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Secretariat: **ANSI**
Committee manager: **Rajchel Lisa Mrs.**

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Description

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INTERNATIONAL ELECTROTECHNICAL COMMISSION / INTERNATIONAL STANDARDISATION ORGANISATION

JOINT TECHNICAL COMMITTEE 1: Information technology

SUBCOMMITTEE No. SC 43: Brain-computer Interfaces

Subject: Strategic Business Plan for JTC 1/SC 43 in 2025

STRATEGIC BUSINESS PLAN FOR JTC 1/SC 43
BRAIN-COMPUTER INTERFACES

1 Executive Summary

Based on the ISO/IEC JTC 1/AG16, JTC 1/SC 43 was established at the ISO/IEC JTC 1 plenary November 2021. The National Body of China serves as Secretariat, Ms. Yuntao Yu serves as the Chair for JTC 1/SC 43, and Mr. Bing Cui the Committee Manager. At the same plenary, the working item ISO/IEC 8663 was assigned to JTC 1/SC 43 for development.

Up to now, JTC 1/SC 43 has held 7 plenaries. The first 2 plenaries were conducted virtually while the following 4 were hybrid holding in Hangzhou, Tianjin, Sydney, Seongnam-si and New Delhi respectively. At present, JTC 1/SC 43 consists of 4 WGs, 2 AGs and 2 AhGs. Currently 1 project has published while a total of 14 work programmes are under the development of JTC 1/SC 43. Great progress in global participation and cooperation has also been made since the committee's establishment.

JTC 1/SC 43 aims to develop Brain-computer Interfaces standards that are beneficial to industry development and UN Sustainable Development Goals (SDGs). This business plan is the third version and the focuses on the information and output of the committee.

2 Scope

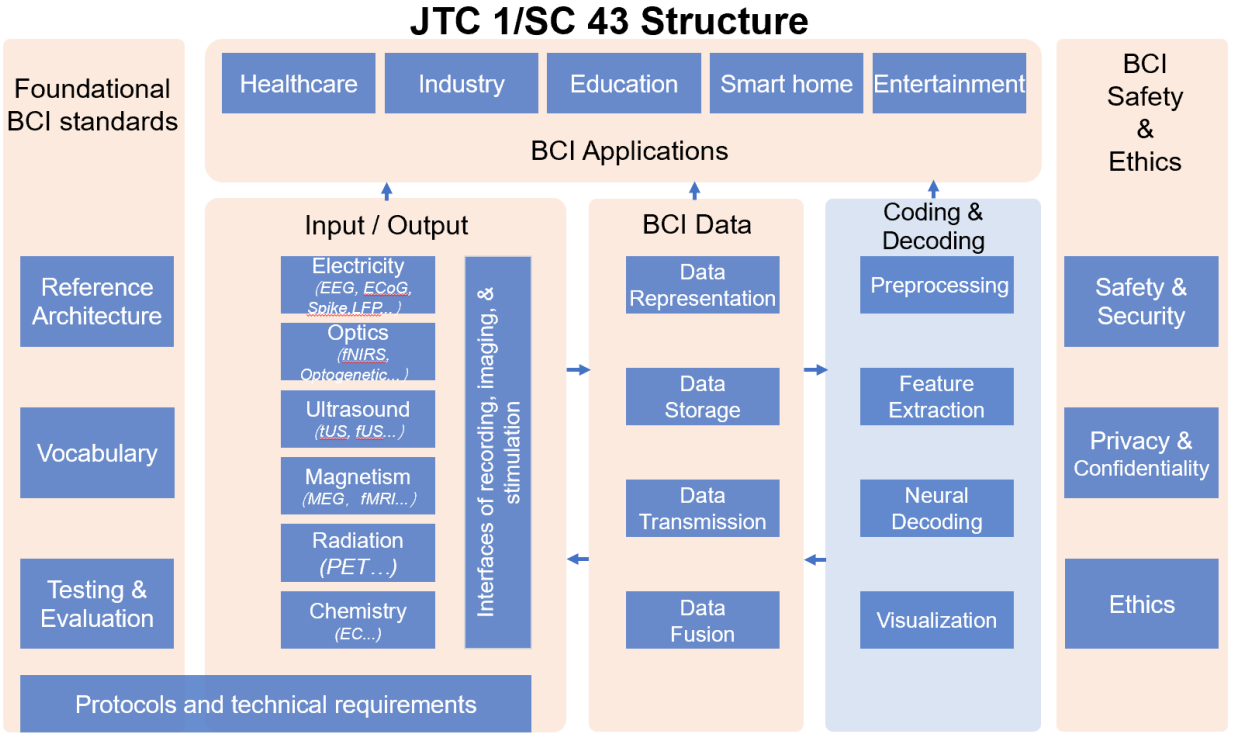
JTC 1/SC 43 is a System Integration Entity with a scope as below:

Standardization in the area of Brain-computer Interfaces for information technology to enable communication and interaction between brain and computers that are applicable across application areas.

- Serve as the focus and proponent for JTC 1's standardization program on Brain- computer Interfaces, including the development of foundational standards;
- Guide Brain-computer Interfaces to JTC 1, IEC, ISO, and other entities developing applications of BCI.

Excluded: standards for human implants and medical applications.

Though JTC 1/SC 43 won't directly develop the standards for human implants and medical applications, it is responsible for the indispensable IT standards that enable these applications. Additionally, JTC 1/SC 43 will work closely with liaisons to ensure that its standards align systematically with existing medical standards related to BCI. The following diagram further illustrates JTC 1/SC 43's current standardization work on BCI technology within its scope.



3 Environment

3.1 Market dynamics

The past decade has seen significant growth in research groups and new startups working on Brain-computer Interfaces (BCI) technologies and products. In 2021 the global BCI market size was valued at USD 1.43 billion and is anticipated to grow at a compound annual growth rate (CAGR) of 14.58% during the next decade. Large technological companies (e.g., Meta, Google, and Kernel), government agencies (e.g., US Department of Defense), and best-known investors (e.g., Elon Musk, Jeff Bezos, and Bill Gates) have shown a massive interest in this emerging industry. A dynamic market of VC-based start-up companies like Blackrock Microsystems, Synchron, NeuroOne, Precision Neuroscience, CorTec, Neuralink, and others are working on the commercialization of BCI for medical purposes, gained IDE and are either established in clinical studies or about to start soon.

