Standards & Requirements Affecting Ultrasonics

or

How did we get here?

Mission Statement

- Why does our organization exist?
  - We are manufacturers, users, researchers and people with an interest in *Ultrasonics.*
  - As such we need to be knowledgeable about the capabilities and effects of this special energy form.
  - Our organization has developed over the years to help in this endeavor.

Note: On subsequent slides the symbol ◯ indicates that a source document has been provided in the list of references.

Beginnings

- The UMA (Ultrasonic Manufacturers Association) was established in 1956:

  - "To collect and to disseminate sound and accurate information relating to ultrasonic equipment and its application.

  - To collect and disseminate information and statistics to interest and value to the membership so as to promote the development and applications of ultrasonic products and to improve the usefulness and quality of such products manufactured by or supplied by the membership. -----

  - To assist and cooperate with the members in their relations with governmental administrative agencies concerned with the field of ultrasonics.___

Continuation

- The UIA (Ultrasonic Industry Association) was established in 1975:

"To consider and deal with intra-industry problems and to foster and further, in every lawful manner, the interests of the manufacturers of ultrasonic materials, products and supplies; and in furtherance of these objectives:.

- To promote the growth of the industry on a firm and lasting basis.
- To collect and disseminate information of interest and value to the membership, so as to promote the development and application of ultrasonic products."

Evolution

- Over the years, the UIA has evolved into an organization dedicated to the ***advancement of the technology and applications of ultrasonics*** used to create changes in materials. As such, we now include as members:

- A Manufacturer or purchaser of ultrasonic equipment and related items for sale or use.
- A Company or institution that uses ultrasonic equipment, does research, or provides services, in the field of ultrasonics.
- Persons with an interest in the field of ultrasonics.
- Professional or trade organizations sharing common interests with the UIA.
- Students enrolled at an academic institution in a degree program in science, engineering, or technology.

Early Work

- In the 1960's The UMA zealously protected their proprietary knowledge of the mechanisms of interaction. Never the less they published:
  - A List of Standard Definitions
  - A System of Standard Ratings Covering Ultrasonic Electrical Generators
  - A Bibliography of Ultrasonics in Medicine (November 1963)
  - A Recommended Standard – Cavitation Activity Measuring Procedure (Copyright August 1964)

Expanding Horizons

- Cavitron Corporation, a sustaining member of the UMA and UIA had an business philosophy.
  - Participation in the industry association.
  - Sponsorship of its personnel in the cross disciplinary activities of in the industry.
  - Participation in the formulation of voluntary and governmental standards.

Personal Development

- In 1969, Alan Broadwin joined Cavitron to participate in the ground breaking development of the Phaco Emulsifier for cataract surgery. He was encouraged to:

  - Become an active member of the association.
  - Take a leadership role in the industry association activities.
  - Help to develop the company strategy to address the new governmental requirements being promulgated for medical device manufacturers.

Exposure

- During those early years with Cavitron, your speaker:
  - Was exposed to a broad spectrum of applications in the ultrasonic field from power ultrasonic welding to various ultrasonic surgical modalities.
  - Did some initial experimentation on the effects of ultrasonic vibrations in the eye.
  - Helped bring the Phaco Emulsifier to the market.
  - Evaluated the application of ultrasonic vibration to other surgical modalities.
  - Participated in the development, clinical trials and marketing of the CUSA (Cavitron Ultrasonic Surgical Aspirator).

