



SESEC IV

China Standardisation Newsletter

April – May 2021

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Takeaways

SAMR Updated Its Legislative Work Plan for 2021

In April 2021, the State Administration for Market Regulation (SAMR) announced the legislative work plan for 2021. The work plan includes 67 legislative items to be formulated or revised throughout the year – including 6 drafts of laws and administrative regulations, and 61 departmental rules and regulations (36 legislative items of the first category and 25 of the second category*). The following is a summary of legislative items in key areas.

Personal Information Protection Law of China Called for Public Comments

On April 29, 2021, the National People’s Congress Standing Committee published the second draft of the Personal Information Protection Law of the People’s Republic of China, calling for public comments. Compared with the first draft, the second draft revised some provisions and added new ones, based on the feedback received during the first round of public comments.

Annual Conference Week of SAC/TC 260 Held in Wuhan

On 10 May 2021, the first plenary meeting in 2021 of the National Information Security Standardisation Technical Committee (TC 260) was held in the Wuhan National Cybersecurity Talent and Innovation Base. The meeting, whose theme was “cybersecurity standards leading the sound development of digital economy”, also marked the beginning of the annual TC 260 conference week. Leaders of all working groups of TC 260 and more than 900 representatives from 370 domestic and foreign enterprises, scientific research institutions, and universities attended this plenary meeting.

Regulations on Automobile Data Security Management: Strengthen the Supervision of Automobile Data

From May 12, 2021 to June 11, CAC called for public comments on the Regulations on Automobile Data Security Management (Draft for Comments). The document aims to regulate automobile data processing activities and safeguard national security and public interests.

MIIT: 5G Application Standards System Expected to be Completed by the End of 2023

On May 1, 2021, MIIT held a public consultation session on its draft Action Plan for 5G Applications (2021-2023). The document aims to implement General Secretary Xi Jinping’s instructions on expanding the application scenarios of 5G technology and accelerating the overall development of 5G application. It indicates key goals to be achieved by 2023.

China Promotes Its DC Charging Solution “Chaoji” in IEC

China’s proposal to establish an ad hoc working group for China’s DC charging technology “Chaoji” in IEC/TC69 was unanimously approved in the TC’s plenary meeting on 28 April 2021. Composed of experts from IEC/TC69 and SC23H, the working group will focus on the safety and interoperability issues of this Chinese charging technology for interacting with other DC charging systems.

New Changes in Medical Device: Revised Regulations on Supervision and Registration

On 18 March 2021, the National Medical Products Administration issued the revised version of the Regulations on the Supervision and Administration of Medical Devices. In line with the Regulations on the Supervision and Administration of Medical Devices, the Regulations on the Registration of Medical Devices was also revised. From 26 March to 25 April 2021, NMPA called for public comments on the revised document.



Horizontal Issues

1. SESEC Training on European Standardisation System in Chinese Company #Training #ESS

On 27 May 2021, Dr. Betty XU, the Director of SESEC Project, was invited by China Goldwind Group – one of China’s leading provider for wind turbine technology and energy solutions – to participate in the Interpretation and Sharing Forum on International Standard Systems 2021. As the keynote speaker, Dr. XU introduced the European Standardisation System as well as the core contents of CEN-CENELEC Strategy 2030 and CEN-CENELEC Work Plan 2021.



Understanding the European Standardization System is a fundamental requirement for enterprises to engage in EU-China business activities. Dr. Betty XU first explained the organizational structure and operation mechanisms of the three European standardization organizations (namely CEN, CENELEC and ETSI), also providing an overview of their current cooperation with China in the field of standardization. Dr. Betty XU also analyzed the core and the objectives of the European Standardization System, its close relationship with international standards, market influence, its relationship with the EU legislation and New Legislative Frame, the development and implementation of EN standards, and how to participate in international standardization.



The keynote speech by Dr. XU was highly appreciated by the audience, and the presentation provided the audience with a clearer picture on European Standardisation System, the CEN-CENELEC Strategy 2030, and CEN-CENELEC Work Plan 2021. SESEC will continue to promote the European Standardisation System and international standards in China, and to foster further cooperation between EU and China in standardisation activities.

2. ITEI and DKE Renews Their MOU

#ITEI #DKE

During an online meeting held on 8 April, the Instrumentation Technology and Economy Institute of China (ITEI) and DKE renewed their Memorandum of Understanding (MOU).

ITEI and DKE first signed the MOU in 2014, with the aim to facilitate information exchanges, and to carry out cooperation, both at national- and IEC-level, on standardization topics of mutual interest, such as reliability of measuring and controlling devices, industry 4.0, IoT, industrial wireless communication, information security, and semantic standards.

The renewal of the MOU brings in new areas for cooperation, including intelligent manufacturing and standards' digital transformation. In the MOU, both parties agreed that intelligent and digital transition are the key development directions, therefore cooperation in international standardization should be strengthened, especially addressing digitalized standards and machine-readable standards.

In addition to the renewal of the MOU, during the meeting representatives from ITEI introduced China's recent progress in intelligent manufacturing standardization; after reviewing successful cooperation cases with Germany on industrial ethernet, predictive maintenance, system reliability, function safety, and information security, ITEI representatives outlined China's work plan for international standardization in key fields such as 5G's industrial application, industrial internet platform, digitalized standards, and machine-readable standards.

Representatives from DKE stressed the positive role of the cooperation between the two organizations, especially on the China-Germany Intelligent Manufacturing Security White Paper, IEC/SyCSM, asset administration shell and public data dictionary, and machine-readable standards; they also proposed to deepen cooperation on standardization research, test, and training, on the basis of the current achievements of the cooperation.

3. SAMR: Standardize and Improve Certification Services

#SAMR #Certification

On 15 April 2021, the State Council Information Office held a regular State Council policy briefing in Beijing, introducing the Comments on Serving the "Six Stabilities" and "Six Guarantees", and Further Advance the Reform of "Decentralization, Management and Services", and answering questions from reporters. In particular, LIU Weijun, Director of the Certification Supervision Department of the State Administration for Market Regulation, pointed out three main problems to be solved for standardizing and improving certification services.

Firstly, a fair and competitive market environment should be created to stimulate the vitality of the certification market. In accordance with the requirements of the document, the transformation of certification agencies to enterprises, thus decoupling from government departments, should be promoted: this will increase the openness of the market and promote fair and orderly competition, giving full play to the independent attributes of certification bodies. One example is the China Inspection and Certification Group is China's largest inspection and

certification organization; last year, it was decoupled from the State Administration for Market Supervision and handed over to the State-owned Assets Supervision and Administration Commission for general supervision. At the same time, this document also particularly emphasizes the need to strengthen the supervision of certification bodies and to investigate and punish unregulated certification activities. Finally, certification bodies are required to publish relevant information about certification activities through websites or other means, highlighting the areas of certification, certification rules, rates, results, etc., all with the purpose of improving the quality of certification services.

Secondly, in order to reduce the institutional transaction costs faced by enterprises, the current evaluation system involving certification must be revised, streamlined, and standardized. According to the Opinions of the State Council on Strengthening the Construction of Quality Certification System and Promoting Total Quality Management, for those with an existing unified national certification system, similar evaluation projects shall no longer be established. For example, the original evaluation projects of energy-saving, environmental protection, recycling, low-carbon, and recycling products, are in the process of being integrated; a unified national green product certification and labeling system was established with positive results. Currently, the national unified green product certification system covers building materials, express packaging, electronic appliances and other fields, and more than 10,000 certificates have been issued.

Finally, efforts should be made to improve the multi-faceted certification and acceptance mechanism of the government, industry and society, with the objective to avoid repetitive certification evaluations and to promote active acceptance and mutual recognition of certification results by all relevant parties. The ultimate goal is to facilitate market operations by guaranteeing full market access with one certificate.

Background:

On 15 April 2021, the General Office of the State Council issued the Comments on Serving the "Six Stabilities" and "Six Guarantees", and Further Advance the Reform of "Decentralization, Management and Services". The document emphasizes the following requirements: standardization and improvement of certification services; promoting the transformation of certification agencies into enterprises by decoupling agencies from government departments; increasing market openness and promoting fair and orderly competition; strengthening the supervision of certification agencies, and improving the quality of services while urging certification agencies to disclose rates and other certification information in a timely manner; setting up standards involving the evaluation system of certification and promoting the transformation to a unified national certification system; and improving and promoting the mutual recognition of certification results among different departments and regions.

