



## Short Course on October 7, 2012

Title: **Regulatory and Safety Issues in Medical Ultrasound**

Instructors: **Charles C. Church**, National Center for Physical Acoustics and University of Mississippi, **Jeffery Brian Fowlkes**, University of Michigan, **Peter A. Lewin**, Drexel University, **Michael L. Oelze**, University of Illinois, Urbana-Champaign, and **Keith A. Wear**, US Food and Drug Administration

### **Course Description**

Many studies have demonstrated potential bioeffects associated with ultrasound exposure. In order to address the safety as well as the performance of medical ultrasound devices, the FDA has developed regulatory guidance for pre-clinical testing and evaluation, including establishing recommended levels regarding diagnostic ultrasound acoustic output. This course will consider legal and scientific foundations for the FDA acoustic output exposure levels. Topics will include basic medical device regulatory law, regulatory guidance, indexes of acoustic output, methods of and advances in measuring acoustic output, thermal bioeffects, mechanical bioeffects, and bioeffects associated with ultrasound contrast agents.

**Charles C. Church** received his B.S. in Physics from Westminster College, New Wilmington, Pennsylvania in 1975, and his M.S. and Ph.D. in Radiation Biology in 1978 and 1983, respectively, from the University of Rochester, Rochester, NY. He has a long-standing interest in diagnostic and therapeutic ultrasound and the mechanisms by which it may induce adverse biological effects, particularly acoustic cavitation, and also in the development of international standards for the safe use of medical acoustics devices. He previously was a research scientist at Molecular Biosystems, Inc., in San Diego, California, and a principal investigator for Acusphere, Inc., in Watertown, Massachusetts. Since 2002, he has been a senior research scientist at the National Center for Physical Acoustics and an associate research professor of physics at the University of Mississippi, Oxford, Mississippi. He is a Fellow of the American Institute of Ultrasound in Medicine (AIUM) and of the Acoustical Society of America (ASA). He has served on several committees of these organizations, notably the Technical Standards and Bioeffects Committees of the AIUM. He received the AIUM's Joseph H. Holmes Basic Science Pioneer Award in 2012. He is a member of International Electrotechnical Commission, Technical Committee 87 on Ultrasonics and of Scientific Committee 62B on Diagnostic Imaging Equipment. He serves as an associate editor for biomedical acoustics for the Journal of the ASA, for JASA-Express Letters, and for Proceedings of Meetings on Acoustics.

**Jeffery Brian Fowlkes** is a Professor of Radiology and Professor of Biomedical Engineering. He is currently directing and conducting research in medical ultrasound including the use of gas bubbles for diagnostic and therapeutic applications. His work includes studies of ultrasound contrast agents for monitoring tissue perfusion, acoustic droplet vaporization for bubble production in cancer therapy and phase aberration correction, effects of gas bubbles in high intensity ultrasound and volume flow estimation for ultrasonic imaging. Dr. Fowlkes received his B.S. degree in physics from the University of Central Arkansas in 1983 and his M. S. and Ph.D. degrees from the University of Mississippi in 1986 and 1988, respectively, both in physics. Dr. Fowlkes is a fellow of the American Institute of Ultrasound in Medicine and has served as Secretary and as a member of its Board of Governors. He also received the AIUM Presidential Recognition Award for outstanding contributions and service to the expanding future of ultrasound in medicine. As a member of the Acoustical Society of America, Dr. Fowlkes has served on the Physical Acoustics Technical Committee and the Medical Acoustics and Bioresponse to Vibration Technical Committee. As a Member of the IEEE, he has worked with the IEEE I & M Society Technical Committee on Imaging Systems. Dr. Fowlkes is a fellow of the American Institute of Medical and Biomedical Engineering.

**Peter A. Lewin** is an R.B. Beard Distinguished University Professor of Electrical and Computer Engineering and

Director of the Ultrasound Research and Education Center in the School of Bioengineering, Bioscience and Health Systems at Drexel University. He obtained his M.S. degree in Electrical Engineering in 1969 and his Ph.D. in Physical Acoustics in 1979 in Copenhagen, Denmark. Dr. Lewin has authored or co-authored over 220 scientific publications, most of them on topics in ultrasound, and is co-editor (with Prof. M. C. Ziskin) of a book, *Ultrasonic Exposimetry* (CRC Press, 1993). His current interests are primarily in the field of biomedical ultrasonics and industrial applications of ultrasound, including the design and testing of piezoelectric transducers and sensors, power ultrasonics, ultrasonic exposimetry, tissue characterization using nonlinear acoustics, biological effects of ultrasound, power ultrasonics and applications of shock waves in medicine and image reconstruction and processing. Dr. Lewin is a Fellow of the IEEE, the American Institute for Medical and Biological Engineering (AIMBE), American Institute of Ultrasound in Medicine (AIUM) and Acoustical Society of America (ASA). He has served on AIUM's Board of Governors (2004-2006) and as a Chair (1997-1999) of the AIUM's Technical Standards Committee. He currently serves as a consultant to the U.S. Food and Drug Administration, Center for Devices and Radiological Health and as a member of the US TAG participating in the work of the International Electrotechnical Commission, Technical Committee on Ultrasonics. Most recently he was appointed for life as consulting resource member of the prestigious Franklin Institute Science and Awards Committee, Philadelphia.

**Michael L. Oelze** earned his B.S. degree in physics and mathematics in 1994 from Harding University, Searcy, AR, his M.S. degree in physics in 1996 from the University of Louisiana at Lafayette, Lafayette, LA, and his Ph.D. degree in physics in 2000 from the University of Mississippi, Oxford, MS. Dr. Oelze was a post-doctoral fellow at the University of Illinois at Urbana-Champaign from 2000 to 2004 conducting research in ultrasound. Currently, Dr. Oelze is an associate professor in the Department of Electrical and Computer Engineering at the University of Illinois at Urbana-Champaign. His research interests include the acoustic interaction with soil, ultrasound tissue characterization, quantitative ultrasound, ultrasound bioeffects, ultrasound tomography techniques, therapeutic ultrasound, and application of coded excitation to ultrasound imaging. Dr. Oelze has served as a member of the Editorial Board for Ultrasonic Imaging and on the Advisory Editorial Board of Ultrasound in Medicine and Biology. Dr. Oelze is a member of the Acoustical Society of America (ASA), a senior member of IEEE, and a fellow of the American Institute of Ultrasound in Medicine (AIUM).

**Keith A. Wear** received his B.A. in Applied Physics from the University of California at San Diego in 1980. He received his M.S. and Ph.D. in Applied Physics with a Ph.D. minor in Electrical Engineering from Stanford University in 1982 and 1987. He was a post-doctoral research fellow with the Physics department at Washington University, St. Louis from 1987-1989. He has been a research physicist specializing in biomedical ultrasound at the FDA Center for Devices and Radiological Health since 1989. He has served as Secretary (2010-2012), Vice-Chairman (2002-2004), and Chairman (2004-2006) of the American Institute of Ultrasound in Medicine (AIUM) Basic Science and Instrumentation Section. He is a senior member of IEEE. He was the Technical Program Chair of the 2008 IEEE International Ultrasonics Symposium in Beijing. He is an Associate Editor of IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control. He is a Fellow of the Acoustical Society of America, the American Institute for Medical and Biological Engineering, and the AIUM.

Conference website: [http://ewh.ieee.org/conf/ius\\_2012](http://ewh.ieee.org/conf/ius_2012)

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