The major drivers of the BCI market include the increasing prevalence of neuropsychiatric disorders, the increasing base of the global elderly population, and the rapid development of technology that facilitates communication and movement of paralyzed patients. In addition, the use of technology in virtual gaming, home control systems, and military operations has enhanced the market applicability and driven its growth.

In terms of the application field, the healthcare segment contributed to the majority of the current BCI market size. BCI is used to facilitate communication or allow control of prosthetic limbs for patients with paralysis or amputation. It is also used for rehabilitation of stroke patients. The increasing prevalence of neurodevelopmental disorders (e.g., attention deficit hyperactivity disorder and autism spectrum disorder) and neurodegenerative disorders (e.g., Parkinson's disease) are indications creating potential demand for BCI technology in

healthcare industry. In parallel, virtual gaming has opened up new opportunities for BCI devices. For instance, Emotiv, Inc. has developed video games using the non-invasive BCI technique that analyses the mood of the user and accordingly adjusts visual and auditory stimuli. Meanwhile, BCI applications focusing on emotion recognition and cognitive enhancement, comprising the healthy population and individuals suffering from mental disorders like anxiety or depression are growing. The use of BCI in smart home control, sports training, and military operations also broadens the applicability of the market, fueling its growth. Applications and application scenarios vary whether a BCI is applied on the surface of the skin (non-invasive) or needs surgical procedures for implantation (non-invasice). While current applications of invasive BCI are medical, only, non-invasive BCI are also envisioned for non-medical applications as mentioned above. Overall, the BCI market can be segmented into invasive, partially invasive, and non- invasive BCI. The non-invasive segment currently holds a major revenue share and is expected to increase the mainstream accessibility of BCI technology. The invasive and partially invasive segments are expected to witness the fastest CAGR in the future due to their application in assistive devices for people with disabilities.

3.2 Technology trends

BCI technology provides a realistic path to human-computer fusion, which has broad application from replace, restore, improve, enhance function to as a research tool to study function (The future in brain-neural-computer interaction: Horizon 2020, International BCI Society). To achieving these implementations, it shows the following trends:

- With the continuous innovation and progress of micro and nano processing technology and material technology, the hardware of Brain-computer Interfaces is developing towards flexible, wireless, and more miniaturized, high-throughput and low power consumption solutions. The future development direction of non-invasive BCI is to develop more portable and comfortable devices to better serve humans.

- Brain signal acquisition technology, stimulation technology, paradigm coding technology, and decoding algorithm technology are the core technologies of BCI, among which decoding algorithm is the key to achieving efficient and reliable information transmission. In the future, with the help of artificial intelligence methods such as deep learning, brain signals will be more accurately identified and interpreted, and more accurate control and feedback be made. Future BCI technologies may also include more advanced autonomous learning capabilities, which will allow the system to better adapt to an individual's differences and better adapt to the requirements of different environments and tasks.

- BCI application gradually ranges from the repair of motor behavior to the enhancement of various perceptions and advanced cognition. In the future, the development of technology can realize personalized and precise monitoring and intervention of brain function, which is expected to be applied to large populations in the diagnosis, treatment, rehabilitation, and other clinical fields of neurological/mental diseases.

3.3 Customer/stakeholder needs

The stakeholders of BCI include developers, investors and customers. Different stakeholders have different needs and expectations for BCI technologies.

- Developers are the creators and promoters of BCI technology, and they need multidisciplinary and professional talents, sufficient financial support, and standards and specifications to ensure technological innovation and application.
- Investors are supporters and participants of BCI technology. They need clear and feasible business models and project plans with compelling market prospects to obtain good investment returns.
- Customers of BCI primarily include end users, medical professionals and carers. Their requirements for BCI vary by application and location but generally can be summed up as the following: safety, effectiveness, accessibility, and versatility and affordability. Safety refers to whether the BCI will cause physical or psychological harm to the user, effectiveness refers to whether the BCI can achieve the expected functions and effects; accessibility refers to whether the BCI is easy to use and maintain; and versatility refers to whether the BCI can adapt to the user's differences and preferences. Affordability can allow more people in need to obtain and benefit from BCI without financial strain.

3.4 Potential policies and regulations

In the public sector, massive investments from governments in neuroscience technological innovation is a chief factor that may accelerate the growth of the global BCI market. Examples include the E.U. Human Brain Project, the U.S. BRAIN Initiative, the Japan Brain/MINDS project, and the recent China Brain Project. Considering the huge potential of BCI in medical applications, the US Food and Drug Administration (FDA) also issued guidance on clinical and non-clinical testing considerations for implanted BCI devices in 2021. Worldwide, soft law initiatives (e.g. UNESCO, OECD) currently formulate the broader framework of human rights and public international law in which more detailed standards may be formulated.

BCI technology involves several legal and ethical issues, from security to privacy, also including neural and mental data processing, as well as psychological manipulation, discrimination and emotional bonds. Invasive BCI which need a surgical intervention for implantation are medical devices and need to be handled under medical device regulations. It is necessary to formulate corresponding standards and norms to protect the rights and interests of users and social stability. At present, the standardization of BCI technology worldwide is still in its infancy, lacking unified and reliable systems.

4 Achievements and benefits

4.1 Achievements of JTC 1/SC 43

After being established for nearly 4 years, JTC 1/SC 43 has been expanding its international corporation from 7 P-members to 13, indicating a growing interest and commitment from stakeholders worldwide to contribute to the standardization efforts. The ongoing projects under JTC 1/SC 43 have also increased from 2 to 14 work programs with its aim to addressing a broader range of standardization needs within its scope.

In September 2023, JTC 1/SC 43 held its first face-to-face meeting with remote participation in Hangzhou, China, which represents a significant milestone for the committee. Face-to-face

meetings provide an invaluable opportunity for members to come together in person, fostering collaboration, discussion, and consensus-building on key standardization initiatives.

At the end of 2024, JTC 1/SC 43 has conducted four symposiums with a total of approximately 600 attendees to promote international communication on the development of Brain-Computer Interface (BCI) technology and its standardization needs. Notably, the symposium held in Sydney, Australia in September 2024, collaborated with the IEC Academy and resulted in a technology report that summarizes the key discussions and outcomes from the event.