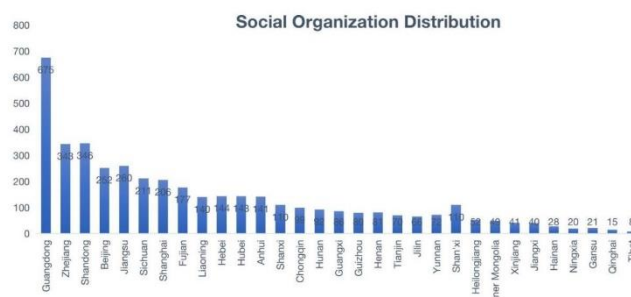
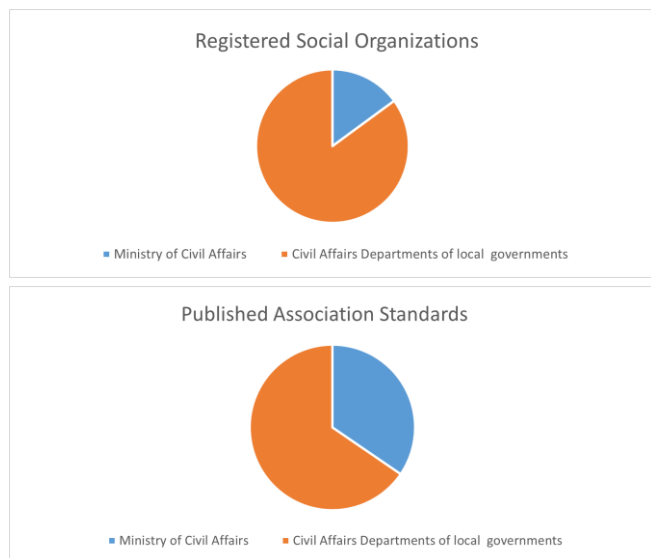
4. New Developments of Association Standards in China – as of May 2021

#Association Standards

In early May 2021, the National Association Standards Information Platform published the statistics of China's association standards – updated as of April 30, 2021. The main contents are as follows:

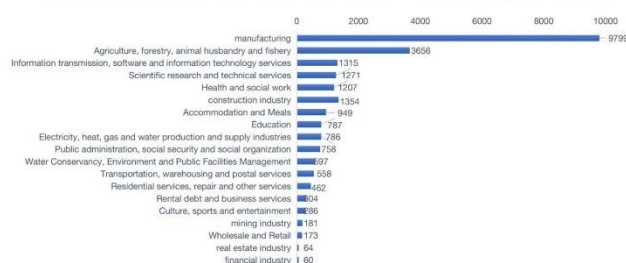
A total of 4,845 social organizations had been registered on the National Association Standards Information Platform. Among these, 725 are

registered with the Ministry of Civil Affairs, while the remaining 4,120 are registered with local civil affairs departments; these have respectively released 8,484 and 16,077 standards on the National Association Standards Information Platform—for a total of 24,561 standards.



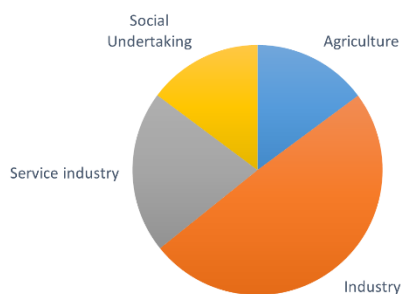
With regards to industry and social distribution, around half of the standards belonged to the industrial sector (12,127, accounting for 49% of the total; 5,149 standards (21%) belonged to the service sector; while

Organization Standard Distributed According To National Economy Sectors



3,650 standards (15%) and 3,635 standards (15%) belonged respectively to the agricultural sector and social undertakings.

Organization standards distributed by industry and society



5. SAC Launches Statistical Analysis on Implementation of Mandatory National Standards in 2021

#GB Standards

The *Standardization Law of the People's Republic of China* stipulates that the State shall establish a statistical analysis report system on the implementation of mandatory standards. On this basis, SAC has started a pilot statistical analysis on the implementation of mandatory national standards among the standard-drafting departments, which will cover the period between May and September 2021.

According to the mandatory national standards under centralized management, the standard-drafting departments shall focus on the implementation of mandatory national standards, which have been implemented for more than 2 years, and that have attracted high attention from consumers, have large impact on the industry, and cover a wide range of areas. The specific number of standards shall be determined by the organization and drafting department.

The main contents of this statistical analysis include:

- Standard applicability. Focusing on (i) whether the applicable scope of the standard matches the current level of industrial development, that is, whether there are new technologies and new products that have not been covered by the standard; (ii) whether the normative reference documents are currently valid, that is, whether the standard of the test method cited has been updated or not; (iii) whether the standard technical indicators are comprehensive and whether the standard technical requirements are reasonable, compared with the new situation, new problems and new demands; and (iv) whether the standard needs to be updated, compared with the latest progress of international technical regulations and standards.
- Standard compatibility. Focusing on (i) analyzing whether there are problems inconsistent with the main technical indicators of other mandatory standards, and whether new supporting standards are needed to support the implementation of the standard; (ii) whether there is any inconsistency with relevant laws and regulations, departmental rules or industrial policies.
- Implementation of the standard. Focusing on the analysis of (i) the overall implementation and compliance rate of the standard by enterprises, (ii) the application of the standard by the government in the aspects of market access, ongoing and ex post supervision and reference of policy documents, and (iii) consumers' awareness of the standard. At the same time, statistics can be carried out by the relevant parties to promote standards and training.
- Standard technical economic analysis. Focusing on the main technologies adopted by relevant enterprises to meet the requirements of the standard, as well as the applicability of the main technologies and the results of the standard. The standard cost analysis includes the technical transformation and increased cost inputs of the enterprise in order to be compliant, as well as the proportion of the new costs on the total cost.
- Standard implementation benefit analysis. Focusing on the analysis of the contribution and impact of the standard to (i) safeguard people's livelihood and safety, (ii) to promote the high-quality development of the industry, (iii) to promote international trade, (iv) to protecting the ecological environment, etc. This shall be based on qualitative and quantitative methods, and shall put forward differentiated indicators of economic, environmental and social benefits. The evaluation methods of economic and social benefits can refer to the national standards of *Standardized Benefit Evaluation Part 1: General Rules for Economic Benefit Evaluation (GB/T 3533.1-2017)* and *Standardized Benefit Evaluation Part 2: General Rules for Social Benefit Evaluation (GB/T 3533.2-2017)*.



Laws and Regulations

6. SAMR Updated Its Legislative Work Plan for 2021 #SAMR #Legislation

In April 2021, the State Administration for Market Regulation (SAMR) announced the legislative work plan for 2021. The work plan includes 67 legislative items to be formulated or revised throughout the year – including 6 drafts of laws and administrative regulations, and 61 departmental rules and regulations (36 legislative items of the first category and 25 of the second category*). The following is a summary of legislative items in key areas.

Anti-monopoly and anti-unfair competition

In order to strengthen the enforcement of anti-monopoly and anti-unfair competition, thus safeguarding fair market competition, China will revise the *Anti-Monopoly Law of the People's Republic of China*, formulate the *Provisions on the Prohibition of Unfair Competition on the Internet*, and revise the *Provisions on the Protection of Trade Secrets* – among other regulations.

Food safety

The *Measures for the Supervision and Inspection of Food Production and Marketing* and the *Measures for the Supervision and Administration of Drug Distribution* will be revised, with the aim to improve the comprehensive control of food safety and strengthen the whole-process supervision of drug safety.

Special equipment

The *Administrative Measures for Safety Supervision and Inspection of Special Equipment* and other regulations will be revised.

Market order

The *Interim Provisions on Information Disclosure of Administrative Penalties for Market Supervision and Administration* and the *Measures for the Supervision and Handling of Contract-related Violations* will be revised, with the aim to ensure better market order and market supervision system rules.

Product quality

In order to further improve the quality of products and services, SAMR will revise the *Measures for the Administration of New Products of Measurement Instruments*, the *Measures for the Administration of National Standards*, the *Administrative Measures for the Standardization of Enterprises*, and the *Measures for the Administration of Organic Product Certification* – among other regulations.

Intellectual property rights

SAMR will submit the *Implementation Regulations of the Patent Law of the People's Republic of China (Revised Draft)* to the State Council, and revise the *Several Provisions on Regulating Patent Application Activities* and other regulations for the protection of intellectual property rights.

According to SAMR, the fundamental aim of the legislative work in 2021 is to build a modern legal system for market supervision, strengthen legislation in key areas, speed up the legislative process, optimize the legislative procedures,

and focus on improving the quality and efficiency of legislation, so as to lay a solid legal foundation for the long-term development of market supervision.