Interest in Standards

- Pfizer Hospital Products Group purchased the Cavitron Corporation in 1988. As Director of Ultrasonic Technology for Pfizer:
  - I was asked to take an active role in the development of the international standards under development. (I joined the US TAG for IEC TC 87 Ultrasonics)
  - They supported my request to find out what the mechanisms were that provided such unique tissue interactions when using ultrasonic surgical devices. (I collaborated with Dr. Mark Schafer in determining the mechanism for tissue fragmentation)
  - They encouraged me to reach out to global organizations through the UIA to develop sources of information which would benefit the company. (I reached out to the Ultrasonic & Acoustic Transducer Group at the University of Southhampton, UK and the National Physical Laboratory in Teddington, UK where I met Bajram Zeqiri)

A Continuing Interest

- During the 1988 to 1993 period, I participated in the discussions and drafting of such international standards as:
  - IEC 61847 Ultrasonics – Surgical Systems (Mark Schafer will talk to you).
  - IEC 61205 Ultrasonics – Dental Descalers
  - IEC 60886 Investigation on Test Procedures for Ultrasonic Cleaners (Bajram Zeqiri will talk to you).
  - IEC 61088 Characteristics and measurements of ultrasonic piezo ceramic transducers.

A Growing Understanding

- **When I was retired by Pfizer I started working in both the medical device and aerospace fields. I was surprised by the similarities in these two industries.**
  - Both involve life or death products.
  - Both require the highest level of quality assurance.
  - Both are subject to intense regulatory scrutiny.
  - Both rely on advanced technology for their most spectacular successes.

I looked into how the organizations that contribute to the understanding and control of these industries developed and interact.

US Medical Device Regulation

Year	Event	Reason
1902	Biologics Control	
1906	Pure Food and Drugs Act	
1938	Food Drug & Cosmetic Act	Sulfanilamide
1962	Drug Amendments	Thalidomide
1963	GMP's for Drugs	
1976	Medical Device Amendments	Dalkon Shield
1978	CGMP Drugs & Devices	
1987	Guidelines for Process Validation	Beginning of Design Controls
1990	Safe Medical Devices Act	Shiley Heart Valve
1997	QSR for Medical Devices	Full Quality System Required for Companies
1999	QSIT Inspection Technique	Management, Design, Production & Process, CAPA