4.2 Benefits of BCI standardization

Improved Safety: One of the primary benefits of BCI standardization is improved safety for users. BCI technology involves the direct connection of the brain to an external device, which raises concerns regarding potential risks associated with the use of such devices. Standardization can help address these concerns by establishing safety requirements and protocols that BCI devices must meet. By implementing standardized safety protocols, BCI devices can be tested and certified to meet the highest safety standards, ensuring that they do not pose any harm to users. For example, the IEC 60601-2-26 standard outlines safety requirements for electroencephalographs (EEGs) and serves as a key reference for many BCI devices. JTC 1/SC 43 has approved a PWI on safety general requirements (PWI JTC1-SC43-2) to provide a high-level perspective for security assessment and management for BCI systems.

Improved Interoperability: Another important benefit of BCI standardization is the potential for increased interoperability between different devices. This is particularly important for commercially available products and applications of BCI, where different devices may need to work together to achieve a common goal. Standardized protocols can ensure that different BCI devices can communicate effectively and work together, allowing for more efficient and effective healthcare delivery. For example, In ISO/IEC JTC 1/SC 43, working groups are developing a standard for BCI system reference framework and data structures, which will enable different BCI devices to work together seamlessly. This will be particularly important for applications such as brain-controlled prosthetics and robots, where multiple BCI devices may be used to control different aspects of the prosthetic. Standardized protocols will allow components within a BCI system to properly exchange information, as well as enable BCI systems to communicate with other systems. These two forms of interoperability enable beneficial system operation for the entire catalog of BCI use cases.

Improved Accessibility: Standardization of BCI technology can also lead to improved accessibility for users. By establishing minimum requirements for system design and performance, standardized protocols can ensure that BCI systems are more accessible to a broader range of users, including those with disabilities. This can result in improved quality of life for individuals who would benefit from BCI technology. For example, the IEC has developed the IEC 60601-2-27 standard for the safety and performance requirements of implantable neurostimulators. This standard specifies requirements for the design, testing, and certification of implantable neurostimulators, including those used in BCI technology. BCI systems that comply with this and future JTC 1/SC 43 standards are well positioned to be safe, effective, and can improve accessibility for users.

4.3 Sustainable development goals addressed by JTC 1/SC 43's deliverables

The deliverables would align with several Sustainable Development Goals (SDGs), particularly SDG 3: Good Health and Well-being, SDG 4: Quality Education, and SDG 9: Industry, Innovation, and Infrastructure. By improving the safety and effectiveness of BCI devices, standardization can contribute to achieving SDG 3 by promoting good health and well-being for users. This is particularly relevant for individuals with disabilities or neurological conditions who may benefit from BCI technology to improve their quality of life. Standardization can ensure that BCI systems are safe and effective for use, reducing the risk of harm to users.

In addition, standardization can support SDG 4 by improving access to high-quality education and training programs related to BCI technology. As the field of BCI continues to grow and evolve, there is a need for education and training programs to ensure that professionals have the necessary skills and knowledge to design, develop, and use BCI systems effectively. Standardization can help establish minimum requirements for education and training programs related to BCI technology, ensuring that professionals have the necessary knowledge and skills to work with these devices.

By promoting innovation and infrastructure development in the field, BCI standardization can contribute to achieving SDG 9 by supporting the growth of the BCI industry. Standardization can help establish a common framework for the design, development, and certification of BCI systems, making it easier for companies to enter the market and compete effectively. This can lead to the development of new and innovative BCI devices, which can drive industry growth and promote economic development.

The standardization of BCI technology is a critical step toward ensuring the safety, efficacy, and interoperability of these devices. Standardization is essential for the continued development and growth of the BCI industry, and the work of the JTC 1/SC 43 is critical to achieving these goals.

4.4 ISO and IEC strategies impacted by JTC 1/SC 43's work

JTC 1/SC 43 develops work to cover the ISO goals 2 - Meeting global needs – more comprehensive by addressing the standardization demand in the BCI field. Due to the interdisciplinary nature and complex technology involved in BCI, international standards are necessary to provide guidelines, specifications, and best practices. JTC 1/SC 43 will help fill the standardization gap and explore various directions or aspects for BCI standards, as encouraged by ISO.

On the IEC side, what the JTC 1/SC 43 is responsible for will help IEC to achieve a digital and all-electric society. As a thriving field of bio-digital convergence, BCI holds great promise for fostering inclusivity, accessibility, healthcare, human-machine collaboration, and innovation, empowering individuals to interact with, control, and benefit from digital technologies in novel and transformative ways. The future work of JTC 1/SC 43 may also involve testing and certification in the BCI field.

5 Participation and Cooperation

5.1 Membership (By 2025-03-17)

JTC 1/SC 43 is open to the involvement of NBs and experts from different countries. Up to now, there are 13 P-members and 11 O-members participating in JTC 1/SC 43.

P-Members (13): Australia (AU), Belgium (BE), China (CN), Denmark (DK), Germany (DE), India (IN), Italy (IT), Japan (JP), Korea, Republic of (KR), Russian Federation (RU), Sweden (SE), United Kingdom (GB), United States of America (US).

O-Members (11): Argentina (AR), Austria (AT), Brazil (BR), Finland (FI), France (FR), Hungary (HU), Netherlands (NL), Poland (PL), Singapore (SG), Slovakia (SK), Spain (ES).

Here is the table showing the participation members that attended the previous plenaries.

No.	Date	Location	Total Attendance	Participation Members
The 1st Plenary	2022.09.27-29	Zoom(virtual)	57	10
The 2nd Plenary	2023.03.27-31	Zoom(virtual)	49	7
The 3rd Plenary	2023.09.04-07	Hangzhou, Chian (Hybrid)	62	9
The 4th Plenary	2024.04.15-18	Tianjin, China (Hybrid)	60	9
The 5th Plenary	2024.09.02-06	Sydney, Australia (Hybrid)	50	9
The 6th Plenary	2025.03.03-06	Seongnam-si, Korea (Hybrid)	53	10
The 7th Plenary	2025.09.08-12	New Delhi India (Hybrid)	50+	7

5.2 Cooperation

As an interdisciplinary area concerned with biology, neuroscientist, engineering, computer science, and applied mathematics, BCI requires close cooperation with other SDOs and committees. JTC 1/SC 43 makes efforts to improve cooperation by establishing an extensive network of liaisons. Besides the liaison relationship, JTC 1/SC 43 also registered as the Registered Member (R-Member) of IEC/ISO Joint Systems Committee on Bio-digital Convergence (IEC/ISO JSyC BDC) to strengthen cooperation between them as BCI is a crucial subfield of BDC. The specific liaison and R-member information is listed below.