* *Note: legislative items of the first category refer to the items that must be submitted to the Standing Committee for deliberation that year, which are mandatory plans. Legislative items of the second category refer to those that have already started the research and drafting process and that can be submitted for deliberation that year, which are guidance plans.*

The full list of the 67 legislative items in Chinese is available at:

http://gkml.samr.gov.cn/nsjg/fgs/202104/t20210401_327476.html

7. Personal Information Protection Law of China (Second Draft) Called for Public Comments

#Personal Information Protection



On April 29, 2021, the National People's Congress Standing Committee published the second draft of the *Personal Information Protection Law of the People's Republic of China*, calling for public comments. Compared with the first draft, the second draft revised some provisions and added new ones, based on the feedback received during the first round of public comments. The most significant changes are summarized below:

- Reinforce the cross-border provision of personal information requirements. In the second draft, one of the basic premises for cross-border personal information was changed from "*signing contracts with overseas recipient*" to "*signing contracts with overseas recipient in accordance with the standard contract formulated by the Cyberspace Administration of China*". The objective is to prevent potential security problems arising when enterprises draft relevant contracts by themselves.
- Strengthen the supervision over the personal information given to overseas judicial or law enforcement agencies. In the second draft, the statement "*for the purpose of international judicial assistance or administrative law enforcement assistance, individuals who need to provide personal information abroad shall apply for the approval of the competent authorities according to law*" was changed to "*individuals whose personal information stored in China is required to be provided to overseas judicial or law enforcement agencies, shall not do so without the approval of the competent authorities*". On the one hand, this provision was adjusted to become a prohibition. On the other hand, it expanded the scope of the supervision on personal information: it is no longer confined to "international judicial assistance or administrative law enforcement assistance" only. As long as the overseas judicial or law enforcement

agencies requires personal information stored within China, the provision shall be applied. It is aiming at countering the long arm jurisdiction of foreign institutions.

- Specific personal information protection obligation requirements for super large Internet platforms were added. For instance, Article 57 added a provision that "*entities processing personal information, which provide basic Internet platform services with a large number of users and complex business types, shall fulfill the following obligations: (i) set up an independent organization composed mainly of external members, to supervise personal information processing activities; (ii) stop providing services to the products or service providers on the platforms that deal with personal information in violation with the law and administrative regulations; (iii) regularly release social responsibility reports on personal information protection, and accept social supervision*". This provision explicitly proposes the legal requirements to strengthen the obligation of personal information protection on super-large Internet platforms.
- Clarify the authority of the State Cyberspace Administration for overall coordination. Article 61 points out that "*the Cyberspace Administration of China makes overall plans and coordinates with relevant departments to promote the following work in the field of personal information protection: (i) formulate specific rules and standards for personal information protection; (ii) formulate special personal information protection rules and standards for sensitive personal information, new technologies and applications – such as face recognition and artificial intelligence; (iii) support the research and development of secure and convenient electronic identity authentication technology; (iv) promote the construction of a socialized service system for personal information protection. In addition, the State Cyberspace Administration will also support relevant institutions in carrying out evaluation and certification services for personal information protection*".

8. Administrative Measures for Online Trading Supervision to be Implemented in China

#Administration #Online Trading

On 15 March 2021, the State Administration for Market Regulation (SAMR) issued the *Administrative Measures for Online Trading Supervision*. The document, an important departmental rule formulated to fulfil the requirements of the *E-Commerce Law of the People's Republic of China*, will start to be implemented on 1 May 2021 – replacing the *Administrative Measures for Online Trading* published in 2014 to regulate online trading, protect the legitimate rights and interests of online consumers, and promote the sustained and sound development of China's digital economy.

The Measures consist of 5 chapters and 56 articles, outlining efforts to improve the governance system of the online trading market, by promoting diversified participation and standardised order. Specifically, the Measures stipulate clear provisions on five main issues:

- Registration of network operators: Individuals engaged in cleaning, washing, sewing, hairdressing, house moving, duplication of keys, plumbing, furniture and home appliances repair, and other convenient services that do not require licensing, or whose annual turnover is not more than 100,000 CNY, are not required to register.
- Supervision of new business forms: If network service providers of social networking and live broadcasting provide operators with online trading platform services such as commodity browsing, order

generation and online payment, they shall perform the obligations of online trading platform operators in accordance with the law.

- Responsibility of platform operators: Every six months, online platforms shall submit the identity information of the operators to the provincial market supervision department where they are located. The platforms shall establish an inspection and monitoring system for the business activities they host, and promptly handle and report on illegal activities.
- Protection of consumers' rights and interests: Operators shall not set tie-in commodities as consumers' default consent, and shall not set the options selected by consumers in previous transactions as default choice. The operator of an automatic renewal service shall, five days before the renewal of the service, bring it to the attention of the consumer in an obvious way.
- Protection of personal information: Network trading operators shall clearly state the purpose, methods and scope of collecting and using consumers' personal information, and obtain the consent of consumers. Consumers shall not be forced or disguised to agree to the collection and use of information not directly related to their business activities. Before collecting and using sensitive personal information, consent must be obtained from consumers on an item by item. Without the authorized consent of the consumers, the personal information shall not be provided to any third parties.

In 2019, after the *E-Commerce Law of the People's Republic of China* was officially implemented, the director of SAMR's Department of Laws and Regulations made a public briefing on the scope of application of the law. Specifically, overseas legal persons or unincorporated organizations engaging in business activities through the services of domestic e-commerce platforms, shall equally be subject to the jurisdiction of the E-commerce Law, unless the overseas operators explicitly agree with Chinese platform operators to exclude the application of Chinese laws.

Foreign legal persons or unincorporated organizations that provide goods or services to Chinese consumers through self-established overseas websites, trading platforms and social media, shall be fully subject to the E-commerce Law if the language, payment methods, distribution and other transaction channels used are all clearly directed to consumers in China. As a result, overseas operators have to pay close attention to the development of regulatory rules on the online trading in China to avoid unnecessary barriers.

The Chinese news is available, for reference, at:

http://www.samr.gov.cn/xw/zj/202103/t20210315_326928.html

The original Chinese full text of the *Administrative Measures for Online Trading Supervision* is available at:

http://www.gov.cn/zhengce/zhengceku/2021-03/16/content_5593226.htm



Information Security

9. Annual Conference Week of SAC/TC 260 Held in Wuhan #TC 260 #Cybersecurity

On 10 May 2021, the first plenary meeting in 2021 of the National Information Security Standardisation Technical Committee (TC 260) was held in the Wuhan National Cybersecurity Talent and Innovation Base. The meeting, whose theme was “cybersecurity standards leading the sound development of digital economy”, also marked the beginning of the annual TC 260 conference week. ZHAO Zeliang, the Deputy Director of Cyberspace Administration of China (CAC), and TIAN Shihong, Director of the Standardisation Administration of China (SAC), attended the meeting and delivered keynote speeches. Leaders of all working groups of TC 260 and more than 900 representatives from 370 domestic and foreign enterprises, scientific research institutions, and universities attended this plenary meeting.



According to ZHAO Zeliang, China’s efforts will focus on (i) promoting the integration of cybersecurity standards and platform economy rules; (ii) carrying out an analysis of standardisation demands, and a prospective research on standards for new technologies and new application fields around the *Cybersecurity Law*, the *Data Security Law* and the *Personal Information Protection Law*; and (iii) promoting the development of new technologies and applications, such as intelligent connected vehicles and artificial intelligence.

It is estimated by SAC that currently there are 322 cybersecurity standards. In 2020, MIIT also issued a guide to the construction of the network data security standards system in 2020, focusing on the protection of personal information, network platforms and critical information infrastructure.

The Conference Week lasted for four days in total, during which the working groups of TC 260 discussed on the ongoing development and revision of 73 national cybersecurity standards, conducted the technical review of 86 new standardization project proposals, and exchanges views on how to improve the sub-field standards system of the working groups.

The text of the original Chinese keynote speeches is available at:

<https://www.tc260.org.cn/front/postDetail.html?id=20210510214340>

Background:

TC 260 is a technical committee established by SAC to conduct work related to China's information security standards. There are seven working groups under TC 260, namely:

- WG1 Working Group on Information Security Standards System and Coordination
- WG3 Working Group on Cryptography
- WG4 Working Group on Authentication and Authorisation
- WG5 Working Group on Information Security Assessment
- WG6 Working Group on Communication Security Standards
- WG7 Working Group on Information Security Management
- SWG-BDS Big Data Security Standards Task Force

TC 260 has published the English version of *GB/T 35273-2020 [Personal Information Security Specification](#) and [Cybersecurity Review Measures](#)*. SESEC will continue monitoring the deliverables published by TC 260, and keep analysing China's laws, regulations and policies in the field of cybersecurity.

10. Regulations on Automobile Data Security Management: Strengthen the Supervision of Automobile Data

#Automobile #Data Security

From May 12, 2021 to June 11, CAC called for public comments on the *Regulations on Automobile Data Security Management (Draft for Comments)*.

The document aims to regulate automobile data processing activities and safeguard national security and public interests. Therefore, some relevant automobile data will be affected by this regulation, including:

1. Data involving the flow of people and vehicles in military administrative zones, units involving state secrets such as science and industry for national defense, party and government offices above the county level and other important sensitive areas.
2. Mapping data with a precision higher than the precision issued by government.
3. Operation data of automobile charging networks.
4. Data covering types and flow of vehicles on road.
5. Audio and visual non-vehicle data, including human face, voice, license plate, etc.

