STRATEGIC BUSINESS PLAN (SBP)

IEC/TC OR SC:	SECRETARIAT:	DATE:
87	**UK**	**2016-12-12**

A. STATE TITLE AND SCOPE OF TC

Are there any new or emerging trends in technology that will impact the scope and work activities of the TC? Please describe briefly.

Do you need to update your scope to reflect new and emerging technologies? If yes, will these changes impact another TC's scope or work activities?

If yes, describe how these will impact another TC(s) and list the TC(s) it would impact

TC87 Ultrasonics

The scope of TC87 is to prepare standards related to the characteristics, methods of measurement, safety, and specifications of fields, equipment and systems in the domain of ultrasonics.

Excluded from this scope is:
Safety for medical electrical equipment and systems.
NOTE - Close liaison is maintained with TC 62 and TC 29 in fields of common interest.

Activity started on medical ultrasonic safety standards in 1955 within Working Group 7 of TC 29. SC 29D 'Ultrasonics' was formed following the 1966 Prague meeting and a decision to transform SC 29D into a full Technical Committee (TC 87) was made at the 1985 Budapest meeting. The first meeting of TC87 was held in Wiesbaden, Germany, 29 Sep-2 Oct, 1987.

B. MANAGEMENT STRUCTURE OF THE TC

Describe the management structure of the TC (use of an organizational chart is acceptable) (should be integrated by CO automatically) and, if relevant (for example an unusual structure is used), provide the rationale as to why this structure is used.

Note: Check if the information on the IEC website is complete.

When was the last time the TC reviewed its management structure? Describe any changes made. When does the TC intend to review its current management structure? In the future, will the TC change the current structure, for example due to new and emerging technologies, product withdrawal, change in regulations etc. Please describe.

Make sure the overview includes:

- any joint working groups with other committees,
- any special groups like advisory groups, editing groups, etc.

TC87 comprises 8 Working Groups and 1 Joint working Group with SC62D.

The management structure was last reviewed in September 2016. A joint working group with SC62D was formed in 2016. Underwater Acoustics became a separate WG in 2006: prior to this it was included as a maintenance activity within WG8. The present WG14 was formed from a merger of the previous WGs 12 and 14 in 2008.

Working Groups

- WG 3 High power transducers
- WG 6 High Intensity Therapeutic Ultrasound (HITU) and Focusing transducers
- WG 7 Surgical and therapeutic devices
- WG 8 Ultrasonic field measurement
- WG 9 Pulse-echo diagnostic equipment

- WG 13 Terminology
- WG 14 Determination of ultrasound exposure parameters
- WG 15 Underwater Acoustics

Working Groups

- SC62D/JWG 38 Ultrasound Therapeutic Equipment

C. BUSINESS ENVIRONMENT

Provide the rationale for the market relevance of the future standards being produced in the TC.

If readily available, provide an indication of global or regional sales of products or services related to the TC/SC work and state the source of the data.

Specify if standards will be significantly effective for assessing regulatory compliance.

Ultrasonic technology finds a wide range of applications across virtually all business sectors including medicine, electronics, consumer products, food, manufacturing industries, defence, etc. Medical uses are mainly at megahertz frequencies and include diagnostic, monitoring, surgical and therapeutic applications. Medical uses represent a major area of development and continuing evolution: globally the medical ultrasound imaging market is worth approximately 7 billion USD in 2016 and expected to grow at 3.3% per annum, with the therapy equipment market worth approximately 3 billion USD. High Intensity Focused Ultrasound is the most rapidly expanding sector, expected to grow at 22% per annum until 2022. Industrial use of ultrasound is mainly in the kilohertz frequency range and includes ultrasonic cleaning, welding and industrial monitoring and processing. Ultrasound is also applied industrially, for applications ranging from established practices such as ultrasonic cleaning through to novel material and chemical processing. Ultrasonic cleaning includes areas such as surgical instrument cleaning, automotive and aerospace components manufacture, and the cleaning of printed circuit boards in the microelectronics industry: it is worth approximately $4bn p.a. worldwide). Many of these applications are driven by acoustic cavitation - and there is a need to be able to characterise cavitation to assist in the efficient and effective application of ultrasound and supporting industrial scale-up of novel technologies. Applications of underwater acoustics are wide-ranging and acoustic technology continues to provide the primary imaging and communication modalities for the exploration and exploitation of the ocean, underpinning key sectors such as oceanography, oil and gas exploration and extraction, marine renewable energy, as well as key maritime defence and security applications (the marine acoustic systems sector itself is worth >$800m world-wide). The increasing environmental influence of underwater acoustic noise from human activities has also led to growing concern, and incipient regulation which mandates traceable absolute measurements of ocean sound, increasing the need (and market) for calibrated instrumentation (hydrophones and recorders).