Committee	Description
Liaison	
IEC/TC 62	Medical equipment, software, and systems
IEC TC 65/SC 65A	System aspects
IEC/TC 100	Audio, video and multimedia systems and equipment
IEC/TC 124	Wearable electronic devices and technologies

IEC/SyC AAL	Active Assisted Living
IEC/SyC COMM	Communication Technologies and Architectures
ISO/TC 150	Implants for surgery
ISO/TC 215	Health informatics
JTC 1/AG 15	Standards and Regulations
JTC 1/WG 15	Vocabulary
ISO/IEC JTC 1/SC 6	Telecommunications and information exchange between systems
ISO/IEC JTC 1/SC 27	Information security, cybersecurity and privacy protection
ISO/IEC JTC 1/SC 35	User interfaces
ISO/IEC JTC 1/SC 36	Information technology for learning, education and training
ISO/IEC JTC 1/SC 41	Internet of Things and Digital Twin
ISO/IEC JTC 1/SC 42	Artificial Intelligence
ISO/IEC JTC 1/SC 44	Consumer protection in the field of privacy by design
R-Member	
SyC BDC	IEC/ISO Joint Systems Committee on Bio-digital Convergence (IEC/ISO JSyC BDC)

5.3 Enhancing liaisons

IEC underpins the standardization of design, manufacturing, testing and certification in all electrical and electronic technologies fields. Apart from the established liaisons between JTC 1/SC 43 and some subcommittees within IEC, it is of great necessity to enhance liaisons with SyC, SEG, etc. in thriving technologies fields or system integration entity.

5.4 Plans to support the long-term need for new experts/participants

JTC 1/SC 43 highlights the strategy of fostering collaboration with subcommittees in the field of technological convergence by organizing joint activities such as open symposium or collaborative events. Such activities can enhance resource efficiency while maximizing expert participation. An example of this approach is the joint symposium co-hosted by JTC 1/SC 43 and IEC/ISO JSyC BDC during the IEC GM meeting in 2025. This initiative offers an opportunity for experts from both committees to engage with each other's work in a single, consolidated event. Such joint activities not only reduce travel and time costs but also promote cross-organizational knowledge sharing, increase participation, and strengthen synergies across different standardization efforts. By leveraging these collaborative opportunities, we can better address the evolving needs of standardization while optimizing the use of limited resources.

Besides, JTC 1/SC 43 trends to list other relevant TCs/SCs in the "TC of interest" while circulating the draft or initiating a vote, which is a mechanism in IEC System enable the experts of listed TC access the document of JTC 1/SC 43. JTC 1/SC 43 will also encourage the liaison committee put JTC 1/SC 43 into the "TC of interest" so that both sides can knowledge the main progress of standards that shares common interests. By implementing this approach, information exchange can be conducted more efficiently, reducing time costs and enhancing collaboration across committees.

6 Objectives and strategies to achieve them

6.1 SC Level

Objectives:

JTC 1/SC 43, as a standardization sub-committee, serves as a neutral platform where experts from all over the world come together to develop and agree on BCI standards. Through global collaboration and efforts by our members and secretariat, the committee would like to bring board BCI stakeholders and partners (e.g. implantable Brain-Computer Interface Collaborative Community and BCI Society) together to agree on international standards that it developed to solve the global BCI challenges. By doing that, it is expected that JTC 1/SC 43 standards support the growth and maturity of the BCI innovation and industry, driving widespread adoption and societal impact of this meaningful technology.

Strategies:

JTC 1/SC 43 plays a crucial role in the development of BCI standards. It is challenging to recruit people to join the committees. In this section, we will explore efforts and plans to increase the number of people joining the BCI standard-making committee where it is less than desired.

The first step to increase the number of people joining JTC 1/SC 43 is to increase awareness about the committee's importance and the impact it has on the BCI field. The public must understand that their input is vital in shaping the future of these technologies. Efforts should be made to reach out to the public through various means such as social media, news outlets, and public meetings.

Secondly, recruiting people with expertise and knowledge in BCI fields is crucial. Many individuals in fields such as neuroscience, computer science, engineering, and medicine have valuable insights to contribute to the development of BCI standards. Therefore, reaching out to these experts and inviting them to join JTC 1/SC 43 can help increase its effectiveness. It will also be useful to recruit people with expertise in law and ethics, with particular expertise in certain domains such as privacy and security.

Thirdly, JTC 1/SC 43 can collaborate with other relevant organizations. Collaborating with other organizations that have similar goals or interests can help expand the reach of the organization and attract new members. This can be done through the IEC platform.

Fourthly, JTC 1/SC 43 considers holding the symposium that are open to the public as another strategy. By making these symposiums accessible to a broad audience, JTC 1/SC 43 aims to raise awareness about BCI (Brain-Computer Interface) and its benefits to human life and to encourage more engagement. During the previous 6 plenary weeks, JTC 1/SC 43 has organized 5 open symposiums to foster its participation and advance the understanding of BCI technology. JTC 1/SC 43 also collaborated with the IEC Academy to attract more participation and engagement.

Increasing participation in JTC 1/SC 43 can be achieved through various means, including increasing awareness, recruiting experts, providing incentives, outreach to academic institutions, and creating an inclusive environment. By doing so, the committee can leverage

the expertise and insights of a broad range of individuals to develop effective and comprehensive guidelines that benefit society.

6.2 WG Level

6.2.1 WG1: Foundational standards

Objectives:

a) Development of Information Technology - Brain-computer Interfaces - Vocabulary.

b) Development of foundational standards for Brain-computer Interfaces, such as a reference architecture.

c) Where appropriate, alignment with the standing document by JTC 1/AG8 (JTC 1 N16431) meta reference architecture.

Strategies：

JTC 1/SC 43/WG1 is currently focused on the development of the information technology- BCI-vocabulary project. This project aims to establish a standard set of terms and definitions of BCI technology that can be used consistently across different domains and industries. In December 2024, the CDV document of the project has been approved to get into the FDIS stage. Currently, the project editors are updating the FDIS draft document as per the observations of the WG1 that were agreed upon for the voting comments received for the CDV document. The project defines the vocabulary of BCI technology and makes it aligned with the needs of stakeholders and end-users. Ultimately, the goal is to promote clarity and consistency in communication, reduce ambiguity and misunderstandings, and facilitate interoperability between different systems and applications.