The *Draft* gives particular attention to the operators in China that collect, analyse, store, transmit, inquire, use, delete, or transfer abroad personal information or important data, during their design, production, sales, operations and management processes. The *Draft*, therefore, involves institutions along the whole chain of the automobile market, with the aim of forming a closed-loop protection of automobile data.

The *Draft* also introduces detailed regulations on the whole process of automobile data, proposing that automobile data operators, when processing personal information and important data, should adhere to the principles of in-car processing, anonymous processing, minimum storage period, moderate precision, and default non-collection.

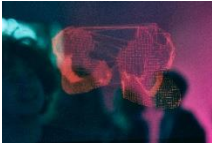
In terms of cross-border data transfers, the requirements for data exit are described in the *Cybersecurity Law*, the *Data Security Law* and the *Personal Information Protection Law (second draft)*. For instance, Article 38 of the *Personal Information Protection Law (second draft)* stipulates that there are three paths for the cross-border provision of personal information: (i) security assessment, (ii) personal information protection certification, (iii) standard contract. Still, Article 12 of the *Draft* indicates that only the security assessment path will be allowed for personal information and important data collected and generated in the process of motor traffic and transportation activities: “*personal information or important data should be stored within China in accordance with the law, and if it is necessary to provide overseas, it should pass the data exit security assessment organized by the Cyberspace Administration of China*”.

Related information:

In December 2020, the Chinese government issued the mandatory national standard *Vehicle Incident Data Recording System*, requiring all vehicles sold to be equipped with EDR recording equipment; however, the standard will not be formally implemented until January 1, 2022. Existing laws from China and abroad attribute the control of driving data to individuals. In fact, it is still the car companies that really master this part of data. The ownership of driving data is relatively vague, while there are no comprehensive domestic laws and regulations on data retrieval. Previously, there was no domestic car enterprise granting data query authority to users, resulting in significant difficulties for car owners to obtain driving data in case of disputes with the car company, given the lack of legal support.

However, improvements at the regulatory level have recently accelerated. On April 28, TC260 released a call for comments on the draft standard *Information Security - Connected Vehicles - Security Requirements for Data Collection*. The draft aims to regulate data processing related activities of mass-production passenger cars with networking capabilities, putting forward security requirements for data transmission, storage and cross-border activities. Similar to the draft from CAC, the draft from TC260 explicitly states that:

1. Vehicles are not allowed to transmit to the outside of the vehicle any data containing personal information, for instance through the network or physical interface, without the individual consent from the person whose personal information are being collected.
2. The transmission of audio, video, image and other data collected in the cockpit of the vehicle is prohibited.
3. Data on roads, buildings, terrain and traffic participants, as well as the position and trace collected outside the vehicle by sensors such as cameras and radars, is not be allowed to be transferred outside China.



Digital Transformation

11. CAICT Issued Standards to Help Evaluate Digital Transformation Capabilities

#Digital Transformation #Evaluation



On 31 March, 2021, CAICT and CCSA jointly held the "2021 Digital Transformation Development Summit Forum" in Beijing – during which the *Enterprise IT Digital Capability and Operational Effectiveness Maturity Model (IOMM)* (hereinafter referred to as "IOMM") and *Digitalization Trusted Service Capability Requirements* series of standards were released.

IOMM has defined nearly 400 capability indicators, which can be used to sort out and pinpoint the development stage of the digital transformation of an enterprise, at the same time giving detailed guidance on the next development directions and paths. IOMM is based on:

- Six major capabilities: development of cloud intelligence to a platform-based model, capability componentization, data valorization, operation systemization, lean production management, and horizontal risk retention.
- Six values: intelligence and agility, efficiency improvement, quality assurance, business innovation, optimal risk control, and customer satisfaction.

Furthermore, IOMM has formulated five maturities for both platform IT and business IT for different industries and enterprises of different sizes. Among them, platform IT maturity mainly includes five categories: (i) basic guarantee, (ii) business support, (iii) platform service, (iv) customer operation, and (v) innovation leadership. Business IT maturity mainly includes five categories: (i) digitalization, (ii) going online, (iii) collaboration, (iv) smartification, and (v) ecosystem. For each category, the corresponding ability is evaluated, and the value score is used to verify the effect.

With the advancement of the digitalization of enterprises, enterprises in various industries have gradually demanded digital product platforms and digital service capabilities of related service providers in business units, such as digital infrastructure integrated cloud platforms, research and transportation digital governance, customer service, human resources, and supply chain.

The *Digitalization Trusted Service Capability Requirements* series of standards propose six capabilities from Three-dimensional Trust. Three-dimensional Trust includes service trustworthiness, security trustworthiness, and ecological trustworthiness. The six capabilities include: (i) customer-centered digital scenarios, (ii) digital governance, (iii) platform products, (iv) digital service operations, (v) digital trust security services, and (vi) trustworthy compatible ecosystem. This standard clarifies the comprehensive and trusted service capability level of digital services, helps manufacturers to upgrade from a single product capability to a credible and comprehensive digital service capability, takes into account customers' digital scenarios, and contributes to the concepts of "trustworthy, common future". For the first time, the standard puts forward the capability requirements for digital ecological compatibility, helping digital service providers adapt to a variety of ecological environments and technical routes, and promoting the healthy development of upstream and downstream digital ecology.

The *Enterprise IT Digital Capability and Operational Effectiveness Maturity Model* and *Digitalization Trusted Service Capability Requirements* series of standards released this time provide a basis for evaluating the status of enterprise IT digital transformation. This assessment can help companies improve their basic software and hardware management platform capabilities, enhance service providers' platform-based governance capabilities, build digital platforms for common components, promote service providers' transformation to perfect scenario-based services, improve service operation systems, and encourage service providers to actively carry out ecological adaptation work.

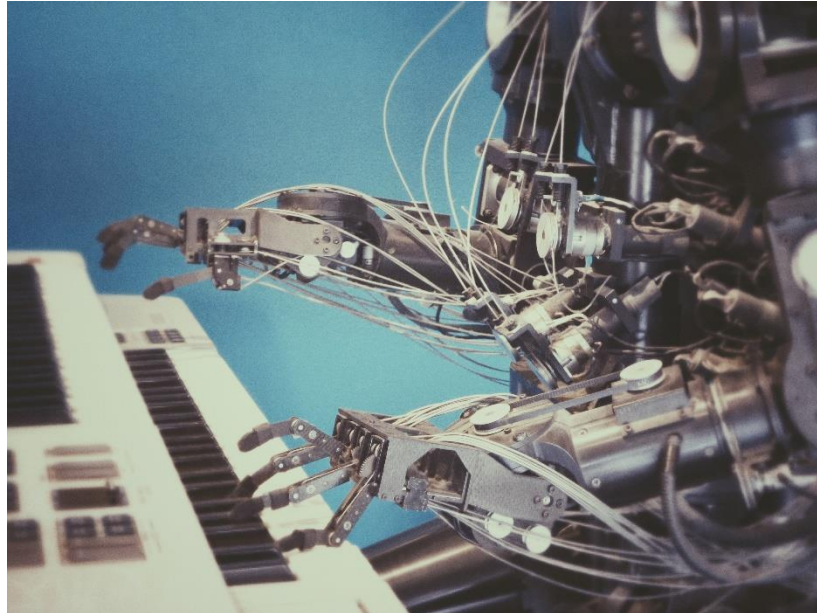
The meeting also released the first evaluation results of IOMM and digital trusted services based on the above standards. The first batch of companies to pass the IOMM assessment include: China Construction Bank, Baosight Software, Alibaba Cloud, China Merchants Group, China Mobile (Zhejiang Company) and China Mobile (information technology company); while the first batch of digital trustworthy service companies to pass the assessment include: Alibaba Cloud, Tencent Cloud, ZTE, China Telecom, China Mobile, AsialInfo, Jiawei Technology, JD Technology.

For CAICT's interpretation of these two types of standards (in Chinese), see: <https://www.doc88.com/p-07347120564170.html?r=1>



Artificial Intelligence

12. TC 28/SC 42 Held Its Conference Week in April # Artificial Intelligence



On 13 April 2021, the Artificial Intelligence Sub-Committee of the National Technical Committee on Information Technology Standardization Administration (TC 28/SC 42) held its first "Conference Week" of 2021 in Beijing.

TC 28/SC 42 was established in August 2020 to respond to the national plan on the development of artificial intelligence and promote the standardization process of artificial intelligence in China. This sub-committee is mainly responsible for the development and revision of national AI standards in the field of AI basics, technology, risk management, trustworthiness, governance, products and applications, which is corresponding to the work fields of ISO/IEC JTC 1/SC 42 sub-technical committee on AI.

During the conference week, TC28/SC42 held artificial intelligence training, sharing the latest trends of artificial intelligence standardization from the development of national standards to the research of cutting-edge technologies in the industry. After that, the meeting focused on the current situation of international artificial intelligence standardization and key work for in-depth discussion, where experts clearly proposed to promote the iterative application of artificial intelligence software, hardware, products and services, deepen the integration of artificial intelligence and various fields, and promote the development of China's artificial intelligence industry.