Although most industrial applications involve the use of ultrasound to perform some sort of process, human exposure to ultrasonic fields and the need to determine the performance of medical ultrasonic equipment, represent the drivers for the work of TC 87. The majority of the current work of TC 87 is therefore oriented towards the ultrasonic aspects of medical equipment and to safety of non-medical applications of ultrasonic fields. This emphasis is reflected by the structure of its working groups and by the qualification of its active experts. Underwater acoustic systems play a wide role in off-shore, oil and gas industries. Communication, control, surveying, and exploration systems all use water-borne sound in some form or another

D. MARKET DEMAND

Provide a list of likely customers of the standards (suppliers, specifiers, testing bodies, regulators, installers, other TC/SC's etc.). Do not specify company names, only categories of customers.

The demand for ultrasonic devices and measurement is worldwide, with many applications and stakeholders, and in many countries the control and measurement of ultrasound is covered by law or legislative directives. The range of users of the standards include governments, the medical profession, manufacturers of ultrasonic devices, manufacturers of measurement equipment, those measuring marine noise, as well as consultants, test houses, calibration laboratories, and metrology institutes around the world. Users of TC 87 standards include international and national standards organizations, and in many countries the international standards are directly adopted with no change as equivalent national standards.

Medical diagnostic ultrasonic equipment is an area of high expansion, more rapid than any other imaging modality, with new developments including acoustic radiation force imaging and ultra-high framerate imaging. Surgical and therapeutic ultrasound has seen a significant continuous growth over the last decade and this trend is expected to continue. A particular area of recent growth has been high intensity focused ultrasound applied to certain surgical procedures. The need to characterise the ultrasonic fields

and to establish means for determining exposure levels is a recognised requirement to meet regulations worldwide. Although some of the industrial applications of ultrasound are well established, there is a need to provide quantitative test methods to enable the performance and safety of these systems. For example, in the case of ultrasonic cleaning, there is a need to provide quantitative test methods to enable the performance of the cleaning systems and the cleaning process to be monitored. Furthermore, the need to understand new industrial processes involving the application of high power ultrasound is leading to a need to measure and characterise high power ultrasonic fields. These needs together with the need for test methods and procedures to support quality systems require the continued development of specification standards in these areas. There is also a growing regulatory need to develop methods of measurement and characterisation of underwater acoustic fields, in particular for the measurement of noise from anthropogenic sources. This is placing a greater demand for calibration of instrumentation. The standards produced by TC87 will be cited by regulatory bodies, and directly used by manufacturers, consultants and researchers.

E. TRENDS IN TECHNOLOGY AND IN THE MARKET

If any, indicate the current or expected trends in the technology or in the market covered by the products of your TC/SC.

Ultrasonic technology finds a wide and increasing range of medical and industrial applications. Medical uses are continuing to develop and evolve. Although industrial uses of ultrasound at kilohertz frequencies have been established for many years, there are significant new developments in areas such as sonochemistry and industrial processing.

In summary, trends in these areas are as follows:

- Technology is continually changing and developing and this situation is likely to continue for the foreseeable future;
- Slower but significant changes are occurring in the well-established industrial applications of ultrasonics;
- There is no major field of ultrasonic technology which is decreasing in importance;
- Underwater acoustic systems play an ever-increasing role in off-shore, oil and gas industries.
- Therapeutic, high frequency and surgical applications are undergoing rapid development.
- Decreasing size and cost leading to greater availability and more widespread use of medical imaging systems (eg emergency room, paramedic and general practice use).
- Increasing human uses outside of the traditional medical environment: for instance as home-use devices or in cosmetic and aesthetic clinics/centres.
- New marine environmental regulation related to marine noise are major drivers for traceable measurement and calibration in underwater acoustics (eg for noise associated with installation and operation of offshore wind and tidal energy infrastructure).
- Growing use of sonochemical processes for cleaning, water-treatment and in the chemical and pharmaceutical industries.
- The effect of underwater noise on sea-life is increasingly of concern in the world’s oceans and is the subject of increasing regulation which drives the need from noise monitoring, for example the EU Marine Strategy Framework Directive (2009), and the NOAA Ocean Noise Strategy Roadmap (in the USA).
- The increased need for traceable measurements of sound in the ocean has led to development of new instrumentation (marine autonomous acoustic recorders, digital hydrophones, particle velocity sensors) which present new calibration challenges
- In the EU, the Medical Devices Directive (MDD) will be replaced by the Medical Device Regulation (MDR). The MDR will impose clearer and more detailed rules which give less room for different interpretation between member states, and ensure legal requirements are implemented at the same time throughout the European Union.