WG 1 is also working on BCI reference architecture. The reference architecture intends to serve as a blueprint for the design and implementation of systems and applications. It will provide a comprehensive and standardized framework that can be used by developers and stakeholders to design and build systems that meet their requirements for interoperability, scalability, and efficiency. The proposed reference architecture will include various components and modules in BCI applications and will specify the interfaces, protocols, and standards that need to be followed to guarantee compatibility and consistency across different systems. Currently the project is in the PCC stage wherein the WG1 is working to compile the comments received for the CD document. In addition, through the alignment with the meta reference architecture, the reference architecture will be built on a solid foundation that is robust, effective, widely accepted, and recognized in the industry. This alignment will also ensure that the proposed architecture is compatible with other systems, thus promoting interoperability and ease of integration.

Moreover, from September 2024, the WG1 also started working on developing the PWI on Information Technology - Brain-computer Interfaces – Hardware Interfaces and Protocols. The purpose of this standard is to establish a comprehensive framework for the hardware interfaces and protocols that govern the interoperability of brain-computer interface (BCI) systems and components. By defining standardized interfaces and communication protocols, this standard aims to facilitate the seamless integration and compatibility of diverse BCI

devices, thereby promoting innovation, enhancing user experience, and expanding the potential applications of BCI technology.

6.2.2 WG2: Applications

Objectives:

a) Guide use cases of Brain-computer Interfaces to JTC 1, IEC, ISO, and other entities developing applications of BCI, which can be of value for a better comprehension of BCI technologies.
b) Identify and rank possible standard gaps/overlaps/recommendations
c) Benefit BCI industries and products by providing support for communications among interested parties/stakeholders (e.g., commercial enterprises, government agencies, not-for-profit organizations) and explore the development of potential BCI standards.

Strategies:

JTC 1/SC 43/WG2 is currently open to collecting use cases mainly using normative representations (questionnaires), including information on BCI applications such as application domain, use case statutes, scope, objective(s), stakeholders, scenario sequence, benefit, challenge and issues and standardization opportunities/requirements. The international projects/reports (e.g., BNCI Horizon 2020) that included BCI use cases can also serve as crucial reference for future developments.

Analysis and development of use cases with detailed information above to support requirements for work items in the area of BCI systems and identifying specific standard needs can help map the main applications over the relevant system architectures within the targeted domain, which may help provide guidelines in offering standard users to select the most appropriate set of standards/specifications (either existing or coming from the IEC but possibly coming from other bodies), develop a comprehensive understanding of the current and potential use cases for BCI technology and fulfilling the set of use cases. This could also help to unravel BCI systems into typical subsystems and modules and introduce new concepts into the BCI domain.

In the end, potential standards are developed to meet national bodies' requirements and stakeholders' needs and concerns.

6.2.3 WG5: BCI Data

Objectives:

a) Development of a BCI Data framework
b) Development of BCI Data processing regarding collection, representation, visualization, transmission and storage in BCI Data framework
c) Development in the following areas:

- BCI Metadata
- Brain information acquisition and data fusion specification
- Standardization of neural data representation

- Characterization, standardization of multiple-modal information

d) Development and integration of a BCI ontology to classify and organize BCI data types, approaches, and methodologies.

Strategies:

JTC 1/SC 43/WG 5 deals with the overall types of BCI data. Since WG 1 deals with the basic terminologies and foundational standards and WG 2 deals with applications, it is necessary to define the various data covered by BCI to ensure effective collaboration with other BCI WGs.

BCI data exists in various types and formats. To achieve high performance in brain computing through communication with BCI data, it is crucial that BCI data is efficiently transmitted, represented, and stored during processing. Therefore, WG 5 should focus on establishing a comprehensive BCI data framework and optimizing data processing, including representation, visualization, transmission, and storage in brain computing.

The justification for WG 5 is as follows:

1) Standardization of neural data representation: Neural signal formats collected by signal acquisition devices vary, as does the signal pre-processing performed by experimenters. This variability complicates system performance evaluation. Therefore, establishing standardized data representation for neural signals is crucial.

2) Input standardization for feedback information: Standardizing the input of feedback information is essential to ensuring the stability of the entire brain-computer interaction system, especially for two-way BCIs.

3) Characterization standardization of multi-modal information: This involves standardizing the representation of sensory information — such as vision, hearing, and touch — to ensure more consistent information feedback input.

4) Understanding the brain (information acquisition) and regulating the brain (information feedback) are paramount in brain science research. BCI technology is evolving from one-way command output to two-way brain-computer integration. Standards for brain information acquisition and data fusion across multiple modes need to be established, including interface specifications for signal acquisition equipment, protocol definitions, metadata formats, and operational paradigms for neural regulation under multiple modes.

6.2.4 WG 9 Ethics and Trustworthiness

Objectives:

Development in the following Brain–computer Interfaces areas: security, safety, privacy, and ethics.

Strategies: JTC 1/SC 43/WG 9 is advancing the ethical and trustworthiness standardization projects for BCI technology, aligning its efforts with the United Nations Sustainable Development Goals (SDGs), particularly SDG 3 (Good Health and Well-being) and SDG 9

(Industry, Innovation, and Infrastructure). Operating under the SC 43 committee focused on BCI standardization, WG 9 focuses to assess the trustworthiness of BCI systems, addressing critical aspects like reliability, security, and transparency, which ties directly into SDG 9's focus on building resilient and inclusive technological systems. This effort underscores the importance of safeguarding users as BCI technology extends beyond different applications and scenarios, amplifying the need for dependable and secure systems that promote sustainable industrial growth and protect well-being, in line with SDG 3.

Since the establishment, WG 9 has embarked on two work programmes titled "Information technology - Brain-computer Interfaces - Overview of ethical and societal concerns" and "PWI JTC1-SC43-2 Information technology - Brain-computer Interfaces - Security and privacy requirements", which aims to establish best practices for protecting user and securing BCI systems, responding to growing concerns as the technology gains traction in commercial sectors, ensuring seamless integration and compatibility across BCI devices while mitigating risks of misuse. Together, these efforts highlight WG 9's pivotal role in aligning innovation with responsibility, contributing to sustainable development goals that prioritize health, innovation, and institutional integrity.

Under the instruction of JTC 1/SC 43, JTC 1/SC 43/WG 9 is seeking collaboration with other TC/SCs and SDOs in the related field.