5G and Industrial Digitalisation

13. 5G+ Industrial Internet Ad Hoc Group of Industrial Internet Industry Alliance Established

#5G #Industrial Internet

On 6 May 2021, the Ministry of Industry and Information Technology (MIIT) officially announced that the 5G+ Industrial Internet Ad Hoc Group was formally established.

Industrial Internet is the key support for the fourth industrial revolution. 5G is an important direction for the evolution and development of the new generation of information and communication technology. The integration and innovation of 5G and the industrial Internet is conducive to the grafting of China's 5G technological advantages and industrial needs. The development of "5G+Industrial Internet" is now in a critical phase.

In order to promote the development of "5G+Industrial Internet", to concentrate industrial forces to tackle the challenges in the early stages of development, and to accelerate the deep integration of 5G and industrial Internet, the resolution of reforming and transforming the previous "Industrial Wireless Ad Hoc Group" into "5G+ Industrial Internet Ad Hoc Group" has been made and approved by Industrial Internet Industry Alliance during its sixteenth plenary meeting.

The Ad Hoc group will build a bridge among ICT-related industries, enterprises, scientific research institutes and experts. It is committed to summarizing developing experience in all phases, exploring 5G technology and network solutions that meet the needs of industrial deployment and application, as well as exploring reproducible application model and sustainable business model, and organizing industry promotion activities such as test bed, application competition, case selection etc.

The Ad Hoc group will be established between May and July of 2021, and experts from all walks of life are invited to participate in and jointly propose suggestions for the development of 5G+Industrial Internet integration.

14. China's White Paper on Standardisation of 5G Cybersecurity Released

#5G #Cybersecurity

On 10 May 2021, during its annual conference week, the National Information Security Standardisation Technical Committee (TC 260) released the White Paper on the Standardisation of 5G Cybersecurity. The White Paper provides an analysis of policies concerning the security of 5G network, 5G development status and key technologies. It also outlines the main security risks and standardisation requirements faced by 5G networks, and puts forward the 5G cybersecurity standards framework and suggestions for standardisation development. Therefore, the White Paper aims to become a reference for the standardisation of 5G cybersecurity.

Based on the demand analysis on the security of 5G network, the 5G cybersecurity standards framework is based on seven categories under which relevant standards are grouped:

Foundation	Reference model
Terminal security	General technical requirements
	Mobile intelligent terminal security
	Internet of Things terminal security
IT network facilities security	Dedicated Terminal Security
	SDN security
	Virtualization Security
Communication network security	Cloud platform security
	Wireless communication security
	Core Network Security
	Edge computing security
Application and service security	Slice security
	5G device security
	General application security
Data security	Industry application security
	Data security technology
Security operation management	Data security management
	Operation and maintenance management security
	Safety emergency response
	Supply chain security

By the end of April 2021, 26 standards have already been published in accordance with this standards system, while 22 standards are under development. The main Chinese standard-setting organisations for 5G cybersecurity are:

- For national standards: SAC/TC 260 and SAC/TC 485 (National Technical Committee 485 on Communication of the Standardisation Administration of China)
- For sector standards: the China Communications Standards Association (CCSA)

In the future, China will continue to promote the application of the 5G cybersecurity standards system, developing key standards, fully studying the security risks of 5G converged applications, promoting the verification and implementation of 5G cybersecurity standards, and participating in international standardisation of 5G cybersecurity in ISO, ITU, 3GPP, ETSI and other international standard-setting organisations.

The original Chinese news is available at:

<https://www.tc260.org.cn/front/postDetail.html?id=20210512165851>

The full text, in Chinese, of the White Paper can be downloaded [here](#).

15. MIIT: 5G Application Standards System Expected to be Completed by the End of 2023

#5G #Standards System



On May 1, 2021, MIIT held a public consultation session on its draft *Action Plan for 5G Applications (2021-2023)*. The document aims to implement General Secretary XI Jinping's instructions on expanding the application scenarios

of 5G technology and accelerating the overall development of 5G application. It indicates key goals to be achieved by 2023, specifically covering:

- Key indicators of 5G application (such as penetration rate of 5G individual users, proportion of 5G network access traffic, average annual growth rate of 5G IoT terminal users, number of virtual private networks in 5G industry, etc.)
- Application effect of 5G in key fields (such as power, mining and other fields, large-scale replication and promotion of 5G application, 5G+ Internet of Vehicles pilot scope, 5G+ smart education, 5G+ smart medical model projects, etc.)
- 5G application ecological environment construction (such as 5G application solution providers, 5G application solutions, etc.)
- Key infrastructure support capacity (such as 5G network coverage level, batch 5G fusion application innovation center, 5G Application Security Innovation Demonstration Center, etc.) and set development goals.

As an important element of the 5G application ecological environment, the document proposes that by the end of 2023, a 5G application standards system for basic commonalities and key industries will have been established, and the development of more than 30 key standards for key industries completed. Specific measures to achieve this goal include:

- Accelerate the opening of cross-industry agreement standards. The overall cross-department, cross-industry and cross-field coordination will be strengthened for standardization matters, and the cooperation mechanisms of relevant standardization organizations improved. Agreements on intercommunication and standards mutual recognition will be realized. The construction of the application standards system for the 5G industry and the implementation of relevant policies and measures will be systematically promoted, and the formulation of integrated application standards promoted. Efforts will be made to leverage on the advantages of the 5G application industry phalanx, and to promote the implementation of integrated application standards.
- Development of application standards for the integration of key industries. The research on 5G convergence application standards in key industries will be systematically pushed ahead, clarifying the key direction of standardization, strengthening the development of basic common standards, convergence equipment standards, and key industry solution standards. The process of standardization and generalization will be accelerated, and breakthroughs made in the research and formulation of convergence standards in key fields.
- Land a batch of key industry standards. Full play will be given to the leading role of key enterprises in key industries, aimed at guiding all relevant parties to further strengthen collaboration, jointly promoting the iteration, evaluation and optimization of application standards in the 5G industry, and promoting the application of relevant standards in key industries.

With regards to specific standardization work, the document emphasizes that significant efforts will be dedicated to the development of chip/module, network, platform, security architecture, application requirements, terminology definition and other basic common standards. Enhanced technical standards in line with industry demands will be launched, such as 5G deterministic network, upstream rate increase, high precision positioning and resistance of electromagnetic interference. The formulation of standards for integration applications in key

industries will be accelerated, and the development of standards for the construction of terminals and networks for industrial integration encouraged. 5G application standards will be promoted in key industries, especially in medical care, industry and media. The capacity of public services for 5G application standards will be enhanced. Efforts will also be made to conduct testing, evaluation and certification of standards for 5G applications in the industry, and to promote the conversion of innovative scientific and technological achievements into standards.



Internet of Things

16. CCSA Establishes Industry and Standards Promotion Committee of IoT and Platform Interconnection #CCSA #IoT

In order to promote application and innovation, reduce costs, and use standards to promote the interconnection of the IoT industry, in November 2020, the 10th meeting of the fourth council of China Communications Standards Association (CCSA) approved the establishment of the Industry and Standards Promotion Committee of IoT and Platform Interconnection (TC620).

On April 13, 2021, CCSA held the inaugural meeting and first meeting of the TC620 in Beijing. Fifteen companies from chip, module manufacturers, equipment manufacturers, solution manufacturers, security manufacturers, Internet companies, scientific research institutes, standards organizations and testing institutions from the IoT industry participated in the meeting.

CCSA Vice Chairman and Deputy Secretary-General, DAI Xiaohui, highlighted that despite the fact that the IoT industry is developing rapidly, there is still a wide lack of standards used in the industry, especially in areas such as IoT object models. Therefore, the establishment of TC620 – tasked to carry out pre-standard research and test verification, aimed at promoting the implementation of standards – becomes extremely necessary. TC620 should combine practices from China's IoT and cloud computing industry development to systematically explore and promote best practices in the technical standards of IoT in various vertical application fields. In the standardization requirements and industrial application promotion, it is necessary to fully consider the connection with existing and future IoT standards, and build a good IoT and platform interconnection ecosystem.

The conference also launched a discussion on IoT and platform interconnection technology. Five participants in particular shared insights on ICA web thing model standards and practices, digital twin city trends and development suggestions, IoT web thing models and digital twin applications in smart parking, analysis of the current status of smart city IoT standards, low-power wide area network standards and industry practices, etc. These are: China Academy of Information and Communications Technology, Alibaba (China) Co., Ltd.; Beijing Tongtong Yilian Technology Co., Ltd.; Shenzhen Youfang Technology; and Hylintech.



