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SESEC IV
China Standardization
Bimonthly Newsletter
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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 sectoral 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 were summarized from China official websites and major news media. Some of them were the first-hand information from TC meetings, forums/workshops, or meetings/dialogues with China government authorities in certain areas. It is brief news in fields related to SESEC horizontal/vertical priorities.

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.

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SESEC IV Services

30. SESEC IV collected all China medical devices standards bibliography data with 1406 standards

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31. SESEC IV translated the “Association Standards Management Rules” and annexed with this Newsletter

Abbreviations

CAC	Cyberspace Administration of China & Office of the Central Cyberspace Affairs Commission	国家互联网信息办公室 & 中共中央网络安全和信息化委员会办公室
CAS	China Association for Standardization	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 Labelling Center	中国能效标识中心
CERT	National Computer Network Emergency Response Technical Team/Coordination Center of China	国家互联网应急中心
CESI	China Electronic Standardization Institute	中国电子标准化研究所
CMDSA	Centre 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
MEE	Ministry of Ecology and Environment	中国环境保护部
MIIT	Ministry of Industry and Information Technology of People's Republic of China	中国工业和信息化部
MOHRSS	Ministry of Human Resources and Social Security of China	人社部
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	中国国家发改委
NHFPC	National health commission	国家卫生健康委员会
NIFDC	National Institute of Food and Drug Control	中国食品药品检定研究院
NMPA	National Medical Products Administration	国家药品管理局
SAC	Standardization Administration of China	国家标准化管理委员会
SAMR	State Administration for Market Regulation	国家质量监督检验检疫总局
SGCC	State Grid Corporation of China	国家电网
TC	Technical Committee for Standard Development	标准化技术委员会

Contents

Horizontal issues

1. SESEC 2018 End-of-Year Reception

On 24th January, SESEC hosted the 2018 year-end reception in Beijing. At the beginning of the reception dinner, Mr. Guo Chenguang, director of international cooperation division, standards innovation department of SAC and Mr. Bojan Pavlek, first secretary of European Union delegation in China and representative of DG GROW of European Committee gave keynote opening speeches. Mr. Guo and Mr. Pavlek both set a high value on SESEC's hard work and effective efforts on standardization's communication, understanding, and cooperation between Europe and China, and also, expressed the perspective of closer, more practical and functional Sino-European standardization cooperation with SESEC's assistance and promotion in 2019. Over 40 Chinese and European partners and stakeholders of CNCA, CNIS, SIEMEN and *etc.* attended the reception. Dr. Betty Xu, on behalf of SESEC, appreciated cordially all participants' recognition and help, and presented good wishes for the happy Chinese New Year.



2. China Released New Policies to European Union

In December, the Peoples' Republic of China released the document of policies to European Union for the third time after 2003 and 2014. The new policies state the cooperative blue map between China and EU in the near future. China welcome EU and European countries to join and develop "Belt & Road" and together further and extend productive cooperation in each sector, such as the third-party market, interconnection, finance and digital economy to consummate "China-EU blue partnership".

The document contains five crucial parts: guiding principles for China-EU relationship; politic, safety and defence cooperation; cooperation on trade, investment interconnection and finance; technical innovation, new emerging industries and sustainable development; society and humanity.

Emphatically, Standards, metering, certification and quality inspection are put forward in the third part of investment interconnection and finance. Both sides shall deepen exchanges and cooperation, give full play to the role of China-EU standards information platform to supply mutual enterprises timely effective and authoritative information.

3. SESEC Participated SAC's Seminar on "Administrative Measures for Compulsory Standards"

On 7th December 2019, SESEC was invited to attend the seminar on "administrative measures for Compulsory Standards" organized by SAC and CNIS. Over the past one month, SESEC were engaging in organizing the comments of European stakeholders effectively including translation, compilation, submission and continual contact with SAC. During the conference, division director of mandatory national standards and president of CNIS stated and explained the background and development situation of the measures. Together with other participants from SDOs, institutes and enterprises, SESEC presented the comments and concerns on complete openness of TC, actual property of Compulsory Standards, inspection of Compulsory Standards' implementation, the validation & transition period and *etc.* At the end of the meeting, officials of SAC ensured that all issues discussed would be taken into consideration and evaluation. SESEC will focus and follow up on the dynamics constantly.

