**ISO/IEC JTC 1 "Information technology"**
Secretariat: **ANSI**
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# SC 43 Business Plan 2023

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**Description**

This document is circulated for review and consideration at the November 2023 JTC 1 Plenary.

# 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 holding in November 2021. The National Body of China serves as Secretariat for JTC 1/SC 43. Ms. Yuntao Yu serves as the Chair for JTC 1/SC 43, and Ms. Fang Lin is Committee Manager. At the same plenary, the working item ISO/IEC 8663 was assigned to SC 43 for development. SC 43 is System Integration Entity. Besides, the Scope of JTC 1/SC 43 is:

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.

In September 2022, SC 43 held the 1st plenary and generated 14 resolutions. It was approved to establish WG1 on Foundational standards, WG2 on Applications, AG3 on Chair’ s Advisory Group (CAG), AG4 on Liaisons and Communications Advisory Group (LCG), liaison relationships, and so on. Moreover, WG1 is responsible for the ISO/IEC 8663 ED1 Information Technology - Brain-computer Interfaces - Vocabulary while WG2 is for PWI TR JTC1-SC43-1 Information Technology - Brain-computer Interfaces - Use Cases (approved for initiation of a TR).

The 2nd plenary was held virtually in March 2023. A total of 11 resolutions were adopted about the projects, organizations, liaisons and future meetings. Remarkably, ISO/IEC 8663 ED1 was approved a new timeframe, a PWI of BCI reference architecture was approved to conduct within SC 43/WG1, and the term of reference of SC 43/AG4 updated. Furthermore, the 3rd Plenary would be held in China as a face-to-face meeting with remote participation.

SC 43 aims to develop brain-computer interface standards that are beneficial to industry development and UN Sustainable Development Goals (SDGs). This business plan is the first vision of SC 43 and it focuses on the information and output of the committee.

## 2 Environment

### 2.1 Market dynamics

The past decade has seen significant growth in research groups and new startups working on brain-computer interface (BCI) technologies and products. The global BCI market size was valued at USD 1.43 billion in 2021 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 burgeoning industry.

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 has contributed to more than 62% of revenue in 2021. The increasing prevalence of neurodegenerative disorders (e.g., Parkinson' s and Alzheimer' s) and neurodevelopmental disorders (e.g., attention deficit hyperactivity disorder and autism spectrum disorder) is expected to create the demand for BCI in the healthcare industry. BCI can also facilitate communication and movement for patients with paralysis or amputation, and be useful for rehabilitation after a stroke. In addition, 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. The use of BCI in smart home control, sports training, and military operations also broadens the applicability of the market, fueling its growth.

By invasiveness, the BCI market can be segmented into invasive, partially invasive, and non-invasive BCI. The non-invasive segment held a major revenue share of over 86% in 2021 and is expected to increase the mainstream accessibility of BCI technology. The invasive and partially invasive segments are expected to witness the fastest CAGR due to their application in assistive devices for people with disabilities.

### 2.2 Technology trends

BCI technology provides a realistic path to human-computer fusion, which has broad application prospects in medical treatment, human augmentation, military operations, education, entertainment, and other fields. 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 technology is developing towards flexible, wireless, and more miniaturized, high-throughput and low power consumption. The future development direction of non-invasive BCI is to develop more portable and comfortable devices to better serve humans. Long-term stable recording of large-scale signals is a central challenge for invasive techniques.

- 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 will be made. Future BCI technologies may also include more advanced autonomous learning capabilities, which will allow the system to better adapt to individual 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.

### 2.3 Customer/stakeholder needs

The stakeholders of BCI mainly include developers, investors, customers, etc. 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.

- Customer requirements for BCI vary by application and location but generally can be summed up as the following: safety, effectiveness, convenience, and comfort. 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; convenience refers to whether the BCI is easy to use and maintain; and comfort refers to whether the BCI can adapt to the user's differences and preferences.

### 2.4 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.

BCI technology involves the privacy, security, ethics, law, and other aspects of the sharing of our thoughts. 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.

## 3 Benefits

The rapid development of brain-computer interface (BCI) technology has led to a growing need for standardization to ensure the safety, efficacy, interoperability, security and privacy of the user of these devices, with a specific focus on ethics aspects and interoperability of these devices. ISO/IEC JTC 1/SC 43 is a key organization working towards standardizing BCI

technology. The SC 43 aims to develop technical standards for BCI systems that address critical issues, such as safety, interoperability, and quality assurance.