ICV

17. China Promotes Its DC Charging Solution “Chaoji” in IEC

#IEC #Charging



China’s proposal to establish an ad hoc working group for China’s DC charging technology “Chaoji” in IEC/TC69 was unanimously approved in the TC’s plenary meeting on 28 April 2021. Composed of experts from IEC/TC69 and SC23H, the working group will focus on the safety and interoperability issues of this Chinese charging technology for interacting with other DC charging systems. A Chinese expert was appointed as the convener of this working group in the meeting.

“Chaoji” is a high-power DC charging technology developed by the China Electricity Council (CEC). CEC started pre-research on the technology and relevant standards early in 2016, and soon after launched numerous rounds of extensive study, discussion, joint technical development, international cooperation, demonstration projects, and international standardization activities. As the technology comes to maturity, China is now striving to promote it up to international stage.

Charging technology and infrastructure play a pivotal role in driving the sustainable development of the new-energy automobile industry. It can significantly improve user experience, by easing drivers’ anxiety on the endurance mileage of their cars. The past few years have witnessed a rapid development on this technology and standards.

During another seminar on “Chaoji” charging technology and standards, held by the China Electrical Vehicle Association on 19 April, experts highlighted the trend and direction of charging technology and standardization in China, namely:

- High-capacity, rapid, safe, and broadly compatible charging is crucial for the integrated development of transport and energy industries.
- Problem- and target-oriented approaches are essential for ensuring the top-level design of standardization.

- Chaoji's development will be facilitated by enhanced international cooperation.
- Broad consensus is vital for achieving high quality charging facilities standards.

Background:

Established in 1988, the China Electricity Council (CEC) is a nationwide association composed of 1,002 members from the whole electric power industry. CEC holds the secretariat of the Standardization Technical Committee for Electric Car Charging Facilities in Energy Industry, leading China's standardization work for electric car charging facilities. CEC has also led the establishment of the standards systems for conductive charging, wireless charging, battery-swap, and charging services.

18. China Industry Innovation Alliance for ICV: Provides Association Standards for ICV

#ICV #Association Standards



On May 24, the China Industry Innovation Alliance for the Intelligent and Connected Vehicles held its second working group leaders' meeting in 2021. The meeting introduced the progress of the work of association standards and industry research, which can be summarized as follows:

- In terms of V2X, the Alliance carried out industrial research work such as *The Impact of V2X on Traffic Benefit*. Two association standards are being prepared, namely (i) *Test and Evaluation Procedure for the Early Warning Application Function of the V2X System of Intelligent Connected Vehicles*, and (ii) *Technical Requirements and Test Methods for the Positioning and Synchronous Technology of Direct Connected Communication under the Condition of LTE-*

based Wireless Communication Technology of Internet of Vehicles without GNSS Signal.

- In terms of information security, the Alliance carried out industry research such as *TSL Data Security Analysis Report* and is developing the association standard *Information Security Test Rules for On-board of Intelligent Connected Vehicles*.
- In terms of autonomous driving, the Alliance is working on the development of *Elements of Autonomous Driving Map Collection Model and Interchange Formations*, as well as industrial research work on high-precision dynamic maps and high-precision satellite positioning.
- In terms of platform and software of basic data, the Alliance started the work of association standards on cloud control platform architecture, and research on the *White Paper 2.0 of Cloud Control System*. It is also developing two association standards of vehicle control operating system functional software architecture and visual perception computing chips.
- In terms of the safety of expected functions, the Alliance conducted the safety test of expected function scenario database,

SOTIF quantitative evaluation system and test specifications. It also completed the white paper on the safety of expected function of intelligent connected vehicles.

Due to the flexibility and timeliness of association standards, they are playing an increasingly important role in some rapidly evolving and iterative technology fields. Compared with government-issued standards, they can respond to market needs more rapidly, and often serve as the basis of or can be upgraded to government standards. Therefore, it is necessary to track the development of association standards in emerging technology fields, especially those issued by social organizations which have close relations with the government, and thus exert a strong influence over the industry.

Background:

The China Industry Innovation Alliance for the Intelligent and Connected Vehicles is a social organization founded in June 2017 by the China Society of Automotive Engineers (SAE) and the China Association of Automobile Manufactures (CAAM) – namely two of the most influential social association in auto industry. It is supported by the Ministry of Industry and Information Technology of the People’s Republic of China. Joint areas include automotive,

communications, transportation, Internet enterprises, universities, and research institutions.

The Alliance works in policy and strategic research, R&D of key technologies, standards and regulations, testing and demonstration, industrial promotion, academic exchanges and international cooperation, and talent cultivation. It aims to support government decision-making and the development of service industry.

Currently, the Alliance has set up several working groups, including on V2X map, information security, automatic driving and positioning, new high-speed network, basic data platform, commercial vehicles, AVP, industrial investment and financing, testing, demonstration, the safety of expected function, basic software and advanced chassis control. To date, it has issued 11 association standards, and a series of research results such as *Innovative Application Roadmap of Intelligent Connected Vehicles*.

In addition, the Alliance has signed standardization cooperation agreements with influential standardization organizations, such as the China ITS Industry Alliance and the Telematics Industry Application Alliance, aimed at jointly promoting the establishment, development and release of standards.



Blockchain

19. Updates on the Progress of Blockchain Standardisation in China

#Blockchain Standardisation

China officially committed to the possibilities of blockchain in late 2019, when it elevated blockchain technology to a national priority. Since then, China has expedited the development of the Blockchain Service Network (BSN). One of the main goals of China's national blockchain infrastructure is to build an open-source protocol that enables enterprises – both domestic and foreign-invested – to access, build and adopt blockchain technology into their businesses.

In addition, coupled with efforts to develop blockchain policies, China has long pushed technical standards to support blockchain technology.

International Standards

In April 2021, [IEEE 2142.1-2021 Recommending Practice for E-invoice Business Using Blockchain Technology](#), promoted by the Shenzhen Taxation Bureau and Tencent Technology, was officially confirmed and released by IEEE-SA. This standard describes the blockchain-based application reference architecture of e-invoice businesses, illustrating in detail the roles of participants, typical business scenarios, platform frameworks, and security requirements.

This is the world's first international standard in IEEE for the application of blockchain-based electronic invoices. As such, it can promote global consensus, and guide the high-quality development of blockchain electronic invoice application all over the world.

In addition, during the plenary meeting of [ITU-T SG16](#) in April 2021, three proposals led by the China Academy of Information and Communications Technology (CAICT) for the development of international blockchain standards were approved, including:

- *ITU-T F.DLT-FAM - Function assessment methods for distributed ledger technology (DLT) platforms*
- *ITU-T H.DLT-PAM - Performance assessment methods for distributed ledger technology (DLT) platforms*
- *ITU-T H.DLT-TFI - Technical Framework for DLT Interoperability*

These standardisation proposals are based on the research results of the China Communications Standardisation Association (CCSA) TC1 and Trusted Blockchain Initiatives; thus they represent the consensus of China's blockchain industry actors, and the same time marking an important step for China's blockchain standardisation to go global.

Association Standards

On 12 April 2021, Beijing Fintech-Industry Alliance officially released the association standard T/BFIA 005-2021 *Reference Framework for Blockchain Technology Financial Application Technology*. This standard is applicable to typical financial scenarios such as supply chain finance, trade finance, payment and settlement, asset securitisation, etc. Specifically, it provides a system-wide technical reference framework for banking, securities, insurance,

payment institutions and financial asset trading institutions, ranging from business application design, interface design, platform design, infrastructure construction and so on.

Technical Committees

On 28 May 2021, the State Administration for Market Regulation (and SAC) approved the establishment of the National Technical Committee for the Standardisation of Blockchain and Distributed Accounting Technology (SAC/TC 590) – with the aim to contribute to the standardisation of the development of blockchain and distributed accounting technology in China. The work of TC 590 corresponds to the Blockchain Technical Committee in ISO (ISO/TC 307); therefore, it will help promote China's active participation in international standardisation activities targeting blockchain technology. According to MIIT, as for now, all the 71 members of TC 590 are representatives from Chinese ministries, institutions, enterprises and universities.

SESEC will keep monitoring the development of emerging technologies in China, providing timely updates to our stakeholders.



