courses in clinical engineering and biomedical engineering. Thesis advisor for Biomedical Engineering students. Advisor to the Graduate Biomedical Engineering program.

**09/1967 to 08/1971:** *University of Wyoming*, Laramie, Wyoming. Electrical Engineering Dept. Substitute lecturer. Research associate in the development of a bio-telemetry system. Taught electronic instrumentation.

**1969 (summer):** *University of Wyoming*, Laramie, Wyoming. Natural Resources Research Institute. Engineering development and application of a temperature-sensing telemetry for an equine fertility study.

**1968 (summer):** *Michigan Technological University*, Houghton, Michigan. Biological Sciences Department. Research assistant in development and application of instrumentation for hibernator energy budgets. Development of computer software to process all data.

**09/1965 to 09/1967:** *Michigan Technological University*, Houghton, Michigan. Physics Department. Teaching assistant. Summer of 1966, employed by the Institute of Wood Research. Summer of 1967, supported by the Biological Sciences Department (NSF grant), worked on a biological direct calorimeter.

### **Selected Publications and Presentations:**

*Biomedical Engineering in Root Cause Analysis—Example: Assessing Infant Apnea-Related Deaths* by B. H. Barkalow, Ph.D., PE, CCE; W. E. Grant, M.A., M.L.I.S.; and F. J. Curran, B.S. Paper presented at the 61<sup>st</sup> Annual Meeting of the American Academy of Forensic Sciences in Denver, CO, February, 2009.

*An Interdisciplinary Forensic Approach to Solving Medical Device Failure Cases* by W. E. Grant, M.A., M.L.I.S.; B. H. Barkalow, Ph.D., PE, CCE; and F. J. Curran, B.S. (2008, October). Biomedical Associations of Wisconsin Conference – October 8, 2008 – Green Bay, WI.

*The Pathologist's Role in Preserving Implanted Pacemakers and Cardiac Defibrillators or How Not to Get Shocked!* by S. D. Parisian, M.D.; B. H. Barkalow, Ph.D., PE, CCE; and W. E. Grant, M.A., M.L.I.S. Paper presented at the 60<sup>th</sup> Annual Meeting of the American Academy of Forensic Sciences in Washington, D.C., February, 2008.

*Health Technology Policy and Standards – The U.S. Approach; Organizing an Equipment Control Program; Preventive Maintenance Management; Corrective Maintenance (Repairs) Management; Review Discussion, Maintenance and Service Management; Technical Administration of Service Contracts; Risk Management; Patient Safety* by B. H. Barkalow, advanced Clinical Engineering Workshop sponsored by the NSEC, Orbis, the American College of Clinical Engineering, and the World Health Organization – February 1-3, 2006 – Addis Ababa, Ethiopia.

*Defibrillators and Legal Action* by B. H. Barkalow, a presentation on the factors related to defibrillator malfunctions that ultimately result in legal action being filed. Advice was given on prevention of defibrillator failures and risk management. AAMI Conference 2005: Medical Equipment Failures and Patient Safety: A Review of Defibrillator Failures, May 17, 2005.

*Medical Devices Under the Radar.* A presentation on how disposable and semi-disposable medical equipment needs to be carefully handled and accommodated in management programs under JCAHO standards. Biomedical Associations of Wisconsin Conference – October 3, 2003 – Green Bay, WI.

*Oxygen Freeze Injury* by B. H. Barkalow, Ph.D., PE, CCE. A presentation of a forensic investigation of a patient facial freeze burn incident in a nursing home. AAMI Meeting June, 2000 in Palo Alto, CA.

*Recommended Practice for a Medical Equipment Management Program* American National Standard, ANSI/AAMI EQ56: 1999 and current update for 2013 available through the Association for the Advancement of Medical Instrumentation (AAMI) Arlington, VA. B. H. Barkalow is a member of the AAMI Medical Equipment Management Committee and contributing author.

*Are You Complying With Equipment Standards?* Interview article with OR Manager, July 1994. Review of

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hospital compliance with JCAHO medical device standards.