### 3.1 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 has developed the IEC 60601-2-26 standard for the safety requirements of electroencephalographs (EEGs) which is the core for many BCI devices in the market. This standard specifies safety requirements for the design, testing, and certification of EEG devices. Compliance with this standard ensures that BCI devices are safe for use. This standard could be used as a base requirement for many other BCI standards. By implementing standardized safety protocols, BCI devices can be made safer and more reliable, which can increase user trust and acceptance of these devices.

**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 SC 43 standards are well positioned to be safe, effective, and can improve accessibility for users.

### 3.2 Sustainable development goals addressed by 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 ISO/IEC JTC 1/SC 43 is critical to achieving these goals.

# 4 Participation and Cooperation

### 4.1 Membership (By 2023-09-15)

SC 43 is open to the involvement of NBs and experts from different countries. Up to now, there are 11 P-members and 9 O-members participating in SC 43.

**P-Members (11)**: Australia (AU), Belgium (BE), China (CN), Denmark (DK), United Kingdom (GB), India (IN), Italy (IT), Japan (JP), Korea, Republic of (KR), Russian Federation (RU), United States of America (US).

**O-Members (9)**: Argentina (AR), Austria (AT), Brazil (BR), Spain (ES), Finland (FI), France (FR) , Netherlands (NL), Singapore (SG), Slovakia (SK).

### 4.2 Cooperation

As an interdisciplinary area concerned with biology, neuroscientist, engineering, computer science, and applied mathematics, BCI requires close cooperation with other SDOs and committees. SC 43 makes efforts to improve cooperation by establishing an extensive network of liaisons both internal and external to IEC. The specific liaison information is listed below.

| Liaison Type | No. of TC | Description |
|---|---|---|

| | | |
|---|---|---|
| Internal liaison within IEC | IEC/TC 124 | Wearable electronic devices and technologies |
| Internal liaison within IEC | IEC/TC 62 | Electrical equipment used in medical practice |
| Internal liaison within IEC | IEC/TC 100 | Audio, video and multimedia systems and equipment |
| Internal liaison within IEC | IEC/SyC AAL | Active Assisted Living |
| Internal liaison within IEC | IEC/SyC COMM | Communication Technologies and Architectures |
| Internal liaison within ISO | ISO/TC 215 | Health informatics |
| Internal liaison within ISO | ISO /TC 150 | Implants for surgery |
| Internal liaison within ISO/IEC JTC 1 | ISO/IEC JTC 1/SC 6 | Telecommunications and information exchange between systems |
| Internal liaison within ISO/IEC JTC 1 | ISO/IEC JTC 1/SC 41 | Internet of Things and Digital Twin |
| Internal liaison within ISO/IEC JTC 1 | ISO/IEC JTC 1/SC 42 | Artificial Intelligence |

### 4.3 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. Especially IEC has done some researches on bio-digital convergence and metaverse, which are closely related to BCI.

## 5 Objectives and strategies to achieve them

### 5.1 SC 43

JTC 1/SC 43 plays a crucial role in the development of BCI standards. It is challenging to

recruit people to join our 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 privacy, ethics and law.

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.

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.

**5.2 SC 43/WGs**

**5.2.1 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/AG8 N647) meta reference architecture.

**Strategies :**

ISO/IEC 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 September 2021, the project has been approved to get into the CD stage and is now seeking feedback before entering into the DIS stage. The discussion and development of the project will continue to conduct by a working group that defines the vocabulary of BCI technology and makes the project 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 proposing a BCI reference architecture. The reference architecture is intended 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.

In addition, the proposed reference architecture will be established based on the JTC 1 Meta Reference Architecture guidance document by JTC 1/AG8 (AG8 had been disbanded in JTC 1 Plenary, May, 2023). Through the alignment with the meta reference architecture, the proposed 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.

### 5.2.2 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:**

ISO/IEC SC 43/WG2 is currently open to collecting use cases 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.

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 Challenges/Risks

SC 43 has been conducting all of its meetings in a fully virtual environment ever since it was established due to the ongoing pandemic. The first plenary meeting and the second meeting, have both been organized in online mode. While the virtual meeting environment has allowed the committee to continue its work despite the restrictions imposed by the pandemic, it has also had some negative impacts on the progress of the work. The lack of face-to-face interaction and the limitations of online communication have hampered the productivity of the committee to some degree.