Energy Efficiency and Environmental Protection

20. Revision of Three Mandatory Standards for the Furniture Industry #Furniture

On May 6, 2021, MIIT published a call for comments on three mandatory standards (draft for comments) for the furniture industry. The period for submitting comments is May 6, 2021 to July 4, 2021. The details of the three standards are as follows:

NO.	Standard	Content	Standard Replaced	Main changes
1.	Limits of harmful substances in furniture	The limits and test methods for harmful substances in furniture were stipulated. The limits of aldehydes, ketones and volatile organic compounds specified in this document can be applied to indoor furniture.	GB 18584-2001, GB 28481-2012	Compared with GB 18584-2001: Definitions, requirements, and test methods for removable harmful elements were added. Compared with GB 28481-2012: The definition and test methods of polycyclic aromatic hydrocarbons (PAHs), phthalate esters, polybrominated biphenyls and polybrominated diphenyl ethers were revised. In addition, this standard adds requirements and test methods for benzene, toluene, xylene, total volatile organic compounds, radionuclides, and dimethyl fumarate in furniture.
2.	Technical specification for structural safety of furniture	The general structural requirements of furniture and the special structural and technical requirements of office screen, folding and turning bed, laboratory furniture, bathroom furniture, bunk bed, glass furniture and other products are stipulated. Apply to all furniture products except for furniture for infants and children.	GB 22792.2-2008, GB 26172.1-2010, GB 24820-2009, GB 24977-2010, GB 28008-2011, GB 28478-2012, GB 24430.1-2009, GB/T 24430.2-2009	Compared with GB 22792.2-2008, some content of screen process requirements and stability test were changed. Compared with GB 26172.1 -- 2010, changes were made to the structural requirements. Compared with GB 24820 -- 2009, the security requirements were changed, and the item classification content was deleted. Compared with GB 24977 -- 2010, the ultimate strength of hanging cabinets (racks) was changed, together with the safety requirements of lamps, sockets, switches, and other electrical appliances. Compared with GB 24430.1 -- 2009, the structure, stability, and impact resistance performance requirements were changed. Compared with GB 28478-2012, changes were made to the safety requirements.
3.	Technical specification for safety of furniture for infants and children	The general safety requirements and specific product structure safety requirements of infant furniture and children furniture are stipulated. Apply to furniture for infants and children.	GB 28007-2011, GB 2793.1-2008, GB 4430.1-2009, QB 2453.1-1999	Compared with GB 22793.1 -- 2008/ISO 9221-1:1992, additional requirements for structural safety, electrical safety, limit of harmful substances, passive restraint system, durability of locking mechanism, backrest height and length of seat front edge radius were added. Compared with GB 24430.1 -- 2009, electrical safety, harmful substance limit requirements, etc., were added.

These revisions reflect the efforts that the furniture industry is taking to simplify and integrate existing standards. Compared with the previous standards, the new standards introduce new requirements for market access and

industry regulation. However, since the new revisions do not involve the adoption of international standards, the level of similarity and difference with international standards implemented by overseas enterprises need further analysis.



Medical Device

21. New Policy from NMPA and SAC to Improve the Standardization of Medical Devices

#NMPA #Medical Devices



On March 30, the National Medical Products Administration (NMPA) and the Standardization Administration of China (SAC) jointly issued the *Opinions on Further Promoting the High-Quality Development of Medical Device Standardization*. Aimed at further clarifying the main goals of the high-quality development of medical device standardization, the Opinions propose 19 tasks in 6 areas, including: (i) optimizing the standard system, (ii) strengthening the refined management of standards, (iii) strengthening the supervision and implementation of standards, (iv) improving the medical device standard organization system, (v) deepening international exchanges and cooperation, and (vi) improving standard technical support capabilities. The main takeaways from the documents are summarized as follows.

In terms of improving the structure of the standards system, the Opinions put forward the requirements to: comprehensively carry out evaluation of mandatory standards; continue to optimize mandatory standards for medical devices; strictly limit the scope of mandatory standards under formulation; and gradually transform mandatory sector standards that are widely applied and influential into mandatory national standards".

In terms of standards management, the Opinions explicitly stipulate that efforts should be made to: establish a standard update mechanism that is aligned with international standards; explore the synchronization of domestic standards and international standards; shorten the conversion cycle of international standards into national standards; strengthen the tracking, comparison and evaluation of international standards; and adopt international standards that are suitable for domestic applications, in order to improve the consistency of domestic and international standards".

In terms of international cooperation and exchanges, the Opinions explicitly stipulate that efforts will be made to: recommend more experts to become registered experts of the International Standards Organization; encourage active participation in the formulation and revision of international standards, by presenting more international standard project proposals in the field of medical devices; and encourage the role that medical devices play in servicing and supporting the Belt and Road Initiative, by encouraging the formulation of national standards and

sector standards in foreign languages, and by promoting cooperation and exchanges on medical device standards with neighboring countries.

In terms of departmental coordination, the Opinions point out that full play must be given to the role of the member units of the Inter-Ministry Joint Conference on Standardization Coordination and Promotion of the State Council, as the highest-level body leading medical device standardization, and at the same time strengthening the communication and coordination with the Ministry of Industry and Information Technology, the National Health Commission, and other relevant departments.

In terms of standard formulation, the Opinions point out the need to accelerate the advancement of common technology research and standard formulation work in the emerging fields of medical devices, such as medical robots, artificial intelligence, active implants, medical software, 5G industrial Internet, and multi-technology integration. At the same time, the establishment of standards for key core components of medical devices should be explored and promoted.

The full text of the document (in Chinese) is available at:

<http://www.sac.gov.cn/sbgs/sytz/202104/P020210408587419741449.pdf>

22. New Changes in Medical Device: Revised Regulations on Supervision and Registration

#Medical Devices

On 18 March 2021, the National Medical Products Administration issued the revised version of the *Regulations on the Supervision and Administration of Medical Devices*. The main contents of the revision include:

1. Medical devices are divided into three management categories from low risk to high risk. The current classified management system of medical device regulation is not satisfactory enough, especially for high-risk products; while for low-risk products, the supervision is too strict, which puts a heavy burden on enterprises. At the same time, the current regulations for enterprises on production and management requirements are simple, and their responsibility is not specific. There are also phenomena such as more attention being paid to product approval rather than process supervision.

Therefore, to address such problems, the *Regulations* stipulate that the product classification catalogue should be timely adjusted according to the production, operation and use of medical devices, as well as the analysis and evaluation of product risk changes. In addition, when formulating and adjusting the catalogue, efforts should be made to listen to the opinions and feedback of production and operation enterprises, users and industrial organizations, at the same time referring to the practice of international classification of medical devices. Concerning the management categories of medical devices, the category I for low-risk devices implements product registration management, category II medical devices are subject to the approval from provincial-level food and drug regulatory authorities, while category III devices are subject to product registration management by the National Medical Products Administration. The revised *Regulations* points out to release the operation of medical devices in category I, implement archival management for the operation of medical devices in category II, and implement licensing management for the operation of medical devices in category III.

2. Medical device production and operation enterprises shall submit regular self-inspection reports. According to the *Regulations*, enterprises are required to establish, maintain and improve quality management systems also to cover product design and development, raw material procurement,

production process control etc., and submit regular self-inspection reports. According to the *Regulations*, a system for purchase inspection and sales records should be established: the enterprise and the specific department using the device(s) should verify the qualification of the supplier and the certificate of product qualification, and then record them into the system. Category II medical device wholesale enterprises and Category III medical device trading enterprises shall also establish sales records. In addition, the *Regulations* adds medical device safety management obligations to users, such as strengthening the technical training of staff to ensure the use of medical devices in accordance with product specifications, technical operation specifications and other requirements. It also clarifies the storage place suitable for the type and quantity of the medical devices in use and carry out the care and maintenance work for large-scale medical devices.

3. Medical devices that can be reused in a safe and effective way, will not be included in the catalogue of disposable use devices. In practice, however, there are problems such as the range of disposable medical devices being too wide, and many duplicates, especially for high-value medical consumable products; these greatly increase the medical costs as well as the burden on patients. Therefore, the *Regulations* stipulate that the research and development of medical devices should follow the principles of safety, effectiveness, and frugality, and require the implementation of catalogue management on this basis. More specifically, the *Regulations* require that (i) the catalogue of disposable medical devices should be formulated, adjusted and published by the National Medical Products Administration and the National Health Commission of the People's Republic of China; (ii) medical devices that can be reused in a safe and effective way, shall not be included in the catalogue of disposable medical devices; (iii) for medical devices that are safe and effective after repeated use, due to improvement in design, production process, disinfection and sterilization technology, etc., the list of disposable medical devices shall be adjusted. This change introduced by the revised *Regulations* can ensure that part of disposable medical devices can be reused on the premise of safety and effectiveness.

4. In view of the common practice of focusing more on examination and approval rather than supervision, as well as the lack of efficiency and means in the supervision of medical devices, the *Regulations* strengthen the routine supervision and add more supervision means. They also add a monitoring system, reevaluation system of registered medical device, and a medical device recall system, etc.

In line with the *Regulations on the Supervision and Administration of Medical Devices*, the *Regulations on the Registration of Medical Devices* was also revised. From 26 March to 25 April 2021, NMPA called for public comments on the revised document. Compared with the previous version, the main changes introduced include:

1. The requirements of the examination report for category II and III medical devices are adjusted. The examination report of the medical device can be issued through self-testing by the applicant or issued by a qualified medical device examination institution.
2. The requirements of certification documents for overseas listing of innovative medical devices are adjusted. In the past, all overseas medical devices needed to submit overseas listing certification documents, while the revised *Regulations* removed this requirement for innovative medical devices that did not list overseas.
3. Implement the system of medical device registrant and recorder. Registrants and recorders of medical devices should strengthen the whole cycle management of medical devices. They are responsible for ensuring the safety, effectiveness and quality control of medical devices in the whole process of

development, production, operation and use. If the production of medical devices is commissioned, the registrant and recorders shall strengthen the management of the production behavior of the commissioned enterprise, supervise its production in accordance with the requirements, and be responsible for the quality of the commissioned production of medical devices. Furthermore, the original requirement that non-innovative medical devices shall not be commissioned for production was removed in the revised *Regulations*.