4. State Council Released "Guiding Advices on Establishment and Perfect of Fundamental Public Services Standards system"

On 12th December, the general office of State council released guiding advices on establishment and perfect of fundamental public services standards system. Key tasks are:

- To perfect the complete levels of public services standards containing nation, industry, location and grass-roots;
- To identify scope and quality requirements of national fundamental public services standards system;
- To clarify the responsibility and duty of governments at all levels;
- To innovate and conduct the implementing mechanism including information disclosure and sharing, inspection, and *etc.*

Chinese website: http://www.gov.cn/xinwen/2018-12/12/content_5348159.htm

5. SAC and MCA jointly issued "management regulations on association standards"

On 18th January, SAC and MCA (Ministry of Civil Affairs) jointly issued "management regulations on association standards" to replace the previous trial of 2017. SESEC team translated the new regulations and laid out changes and comparison to the old version. The Key articles that need to be noticed are listed here:

Article 7: It is encouraged for social groups to participate in international standardization activities and promote the internationalization of association standards.

Article 12: The technical requirements for association standards shall not be lower than the relevant technical requirements for mandatory standards.

Article 13: The formulation of association standards shall meet the needs of the market and innovation, focus on new technologies, new industries, new business types and new models, and fill standard gaps. China encourages social groups to develop association standards with technical requirements higher than relevant technical requirements of the recommended standards; encourages the development of association standards in line with international leading standards

Article 28: If the implementation of association standard is effective and meets the requirements of national standards, sectoral standards or local standards, the association standard issuing agency may apply for converting such association standard to national standards, sectoral standards or local standards.

Article 29: It is encouraged for all departments and local governments to apply association standards in works such as industrial policy formulation, administrative management, government procurement, social management, inspection and testing, certification and accreditation, and bidding.

Article 40: Using association standards to exclude or restrict market competition shall be handled in accordance with the provisions of the Anti-Monopoly Law of the People's Republic of China and other laws and administrative regulations.

6. The 2018 EU-China Standardization Joint WG meeting was Held in Brussels

The 2018 EU-China Standardization Joint WG meeting was held on 04 December 2018 in Brussels, Belgium, attended by the SAC delegation and EU delegation.

The SAC delegation was headed by Mr. CUI Gang, Director General, Standards Innovation Department, SAMR/SAC. The EU delegation was headed by Mr. Joaquim Nunes de Almeida, Director of Single Market Policy, Regulation and Implementation, DG GROW, EC. The heads of the delegations co-chaired the WG meeting.

The two sides have in-depth discussions on the following topics: Update by SAMR/SAC on new organization of SAMR/SAC regarding the new structures and roles related to standardization; Information shared by EU side about EU-China “Ecodesign” work and the related standards cooperation project; discussion on new draft for comments of China “Administrative Measures for Mandatory National Standards”; IEC & ISO standards, adopted as EU and CN standards; and CESIP platform updating.

After the meeting, the common meeting report was signed, and both parties regarded this meeting was successful and fruitful.

7. SAC Released Draft “Main Points of National Standardization Work in 2019”

On 28th January, SAC released draft “Main points of national standardization work in 2019” and called for comments. SESEC summarizes the main contents as follow:

I. Reform of standardization work

1. Streamlining and optimization of national standards
 - Further clarify the dual attributes of “regulations” and “standards” of mandatory national standards and improve the institutional mechanisms for the revision and implementation work of mandatory national standards.
 - Promote reforming measures for mandatory national standards such as “mandatory full text in replace of mandatory provision”, “no longer signing drafting units and drafters” and “adding implementation information feedback channels to standards”.
 - Vigorously promote the integration and reduction of mandatory standards, and promote the integration of sectoral standards and local standards that still need to be mandatory into mandatory national standards

2. Management of ministerial level standards: Organize and carry out self-examination and clean-up of sectoral standards, strengthen sectoral standard review and revision, and promote the transformation of basic and general standards across departments and industries into recommended national standards.
3. Local standards management: Strictly limit the scope of local standards, and prevent actions of eliminating or restricting market competition such as using local standards to hinder the free circulation of commodities and services. Center on the local party committee government work, organize the development of local standards, and continuously optimize the local standards system.