7 Challenges/Risk

Travel restriction in certain countries need measures to ensure participation and networking in digital, hybrid and in-person events. Special care will be taken on changing meeting places to allow best possible participation of participants from different countries.

Moreover, the experiences of the 3rd and 4th plenaries in China underscore a crucial reality that many experts cannot participate in person because of different reasons. Therefore the degree of involvement was impacted due to various factors such as unreliable internet connections. The online experts cannot participate social events for more communication, either. As a result, ensuring broader and more inclusive involvement of the plenary becomes challenging. Solutions and heightened efforts, like technological advancements or diplomatic efforts, to foster greater inclusivity are essential for the effective functioning and impact of plenary on a global scale.

The ongoing ISO/IEC TR 27599 "Information Technology - Brain-computer Interfaces - Use Cases" shall be updated according to the thriving industry developments or contributions from NBs.

Ethical and social challenges of BCI. The physical, psychological and possible social effects of BCI should be well considered. Privacy is another important topic that which BCI standard should refer to.

Risks related to patents exist in BCI field. By thriving industry development, JTC 1/SC 43's standards should incorporate new technologies and ideas of different disciplines, which may

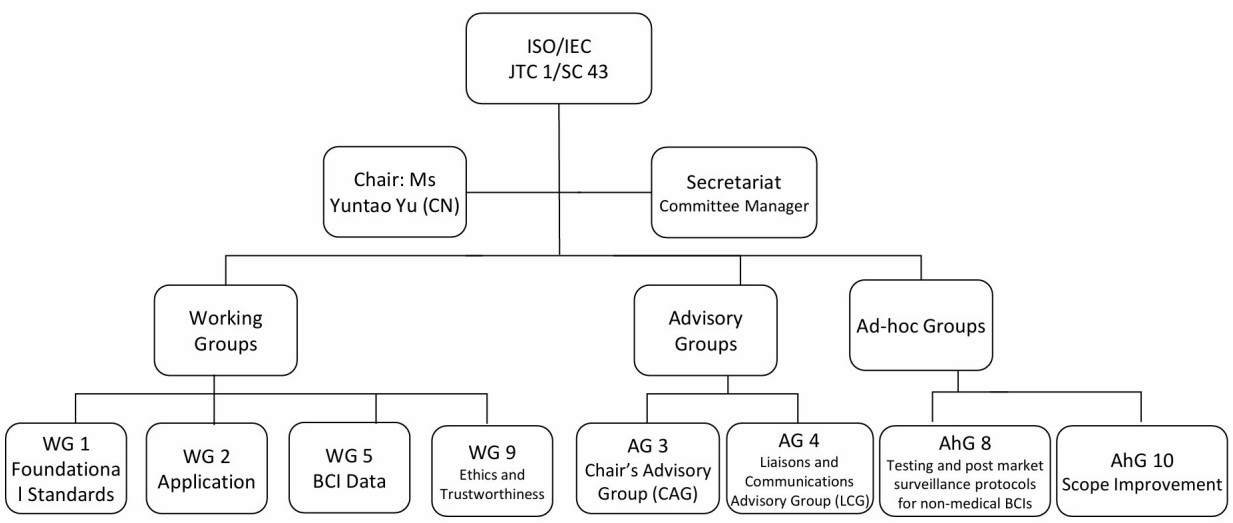
relate to patent rights that require licensing.

Balancing the expansion of the new work item proposal and executing existing projects efficiently is a challenge.

There may be insufficient numbers of people and experts on board to find the best universal agreement on what is contained in the standards. Meanwhile, the interdisciplinary nature of BCI, while complex and prone to overengineering, poses another risk that may hinder consensus adoption.

8 Structure, current projects, and publications

8.1 Structure



8.1.1 WG1: Foundational standards

Terms of Reference:

- Development of Information Technology - Brain-computer Interfaces - Vocabulary.
- Development of foundational standards for Brain-computer Interfaces, such as a reference architecture.
- Where appropriate, alignment with the standing document by JTC1/AG8 (JTC 1 N16431) meta reference architecture.

Program of works:

- ISO/IEC 8663 ED1 Information Technology - Brain-computer Interfaces – Vocabulary
- ISO/IEC 27572 ED1 Information Technology - Brain-computer Interfaces - Reference Architecture
- PWI JTC1-SC43-4 Information Technology - Brain-computer Interfaces - Hardware interfaces and protocols

Convenor: Saurin Parikh (IN)

8.1.2 WG2: Applications

Terms of Reference:

- Develop the Proposed TR: Information Technology - Brain-computer Interfaces - Use cases.
- Develop use cases and applications for Brain-computer Interfaces.

Program of works:

- ISO/IEC TR 27599 ED1 Information Technology – Brain-computer Interfaces - Use Cases
- ISO/IEC TR 27599 ED2 Information Technology – Brain-computer Interfaces - Use Cases
- PWI JTC1-SC43-5 Information technology - Brain-computer Interfaces - Design considerations for BCI developers
- PWI JTC1-SC43-6 Information technology - Brain-computer Interfaces - Guidance on context-based adaptive interfacing for multi-purpose BCl systems
- PWI JTC1-SC43-9 Information technology - Brain-computer Interfaces - Application of non-invasive BCI for Disorders of Consciousness

Convenor: Arpan Banerjee (IN)

8.1.3 WG5 BCI Data

Terms of Reference:

- Development of a BCI Data framework
- Development of BCI Data processing regarding collection, representation, visualization, transmission and storage in BCI Data framework.
- Development in the following areas:
  - BCI Metadata
  - Brain information acquisition and data fusion specification
  - Standardization of neural data representation
  - Characterization, standardization of multiple-modal information

Program of works:

- ISO/IEC TS 27571 Information Technology - Brain-computer Interfaces - BCI data format for Non-Invasive brain information collection
- PWI JTC1-SC43-3 Information technology - Brain-computer Interfaces – Multi-modal neural data format for BCI
- PWI JTC1-SC43-8 Information technology - Brain-computer Interfaces - Coding and decoding methods for non-invasive BCI
- Information technology - Brain-computer Interfaces - Framework for fusion and quality profiling of Non-Invasive BCI data

Convenor: YoungIm Cho (KR)

8.1.4 AG3: Chair’ s Advisory Group (CAG) Terms of Reference:

Terms of Reference:

- Tracks the development of technologies in this field;
- Finds the standardization requirements in this field;
- Develops business plans and roadmaps.