4. The relevant requirements of clinical evaluation and clinical trial were adjusted. The clinical evaluation of medical equipment will be carried out based on the product characteristics, clinical risk, clinical data etc. By analyzing clinical data of a certain kind of device or by conducting clinical trials, the safety and effectiveness of medical devices can be clearly proved. Besides, there are also situations that the clinical evaluation data is not required to submit.

5. The requirements for conditional approval were adjusted. Medical devices that are urgently needed for rare diseases, serious life-threatening disease without effective treatment, or for responding to public health crises, the pharmaceutical supervisory and administrative department can make a conditional approval, clearly indicating the validity period as well as the work needed to be completed after listing.

6. Specification requirements were added. The applicant shall prepare the product specification of the medical device to be registered. The product specification approved by the registration examination shall be issued to the applicant in the form of attachment to the medical device registration certificate. The listed medical device should be consistent with the specification approved by the registration.

7. The requirements for changing registration information were adjusted, while new ones were added for changes of the specifications. The revised *Regulations* clarify that the medicine regulatory department should organize the quality management system verification when necessary for conducting the technical evaluation on the change of the licenses.

8. Relevant contents of clinical trial management were added. The revised *Regulations* clarify that medicine regulatory departments can suspend or terminate the clinical trial, in the event of large-scale and unexpected serious situations in clinical trials, or evidence of serious quality problems of experimental medical devices. It is clarified that the medicine regulatory departments may conduct on-site inspection of the clinical trial, if necessary. Provincial-level medicine regulatory departments shall organize supervision and inspection over clinical trial institutions registered within their jurisdiction.

Annex-SESEC Recent Activities

SESEC Roundtable on Sharing of Standardisation Practice

On 28 April 2021, SESEC held its roundtable on sharing and exchange of standardisation practice, with participants from Siemens, VDMA, Infineon, BSI, USITO, Schneider and other companies. The main content is Dr. Betty XU's introduction to CEN-CENELEC Strategy 2030. Understanding the European Standardization System is the basis for analysing the work of CEN-CENELEC, and its strategies. Dr. Betty XU first explained the organizational structure and operation mechanisms of the three European standardization organizations (namely CEN, CENELEC and ETSI), also providing an overview of their current cooperation with China in the field of standardization. Dr. Betty XU also analysed the core and the objectives of the European Standardization System, its close relationship with international standards, market influence, its relationship with the EU legislation and NLF, the development and implementation of EN standards, and how to participate in international standardization.

Moreover, Dr. Betty XU also extensively introduced the background, time span, scope of application, main content, vision and mission of the CEN-CENELEC Strategy 2030. Dr. Xu pointed out that the core element of the Strategy is to achieve the "double transformation of green and digital" across the EU. Specifically, the Strategy clarifies the future work priorities of emerging information technology standards and green standards, pointing out the directions for improving the value and international influence of the European Standardization System, which is of great significance. Finally, Dr. Xu also analysed the basic framework, strategic focus, standards, and innovations of the CEN-CENELEC 2021 Work Plan from the two aspects of standard development and management.

SESEC Online Event 26: China-EU Eco-design Standardization – Similarities and Differences

Eco design is both a principle and an approach. It consists of integrating environmental protection criteria over a service or a product's lifecycle. The main goal of eco design is to anticipate and minimize negative environmental impacts (of manufacturing, using and disposing of products). Simultaneously, eco design also keeps a product's quality level according to its ideal usage. A number of non-EU countries (USA, Australia, Brazil, China and Japan) have legislation similar to the EU's eco-design and energy labelling directives.

Regarding the importance of eco-design in the context of sustainable development, SESEC project organised this online event on eco-design, providing the analysis on the similarities and differences between China and EU on eco-design standardization.

SESEC would like to share the meeting recording with you:

[Play recording](#) (1 hr 4 mins)

Recording password: 20210511

SESEC Online Event 27: Progress of China Integrated Circuit Standardisation

An integrated circuit (also referred to as an IC) is a set of electronic circuits on one small flat piece (or “chip”) of semiconductor material that is normally silicon. ICs have two main advantages over discrete circuits: cost and performance. Cost is low and performance is high because the IC’s components switch quickly and consume comparatively little power because of their small size and proximity. The main disadvantage of ICs is the high cost to design them and fabricate the required photomasks.

In China, with the rapid development of IC industry, the development and revision of IC related technical standards have been carried out in full swing. China’s IC standards are still based on the conversion and adoption of international standards, and the IC technical standard system still needs improving. On 25 May 2021, SESEC held an online event with Dr. Betty XU introducing China integrated circuit standardisation. Here SESEC would like to share the meeting recording with you:

[Play recording](#)(1 hr 1 mins)

Recording password: 20210525

Introduction of SESEC Project



The Seconded European Standardization Expert in China (SESEC) is a visibility project co-financed by the European Commission (EC), the European Free Trade Association (EFTA) secretariat and the three European Standardization Organizations (CEN, CENELEC and ETSI). Since 2006, there has been three SESEC projects in China, SESEC I (2006-2009), SESEC II (2009- 2012) and SESEC III (2014-2017). In April 2018, SESEC IV was officially launched in Beijing, China. Dr. Betty XU was nominated as the SESEC expert and will spend the next 36 months on promoting EU-China standardization information exchange and EU-China standardization cooperation.

The SESEC project supports the strategic objectives of the European Union, EFTA and the European Standardization Organizations (ESOs). The purpose of SESEC project is to:

- **Promote European and international standards in China;**

- **Improve contacts with different levels of the Chinese administration, industry and standardization bodies;**
- **Improve the visibility and understanding of the European Standardization System (ESS) in China;**
- **Gather regulatory and standardization intelligence.**

The following areas have been identified as sectorial project priorities by the SESEC project partners: Internet of Things (IoT) & Machine-to-Machine(M2M) communication, communication networks & services, cybersecurity & digital identity, Smart Cities (including transport, power grids & metering), electrical & electronic products, general product safety, medical devices, cosmetics, energy management & environmental protection (including eco-design & labelling, as well as environmental performance of buildings).

SESEC IV China Standardization and Technical Regulation Bimonthly Newsletter

SESEC IV China Standardization and Technical Regulation Bimonthly Newsletter is the gathering of China regulatory and standardization intelligence. Most information of the Monthly Newsletter was summarized from China news media or websites. Some of them were the first-hand information from TC meetings, forums/workshops, or meetings/dialogues with China government authorities in certain areas.

In this Bimonthly Newsletter

In this Bimonthly Newsletter, some news articles were abstracted from Chinese government organizations. All new published standards, implementation or management regulations and notice are summarized; original document and English version are available.

Abbreviations

SAMR	State Administration for Market Regulation	国家市场监管总局
CAS	China Association	中国标准化协会
CCC	China Compulsory Certification	中国强制认证
CCSA	China Communication Standardization Association	中国通信标准化协会
CEC	China Electricity Council	中国电力企业联合会
CEEIA	China Electrical Equipment Industrial Association	中国电器工业协会
CELC	China Energy Labeling Center	中国能效标识中心
CESI	China Electronic Standardization Institute	中国电子标准化研究所
CMDSA	Center for Medical Device Standardization Administration	医疗器械标准管理中心
CNCA	Certification and Accreditation Administration of China	中国国家认证认可监督管理委员会
CNIS	China National Institute of Standardization	中国国家标准化研究院
CNREC	China National Renewable Energy Center	中国国家可再生能源中心
EPPEI	Electric Power Planning and Engineering Institute	电力规划设计总院
IEC	International Electrotechnical Commission	国际电工委员会
ITEI	Instrumentation Technology and Economy Institute	机械工业仪器仪表综合技术与经济研究所
MEE	Ministry of Ecology and Environment	中国生态环境部
MIIT	Ministry of Industry and Information Technology of People's Republic of China	中国工业和信息化部
MoH	Ministry of Health	卫生部
MoHURD	Ministry of Housing and Urban-Rural Development	住房与建设部
MOT	Ministry of Transport	中国交通运输部
MOST	Ministry of Science and Technology	中国科学技术部
NDRC	National development and reform commission People's Republic of China	中国国家发改委
NIFDC	National Institute of Food and Drug Control	中国食品药品检定研究院
SAC	Standardization Administration of China	国家标准化管理委员
SGCC	State Grid Corporation of China	国家电网
TC	Technical Committee for Standard Development	标准化技术委员会