II. To improve the standard level and build a more advanced and applicable standard system

- In the fields of children's products, household appliances, furniture, cosmetics, etc., accelerate the formulation of a number of mandatory national standards with broad coverage and applicability, and simultaneously promote the formulation of recommended standards coordinated with mandatory standards, so that the people can purchase, use and eat without worries.
- Strengthen the construction of a manufacturing standard system and strive to reach 90% conversion and adoption rate of international standards in key fields
- Accelerate the improvement of next-generation information technology standards systems such as artificial intelligence, integrated circuits, Internet of things, big data, network security, smart cities, and Internet of vehicles, strengthen the construction and application of standard systems such as industrial Internet, robots, and informationization and industrialization integrated management and promote the in-depth integration of informationization and industrialization.

III. Internationalization

- Deeply participate in international standardization
- Accelerate the process of international and domestic standards integration
- Implement the collaborative construction of "Belt and Road" action plan

8. China and Denmark signed "Proposal for the Project of Cooperation in the Strategic Field of Pharmaceutical and Medical Devices"

On 29 January 2019, Jiao Hong, Director-General of the NMPA (National Medical Devices Administration), and Thomas Sendlovitz, Director-General of the Danish Drug Administration signed the Proposal for the Project of Cooperation in the Strategic Field of Pharmaceutical and Medical Devices between China and Denmark. The "Project Proposal" clearly defines the future areas and directions of cooperation between the two sides, and the following two sides will formulate specific cooperation projects in the field of drug and medical device supervision in accordance with the "Project Proposal".

Before the signing of the Project Proposal, Jiao Hong held working talks with Per Okells, Permanent Secretary of the Danish Ministry of Health, and Thomas Sendlovitz, Director-General of the Danish Drug Administration. The two sides reviewed their cooperation in the field of drug supervision in recent years and reached consensus on further strengthening exchanges and deepening cooperation in the future.

Communication Network and Service

9. CAC issued “management regulations for block chain information services”

On 10th January, CAC (Cyberspace administration of China) issued management regulations for block chain information services which shall come into force on the 15th of February, 2019.

SESEC summarizes the main contents:

- Information services of block chain defined as information services through websites, applications to the publics on the base of block chain technology or system;
- Services providers are responsible for cyber security with proper technology, identity verifying system;
- Providers should develop and publish self-management rules;
- Related information should be backed up for at least six months;
- Services providers should report on record in CAC’s filing system in ten days after services

Chinese Website: http://www.cac.gov.cn/2019-01/10/c_1123971164.htm

10. MIIT published draft “measures for utilization of satellite communication network radio frequency and earth station”

On 16th January, MIIT published the draft measures for utilization of satellite communication network radio frequency and earth station and called for public comments. The deadline for feedback to SRRC (State Radio Regulation) via post is the 25th of February.

<http://www.miit.gov.cn/n1146285/n1146352/n3054355/n3057735/n6161863/c6601221/content.html>

11. MIIT issued the 5th batch of standards developing plan of 2018

On 16th January, MIIT issued the 5th batch of standards developing plan of 2018. The detailed category and number are abstracted and summarized as below, 158 standards are covered.

Industrial sector	Number	Type				International adoption
		GB	GB/T	Development	Revision	
Total	158	0	158	131	27	3
Shipbuilding	6	0	6	6	0	0
Chemical engineering	34	0	34	25	9	0
Construction Materials	11	0	11	10	1	0
Steel	23	0	23	18	5	0
Gold	2	0	2	1	1	0
Aviation	1	0	1	0	1	1
Light industry	20	0	20	10	10	1

Industrial sector	Number	Type				International adoption
		GB	GB/T	Development	Revision	
Total	158	0	158	131	27	3
Food	1	0	1	1	0	0
Electronic	2	0	2	2	0	0
IT/ICT	58	0	58	58	0	1