However, in 2023, the committee members are expected that the situation will improve as they plan to hold the third plenary meeting in an offline, in-person format. This presents an opportunity for the committee members to engage in face-to-face discussions, which will not only allow for a better exchange of ideas but also help accelerate the progress of the standardization work. With the chance to meet in person, the committee members can more easily collaborate, share their knowledge and expertise, and work together towards achieving their goals. The offline meeting format is expected to facilitate better communication and foster a more collaborative atmosphere, which should translate into more productive meetings and a more efficient standardization process.

The ongoing PWI TR JTC 1-SC 43-1 "Information Technology - Brain-computer Interfaces - Use Cases (approved for initiation of a TR)" shall be updated according to the thriving industry developments or contributions from NBs.

After the pandemic, travel between countries may still be subject to restrictions. Travelers may need to provide a detailed itinerary and contact information for an entry permit. It is important to stay up-to-date on the latest travel regulations and advisories before planning any international trips.

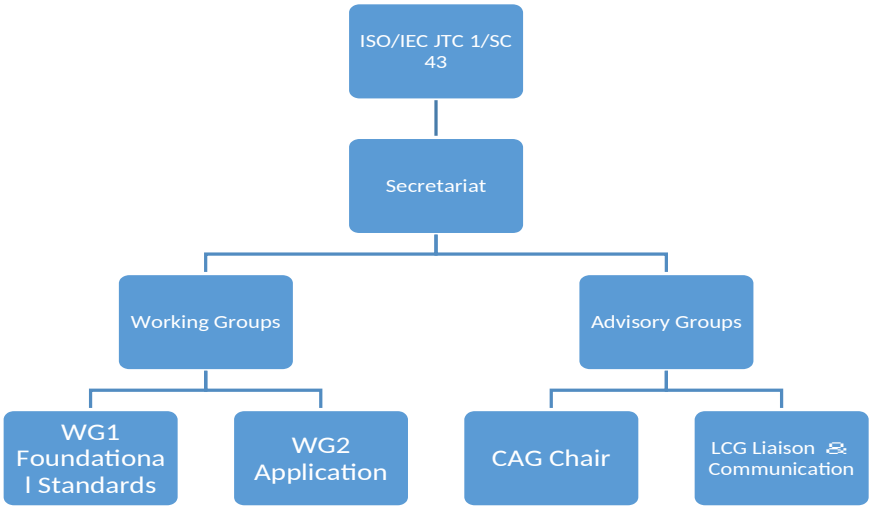
Ethical and social challenges of BCI, especially invasive BCI: The physical, psychological and possible social effects of BCI should be well considered. Privacy is another important topic that which BCI standard should refer to.

Risk related to patents: By thriving industry development, 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.

# 7 Structure, current projects, and publications

## 7.1 Structure




### 7.1.1 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 Interface - Vocabulary

**Convenor:**

Saurin Parikh

### 7.1.2 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:**

PWI TR JTC 1-SC 43-1 ED1 Information Technology - Brain Computer Interfaces - Use Cases (approved for initiation of a TR)

**Convenor:**

Arpan Banerjee

**7.1.3 AG3: Chair' s Advisory Group (CAG)**

**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

**7.1.4 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

**7.2 Current projects**

**7.2.1 ISO/IEC 8663 ED1**

ISO/IEC 8663 ED1 Information Technology - Brain-computer Interfaces - Vocabulary

**Project Editors:** Jiangbo PU (CN), Aziz Khan (IN)

**Scope:** This document 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.

**Current Status:** WD stage

### 7.2.2 PWI TR JTC 1-SC 43-1

PWI TR JTC 1-SC 43-1 Information Technology – Brain-computer Interfaces - Use Cases (approved for initiation of a TR)

**Project Editor:** Jiahui Pan (CN)

**Scope:** This document provides a collection of representative use cases of Brain-computer Interface applications in a variety of domains, e.g., medical and health, industrial controls, smart environment, etc. It can be used in 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/stakeholders. It applies to all types of organizations (e.g., commercial enterprises, government agencies, and not-for-profit organizations)

**Current Status:** WD stage

### 7.2.3 PNW TS JTC1-SC 43-53

PNW TS JTC1-SC 43-53 Information Technology - Brain-computer Interfaces - BCI data format for Non-Invasive brain information collection

**Project Editor:** Mr. Doniyorjon Mukhtorov (KR)

**Scope:** This document 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.

**Current Status:** PWI stage

### 7.3 Publications

None.