Membership of the CAG is open to:

a) SC 43 Officers;
b) One representative per National Body (representing the interests of their NB);
c) Convenors of SC 43/WG or SC 43/AG;
d) ITTF.

Convenor: Yuntao Yu (CN)

8.1.5 AG4: Liaisons and Communications Advisory Group (LCG).

Terms of Reference:

- Provide support for the liaisons and communications with other SDOs.
- Strengthen the communications between SC 43 and its liaisons and other SDOs

Membership in the LCG is open to:

a) One or more representatives per National Body (representing the interests of their NB);
b) Convenors of SC 43/WG or SC 43/AG.
c) One or more representatives per SC 43 Liaison Organization

Convenor: John Strassner (US), Xin Zhang (CN)

8.1.6 AhG 8: Testing and post market surveillance protocols for non-medical BCIs

Terms of Reference:

- To facilitate the development of the work for the proposed technical specification "Testing and post market surveillance protocols for non-medical BCIs"
- The framework and guidelines will be developed with the aim of ensuring manufacturers inform users about the scope of testing, known limitations, and potential long-term side effects.

Program of works:

- PWI JTC1-SC43-7 Information Technology - Brain-computer Interfaces - Testing and post market surveillance protocols for non-medical BCIs

Convenor: Dave Board (GB)

8.1.7 WG 9: Ethics and Trustworthiness

Terms of Reference:

- Development in the following Brain–computer Interfaces areas: security, safety, privacy, and ethics.

Program of works:

- PWI TR 62XXX-1 ED1 Information technology – Brain-computer Interfaces – Overview of Ethical and Societal Concerns (the project number will be assigned after uploading the CD draft).
- PWI JTC1-SC43-2 Information technology – Brain computer Interfaces - Security and privacy requirements

Convenor: Jiangbo Pu (CN)

8.1.8 AhG 10: Scope Improvement

Terms of Reference:

- To redefine the scope of JTC 1/SC 43 in alignment with the purpose of the committee and its existing boundaries.

Convenor: Jacek Eisler (DE)
Co-convenor: David Board (GB)

8.2 Current projects

Currently, 6 ongoing standards projects and 8 Preliminary work items (PWI) are developed under JTC 1/SC 43 as shown in the following table (ordered by approved date).

No.	Project Reference	Title	Project Editor(s)	Current Stage	WG	Note
1.	ISO/IEC 8663 ED1	Information Technology - Brain-computer Interfaces – Vocabulary	Jiangbo PU (CN)	CDV	WG1	• Will publish in 2025
2.	ISO/IEC TS 27571 ED1	Information Technology - Brain-computer Interfaces - BCI data format for Non-Invasive brain information collection	Doniyorjon Mukhtorov (KR)	CD	WG5	•High priority
3.	ISO/IEC 27572 ED1	Information Technology - Brain-computer Interfaces - Reference Architecture	Nan Li (CN)	CD	WG1	• High priority

4.	ISO/IEC TR 27599 ED2	Information Technology — Brain-computer Interfaces - Use Cases	Jiahui Pan (CN)	WD	WG2	
5.	PWI TR JTC1-SC43-1	Information Technology - Overview of Ethical and Societal Concerns	Jiangbo PU (CN)	WD	WG 9	• The project number will be assigned after uploading the CD draft
6.	PWI JTC1-SC43-2	Information Technology – Brain-computer Interfaces - Security and privacy requirements	Zhen YANG (CN), Ruiping Yin (CN)	PWI	WG 9	
7.	PWI JTC1-SC43-3	Information technology - Brain-computer Interfaces – Multi-modal neural data format for BCI	Lin Yao (CN)	PWI	WG5	
8.	PWI JTC1-SC43-4	Information Technology - Brain-computer Interfaces - Hardware interfaces and protocols	Zheng Zhang (CN)	PWI	WG1	
9.	PWI JTC1-SC43-5	Information technology - Brain-computer Interfaces - Design considerations for BCI developers	Taehwa Han (KR)	PWI	WG2	
10.	PWI JTC1-SC43-6	Information technology - Brain-computer Interfaces - Guidance on context-based adaptive interfacing for multi-purpose BCI systems	Kiwon Lee (KR)	PWI	WG2	

11.	PWI JTC1-SC43-7	Information Technology - Brain-computer Interfaces - Testing and post market surveillance protocols for non-medical BCIs	Tamar Makin (GB)	PWI	AhG8	
12.	PWI JTC1-SC43-8	Information technology - Brain-computer Interfaces - Coding and decoding methods for non-invasive BCI	Yongzhi Huang (CN)	PWI	WG5	
13.	PWI JTC1-SC43-9	Information technology - Brain-computer Interfaces - Application of non-invasive BCI for Disorders of Consciousness	Jun Xiao (CN)	PWI	WG2	
14.	/	Information technology - Brain-computer Interfaces - Framework for fusion and quality profiling of Non-Invasive BCI data	Young-Im Cho (KR), Hunju Lee (KR)	PWI	WG5	

8.2.1 ISO/IEC 8663 ED1

ISO/IEC 8663 (Information Technology - Brain-computer Interfaces – Vocabulary) specifies the terms and definitions commonly used in the field of BCI, including basic concepts and classifications of BCI, hardware, experiment setups and protocols used in BCI, related neuroscience concepts of BCI (e.g., coding and decoding, feedback and stimulation), and its applications, etc. It applies to the understanding of Brain- Computer Interface concepts and the exchange of information and to regulate the usage of terms.

8.2.2 ISO/IEC TS 27571 ED1

ISO/IEC TS 27571 (Information Technology - Brain-computer Interfaces - BCI data format for Non-Invasive brain information collection) includes the definition of basic data elements, technology-specific information and metadata, design of an extensible and modular data structure, specification of metadata and annotation information, and the development of a standardized data format and naming convention for BCI data files.

Due to the compatibility issues of different BCI devices and the storage of complex information in BCI data collection, it is necessary to develop a flexible and adaptable BCI data standard that

can establish principles for names, definitions, formats, and rules for data information elements scattered by systems while allowing for integration with new and emerging data formats. This project aims to reduce data conversion and refinement costs between information systems, improved BCI data quality, as well as prevent privacy issues. All these aspects are beneficial for the BCI development, so it should be attached great visibility.