*Peripheral Vessel Diagnostic Angiography Using Mobile and Fixed C-Arm Systems* by B. H. Barkalow, Ph.D., P.E., CCE. A presentation comparing technical and user features of mobile versus fixed C-Arm imaging systems for vascular surgeons. Presented at The International Congress VI on Endovascular Interventions. Phoenix, Arizona, January 28, 1993.

*Surgical Lasers and Applications* by B. H. Barkalow, Ph.D., P.E., CCE. An 8-hour continuing education for credit course for clinical engineers and biomedical equipment technicians. Presented at The Canadian Annual Meeting of Biomedical Engineering in Medicine and Biological Sciences. Toronto, Ontario, June 1989.

*Hospital Electrical Safety – An Update*, B. H. Barkalow, Ph.D., P.E., CCE. Presented at the American Society for Hospital Engineering of the American Hospital Association 26<sup>th</sup> Annual Conference and Technical Exhibition, Grand Rapids, Michigan, March 16, 1989.

*Recommendations for Clinical Engineering Department Management* by B. H. Barkalow, Ph.D., P.E., CCE. Presented at the Biomedical Engineering Program Quality Assessment – New Standards Requiring New Methods B. H. Barkalow, Ph.D., P.E. CCE, Session Chairman and Speaker. The AAMI 1988 Philadelphia Regional Meeting, Cherry Hill, New Jersey, October 25, 1988.

*The Role of Biomedical Engineering Consulting in Hospital Management* by B. H. Barkalow, Ph.D., P.E. CCE. Banquet Speaker. Presented at The Oregon Society for Hospital Engineering, Inc., Annual Meeting and Banquet, Eugene, Oregon, May 1982.

*Management of Technology*, B. H. Barkalow, Ph.D., P.E., CCE. General Session Chairman and Moderator. Presented at The AAMI National Convention, May 1980.

*Hospital Based vs. Consulting Clinical Engineering* by B. H. Barkalow, Ph.D., P.E., CCE. Invited Speaker. Presented at The AAMI National Convention, May 1979.

*The Clinical Engineering Program* by B. H. Barkalow, Ph.D., P.E., CCE. Chapter 6 in the text, Clinical Engineering: Principles and Practices, edited by J. G. Webster and A. M. Cook. Published by Prentice Hall, Englewood Cliffs, New Jersey, 1979.

*Cost Effective Clinical Engineering Internships in Community Hospitals* by A. M. Cook, Ph.D., L. E. Rose, M.S.; and B. H. Barkalow, Ph.D., PE, CCE, Journal of Clinical Engineering, April-June, 1978, vol. 3 (2): 173-178.

*The Differential Emissivity Calorimeter in Small Mammalian Thermal Stress Energy Studies* by H. D. Alpert and B. H. Barkalow, Ph.D., PE, CCE, Paper presented at the 30<sup>th</sup> annual ACEMB, Los Angeles, California, November, 1977.

*Calorimetry for Biological Heat Studies* by B. H. Barkalow, Ph.D., PE, CCE and L. E. Rose, M.S., Paper presented at the 7<sup>th</sup> Asilomar Conference on Circuits, Systems, and Computers, Pacific Grove, California, November, 1974.

*Graduate Bioengineering Assistantships in a Community Hospital* by A. M. Cook, Ph.D.; B. H. Barkalow, Ph.D., PE, CCE; and B. H. Hyndman, Engineering Education, December, 1973, 194-197.

*Transient Heat Measurements: A Transducer Model* by B. H. Barkalow, Ph.D., PE, CCE; A. M. Cook, Ph.D.; L. E. Rose, M.S.; and F. M. Long, IEEE Transactions on Biomedical Engineering, March, 1972, vol. BME-19 (2): 143-147.

*A Differential Emissivity Calorimeter* by B. H. Barkalow, Ph.D., PE, CCE, and K. M. Baldwin, The Review of Scientific Instruments, April, 1969, vol. 40 (4): 535-538.