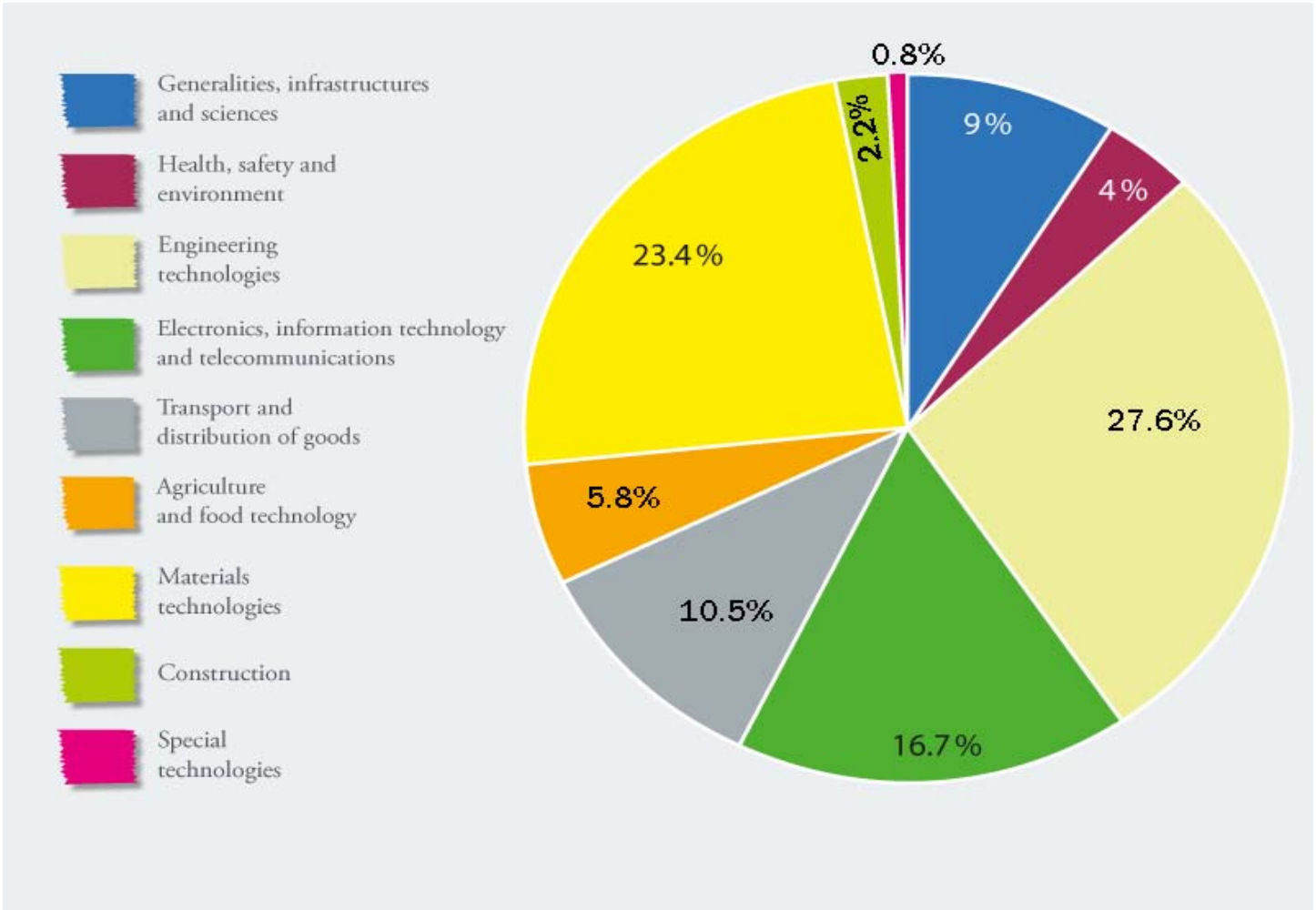
US Aerospace Activities

Year	Event	Reason
1903	First Powered Flight	
1918	US Post Office Airmail	
1926	Air Commerce Act	
1934	Air Mail Act	66 Crashes
1946	Federal Airport Act	
1958	Federal Aviation Act	3 Mid Air Collisions
1959	MIL-Q-9858	Quality Requirements
1997	AS9000	Application of ISO 9001 to Aerospace Requirements
2009	AS9100	Quality Management Systems for Aviation

International Activities

Year	Event	Reason
1906	IEC International Electro Technical Commission	Formed
1926	ISA International Federation of National Standards Associations	New York & Switzerland
1946	ISO formed	from ISA and UNSCC
1979	BS 5750 Issued	Based on MIL-Q-9858 of 1959
1987	ISO 9000 Issued	Quality Systems Standard
1993	EEA European Economic Area created	CE Marking
1993	MDD Medical Device Directives	Legal Requirements for Medical Device Companies in the EU
1997	EN 46001 Issued	Application of ISO 9001 to Medical Devices
2003	ISO 13485 Issued	Quality Systems Requirements for Medical Companies