8.2.3 ISO/IEC 27572 ED1

ISO/IEC 27572 (Information Technology - Brain-computer Interfaces - Reference Architecture) specifies the Brain-computer Interfaces (BCI) reference architecture. It addresses the stakeholders concerns and the characteristics related with BCI systems. It also addresses the the effects of using BCI technology in applications. Functions within a BCI system and typical implementation patterns of BCI systems are also addressed in this BCI RA.

The Reference architecture is intended to:

- provide a common language for the various stakeholders.;
- provide guidance to system architects in building the BCI systems;
- provide consistency of design and implementation of technology to solve similar problem sets;
- provide technical reference for agencies and the public to understand BCI solutions.

Based on the above items, this project also ranks as one of the top work items that should be given attention. It provides a consensus-based blueprint or system for designing and implementing BCIs, which is quite essential at the beginning development of BCI standardization work.

8.2.4 ISO/IEC TR 27599 ED2

ISO/IEC TR 27599 ED2 (Information Technology – Brain-computer Interfaces - Use Cases) was initiated to collect new BCI use cases.

8.2.5 PWI TR JTC1-SC43-1 (The project number will be assigned after uploading the CD draft)

PWI TR 62XXX-1 (Information Technology - Ethical Guidelines of Brain-computer Interfaces) provides an information in relation to principles, frameworks, processes and methods in the ethical and societal concerns of BCI. And this document is intended for researchers, manufacturers, regulators, interest groups, and society at large.

8.2.6 PWI JTC1-SC43-2

PWI JTC1-SC43-2 (Information Technology – Brain-computer Interfaces - Safety and Security General Requirements) aims to define a framework of BCI safety and security requirements to provide guidance for the development and application in different scenarios.

The value of this standard: it creates a high-level perspective for safety and security assessment and management of BCI systems, both for different scenarios and different stages. Specifically, it can help the stakeholders to achieve BCI system safety: build, assess and

identify issues about BCI system safety, and improve BCI system security.

8.2.7 PWI JTC1-SC43-3

PWI JTC1-SC43-3 (Information technology - Brain-computer Interfaces – Multi-modal neural data format for BCI) includes the raw data (brain & behavior data), preprocessed data (filtering, bipolar, laplace), and computed data (attention, fatigue, arousal state, etc.).

Due to storage and description of invasive neural data and metadata has significant difference between experiments from different equipment and labs, posing challenges for data sharing and data reuse. To addressing this, this PWI will serve as a standardized framework for data recording and sharing, and an efficient supplement for ISO/IEC TS 27571 Non-invasive BCI data format to support broader BCI development.

8.2.8 PWI JTC1-SC43-4

PWI JTC1-SC43-4 (Information Technology - Brain-computer Interfaces - Hardware interfaces and protocols) aims to enhance BCI system compatibility and try to resolve the fragmentation caused by customized BCI systems with different proprietary protocols and technologies. It will establish a framework for the interfaces and protocols of the data communications between the BCI systems and components hardware.

The sensor/effector interface, which will be specified in this PWI, connects electrodes and sensors, with the processing unit handling neural signals and generating stimulation signals, and the communication interface manages data transfer and control signals according to predefined protocols.

8.2.9 PWI JTC1-SC43-5

PWI JTC1-SC43-5 (Information technology - Brain-computer Interfaces - Design considerations for BCI developers) aims to guide design considerations for BCdevelopers about emphasizing usability, accessibility, and ethical considerations. It will take into account related use cases and providing guiding for cognitive fatigue, physical discomfort, and user diversity. To aligning with the scope of JTC 1/SC 43, the clinical-grade medical BCIs and devices are excluded in this PWI.

8.2.10 PWI JTC1-SC43-6

PWI JTC1-SC43-6 (Information technology - Brain-computer Interfaces - Guidance on context-based adaptive interfacing for multi-purpose BCI systems) focuses on providing guidance for the implementation of context-based adaptive interfacing in BCI systems designed for multiple applications. It addresses functional considerations and challenges related to applying such interfacing techniques to multi-purpose BCI systems, while explicitly excluding matters related to laws, regulations, and policies. This document aims to offer practical recommendations tailored to the unique characteristics of multi-purpose BCI systems, ensuring their effective and adaptive operation across diverse contexts.

8.2.11 PWI JTC1-SC43-7

PWI JTC1-SC43-7 (Information Technology - Brain-computer Interfaces - Testing and post market surveillance protocols for non-medical BCIs) seeks to establish a framework for non-medical BCI products on the market, focusing on minimum human testing requirements, post-market surveillance protocols, and marketing transparency standards. It aims to ensure manufacturers inform users about testing, limitations, and potential long-term effects. BCI technology developers, vendors, and professionals who may recommend these products are relevant to this working item.

8.2.12 PWI JTC1-SC43-8

PWI JTC1-SC43-8 (Information technology - Brain-computer Interfaces - Coding and decoding methods for non-invasive BCI) aims to define standards for classical BCI encoding and decoding methods, supplement existing PWI and research standards, and provide guidance for development and application in different scenarios.

8.2.13 PWI JTC1-SC43-9

The aim of PWI JTC1-SC43-9 (Information technology - Brain-computer Interfaces - Application of non-invasive BCI for Disorders of Consciousness) is to provide a reference workflow for the application of BCI in the DOC scenario, including the various stages of paradigm design, signal acquisition and preprocessing, decoding algorithms and performance assessment, as well as to guide its implementation in this specific scenario.

8.2.14 Information technology - Brain-computer Interfaces - Framework for fusion and quality profiling of Non-Invasive BCI data

This document specifies requirements and provides guidance for the acquisition, time synchronization preprocessing, quality control, and cross-modal fusion of BCl data (EEG, fNIRS, and fMR. lt defines methods and metrics to reduce noise and drift, close synchronization gaps, with the aim of enabling regulator-ready BCl systems

8.3 Publications

8.3.1 ISO/IEC TR 27599:2025 Edition 1.0 (2025-05-08)
ISO/IEC TR 27599:2025 (Information technology – Brain-computer interfaces – Use cases) provides a collection of representative use cases of brain-computer interface (BCI) applications in a variety of domains: proposed medical and health, industrial controls, smart environment, etc.
This technical report can be used for the development of potential standards, and it is valuable for a better comprehension of BCI. It is also helpful for BCI industries and products that provide support for communications among interested parties and stakeholders.

ISO/IEC TR 27599:2025 is applicable to all types of organizations (e.g. commercial enterprises, government agencies, not-for-profit organizations).