F. SYSTEM APPROACH ASPECTS (REFERENCE - AC/33/2013)

Does your TC/SC have a need for a systems approach?

If so:

- Will the Systems work be in a single TC or in multiple TCs?
- Will a Systems Evaluation Group (SEG), Systems Committee (SyC), or Systems Resource Group be required?
- Is your TC/SC work of relevance to ISO?
- Is or are there fora or consortia working in parallel to IEC? Is there a chance to integrate this work in your TC/SC?

This should not only be restricted to the customer/supplier relationships with other TC/SCs indicating types of co-operation (e.g. liaisons, joint working groups) but be of a more generic nature.

If there is no need for a systems approach as outlined in AC/33/2013, is it intended a TC would not be requested to report on general systems approach considerations such as customer/supplier relationships, liaisons, joint WGs, etc. as referenced in the system approach matrix illustrated in slide 14 of the presentation attached to AC/37/2006?

TC 87 actively promotes the establishment and maintenance of communication with other committees to ensure consistent and integrated standards. TC87 presently maintains formal liaisons with:

- IEC/TC 29
- IEC/TC 62
- WFUMB (World Federation of Ultrasound in Medicine and Biology) (A-type)

As a customer, TC87 uses standards created by:

- TC 1: IEV
- TC 62/SC62D/MT18: Therapy equipment

TC87 serves as a supplier of standards to:

- TC 62/SC 62A: Common aspects
- TC 62/SC 62B: Diagnostic imaging equipment
- TC 62/SC 62B/MT 34: Revision of IEC 60601-2-37
- TC 62/SC 62D: Electromedical equipment
- TC 62/SC 62D/MT 18: Therapy equipment
- TC 62/SC 62D/MT 24: Extracorporeal lithotripsy equipment

A joint working group has been set up with IEC SC62D - JWG 38 Ultrasound Therapeutic Equipment. JWG 38 has taken over responsibility to maintain IEC 60601-2-5 and IEC 60601-2-62 from 62D/MT18. Also future safety standards related to ultrasound therapeutic equipment will be developed by JWG 38.

The work of TC87 WG15 is directly relevant to the work of ISO TC43 SC3 (Underwater Acoustics) and a formal liaison is maintained between the committees. The division in scopes that has been adopted is analogous to that between IEC TC29 (Electroacoustics) and ISO TC43 SC1 (Environmental Noise) such that IEC TC87 covers electroacoustics and calibration of instrumentation and sensors, and ISO TC43 SC3 covers the physical measurements of sound in the ocean.

G. CONFORMITY ASSESSMENT

With reference to clause 6.7 of Part 2 of the ISO/IEC directives, are all you publications in line with the requirements related to conformity assessment aspects?

Will the TC/SC publications be used for IEC Conformity Assessment Systems (IECEE, IECEx, IECQ, IECRE)?

Will any of your standards include test specifications, reproducible test requirements, and test methods?

Are there likely to be special conformity assessment requirements generated by any standards projects? If yes, list which projects.

Only one TC87 document (IEC TS 62462) is presently listed in IECEE.
However, there are several medical equipment standards from TC 62 which are listed by IECEE and which require test methods specified in TC87 documents. (IEC 60601-2-5, 60601-2-36, 60601-2-37, and 60601-2-62).
Many standards of TC 87 include test specifications, reproducible test requirements and test methods.

EN 45502-1 refers to TC 87 documents regarding measurement methods.

3-5 Year Projected Strategic Objectives, Actions, Target Dates

TC87 aims to anticipate and respond to market need for standards involving new developments in medical diagnostic and therapeutic applications, in industrial equipment and processes, and in underwater acoustics. To better meet these aims, two strategic objectives have been identified.

Strategic Objectives 3-5 years	Actions to support the strategic objectives	Target Date(s) to complete the actions
To seek greater input on the need for new and updated Standards from stakeholders and experts outside of TC87	Establish or renew formal liaison withTC62 (especially SCs 62B and D), TC29 and relevant ISO committees. Ensure Notified Bodies are informed of TC87 Standards and their potential use to support risk assessment within 60601 series. Organize a special session on standards for ultrasound medical devices at a scientific acoustics conference	May 2018 April 2019 June 2017
To increase participation in TC87 by experts from emerging areas and under-represented areas including elastographic imaging/ARFI, ultrasonic cleaning and therapy/HITU.	Encourage TC87 experts to reach out to manufacturers and other expert groups, especially in emerging and under-represented areas. Produce a “tree-diagram” showing the interrelationships and dependencies between TC87 documents and those of other committees, especially TC62.	September 2018 May 2018
Note: The progress on the actions should be reported in the RSMB.		