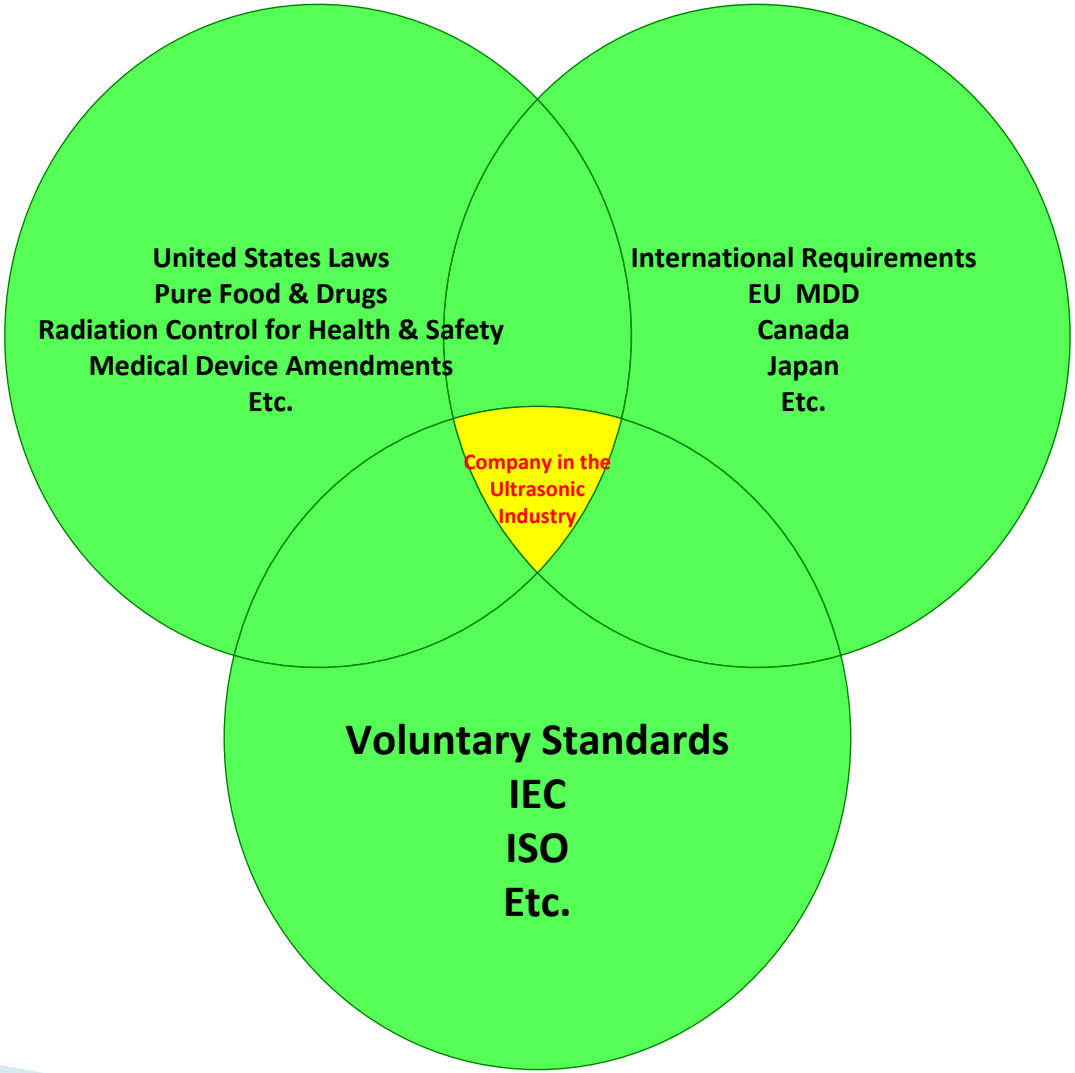
ISO Activities Today



A Convergance of Forces

- Failures in the medical device and aerospace fields are unacceptable. Accidents and mistakes in other fields do happen.
- Companies with Quality Systems have been asked to establish Risk Management processes so that they can analyze and hopefully mitigate failure modes.
- Companies need to be aware of the nature of the overlapping requirements so that they can appropriately plan their actions.

A Ven Diagram



Listing of References 1of 2

Slide	Description of Reference
3	UMA Incorporation & Minutes of Meeting
4	UIA Incorporation
5	www.ultrasonics.org
6	List of Standard Definitions
6	Bibliography of Ultrasonics in Medicine
6	Cavitation Activity Measurement Procedure
10	Bajram Zeqiri – Cleaning Systems
10	Matk Schafer – Acoustical Characterization
10	Ultrasonic & Acoustic Transducer Group

Listing of References 2 of 2

Slide	Description of Reference
12	Introduction to ISO
13	Introduction to QSR by Troutman
13	Medical Device Regulations Come of Age
14	Aerospace Standardization & History
15	Why Was the IEC Created?
15	The ISO Story – Friendship among Equals