### **Meetings Attended (Partial List):**

Association for the Advancement of Medical Instrumentation Standards Meeting - 2012

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American Academy of Forensic Sciences – 2009 – Denver, CO  
American Academy of Forensic Sciences – 2008 – Washington, D.C.  
American Academy of Orthopedic Surgeons – 2007 – San Diego, CA  
Association for the Advancement of Medical Instrumentation – 2005 – Tampa, FL  
Radiological Society of North America – 2004 – Chicago, IL  
Biomedical Association of Wisconsin Conference – 2003 – Green Bay, WI  
Association for the Advancement of Medical Instrumentation – 2003 – Long Beach, CA  
Emergency Cardiovascular Care Conference – 2002 – Washington, D.C.  
Radiological Society of North America – 2000 – Chicago, IL  
Association for the Advancement of Medical Instrumentation – 2000 – Palo Alto, CA  
American College of Orthopedic Surgeons – 2000 – Orlando FL  
American College of Orthopedic Surgeons – 1999 – Anaheim CA  
Radiological Society for North America – 1994 – Chicago, IL  
Association for the Advancement of Medical Instrumentation – 1994 – Washington, D.C.  
Society for Technology in Anesthesia – 1994 – Orlando  
Radiological Society of North America – 1993 – Chicago  
American Heart Association – 1993 – Atlanta  
Association for the Advancement of Medical Instrumentation – 1993 – Boston  
International Congress VI Endovascular Interventions – 1993 – Phoenix  
American Society of Anesthesiologists – 1992 – New Orleans  
MEDMARC Fifth Annual Seminar on the Defense of Health Care Product Liability Claims – 1992 – Kauai  
Laser Centers of America: Holmium Lasers for Surgery – 1991 – Cincinnati  
American Society for Lasers in Medicine – 1990 – Nashville  
International Congress IV Endovascular Interventions – 1990 – Phoenix  
Radiological Society of North America – 1989 – Chicago  
American Society for Lasers in Medicine – 1989 – Washington, D.C.  
AAMI/Joint Commission on Hospital Accreditation – 1989 – Cherry Hill  
ECRI Technology Management – 1989 – Traverse City

### **Professional Affiliations Present and Past:**

Association for the Advancement of Medical Instrumentation  
American College of Clinical Engineering  
Institute of Electrical and Electronic Engineers, Group on Engineering in Medicine and Biology  
International Certification Commission – Trustee  
National Society of Professional Engineers  
International Society for Endovascular Surgery  
American Society for Healthcare Engineering

### **Selected Client and Reference List (Details on Request):**

Emergency Care Research Institute (ECRI), Plymouth Meeting, PA  
Harvard Medical Center, Boston, MA  
Columbia Presbyterian Hospital, New York, NY  
New York University Medical Center, New York, NY  
Harborview Medical Center, Seattle, WA  
United Memorial Hospital, Greenville, MI  
British Oxygen Corporation, Murray Hill, NJ  
Ohmeda, Inc., Madison, WI  
Minnesota Mining and Manufacturing, Inc. (3M), St. Paul, MN  
ZOLL Medical Corporation, Woburn, MA  
Saint Paul Insurance Company, Saint Paul, MN  
Federal Food and Drug Administration, Rockville, MD  
California Food and Drug Administration, Sacramento, CA  
California State University, Sacramento, CA  
Michigan Technological University, Houghton, MI

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International Certification Commission (for Clinical Engineers), Arlington, VA  
Baxter International, Deerfield, IL  
Pfizer, Inc., New York, NY  
Apria Health Care, Inc., Lake Forest, CA  
Lawrence Hospital, New York, NY  
Datex-Ohmeda, Tewksbury, MA  
Sutter Community Hospitals, Sacramento, CA  
Colorado Med Tech, Boulder, CO  
Gerber Memorial Hospital, Fremont, MI  
Aequitron Medical, Minneapolis, MN  
North American Dräger, Telford, PA

### **Other Honorarium:**

Sigma Xi (National Research Honorary), member no. 690550359  
Sigma Tau (Engineering Honorary)  
Tau Beta Pi (Engineering Honorary)

### **Professional and Character References:**

Available upon request