<http://www.miit.gov.cn/n1146295/n1652858/n1652930/n3757020/c6605619/content.html>

12. MIIT released “Regulations on 3000—5000MHz 5G Base Station, Satellite Earth Station and other Radio Station Interference Coordination”

On 20th December 2018, MIIT issued “Regulation on 3000—5000MHz 5G Base Station, Satellite Earth Station and other Radio Station Interference Coordination”. The “regulation” specified the principles and methods for the coordination between 5G base station and satellite earth station, as well as the application scope and relevant responsibilities. It stressed that the relevant organizations that set 5G base station should pay for the cost of interference mitigation.

In addition, it also proposed requirements of earth station equipment, interference protection standard, interference coordination area, process of coordination, interference mitigation measures between 5G base station and 3 different radio station, including satellite earth station, fixed service station, and radio observatory.

The “regulation” is an important normative document for 5G since MIIT has approved the 5G test frequency of three major telecommunication operators. It has great implications for relevant enterprises to address interference between 5G base station and other radio stations, protecting the legitimate rights and interests of satellite earth station, and promoting the development and application of 5G.

13. TC of informatization and industrialization integration Standardization set up 5 working groups

Under the guide of MIIT, national technical committee of informatization and industrialization integration Standardization set up 5 new working groups, the first batch.

- WG1: management system of informatization and industrialization integration
- WG6: industrial internet management
- WG7: industrial cybersecurity
- WG10: digitalization quality management
- WG14: new model of manufacture

SESEC marks: the national TC established in June 2018 authorized by SAC, otherwise directly supervised by MIIT.

14. IEC approved the first Standard on Informatization and Industrialization Integration proposed by China

The plenary meeting and working group meeting of ITU-T SG20 (standardization Bureau of IEC) kicked off in Wuxi of Jiangsu Province, China. The informatization and industrialization integration standard, “Methodology for building Sustainable Capabilities during Enterprises’ Digital Transformation”, was approved officially and expected published on March 2019. The standard was developed by National Industry Cybersecurity Research Centre under the guide of MIIT.

SESEC analyses: the standard was organized on the base of China recommended national standards GB/T 23000-2017 and GB/T 23001-2017, clarifies accurately the definition and term of “informatization and industrialization integration”. The approval by IEC indicates a virtual step of internationalization of China standards.

15. GB/T: Integration of Informatization and Industrialization Management System-Assessment Guidance is published

On 28th December 2018, GB/T23000-2017: Integration of Informatization and Industrialization Management System-Assessment Guidance is published officially by SAMR and SAC. The assessment guide points out clearly organization, process and auditing requirements. The new standard could be applied together with other 3 standards on integration of informatization and industrialization management system (GB/T23000-2017, GB/T23001-2017 and GB/T23002-2017)

16. MIIT published 54 ministerial level standards on telecommunications for comments

On 25th January 2019, MIIT published 54 recommended ministerial level standards on telecommunications for public comment ahead of delivery for approval. The feedback could be submitted online before 5th March 2019 via links:

http://www.ccsa.org.cn/bpggs/gs_content.php?id=40

Cybersecurity

17. SESEC webinar: Cyber Security Laws and Standards in China

In order to promote the understanding of China’s inspection and management on Cyber and Information Security, SESEC held the 3rd webinar on “Cyber Security Laws and Standards in China” in Beijing office on 17th January. Ms. Chen Shu, legal director of the Data Security Department of China Electronics Standardization Institute Information Security Research Center (CESI), was invited to deliver a substantial and valuable presentation. The presentation introduced the in-depth development of China’s cybersecurity laws, regulations and standardization, and also the current and ongoing work of TC 260 (national standardization committee on cybersecurity). Over 150 European partners and stakeholders join the 2 hours’ webinar.

In 2019 SESEC IV will continuously invite pertinent authority specialists and experts and organize webinars on China Standardization.

18. TC260 published 17 draft national standards for public comments

On 26th December, TC260 (National Information Security Standardization Technical Committee) published draft national standard “cyber security: guide on health care information security” for public comments. The feedback shall be emailed to wangjiao@cesi.cn before the 26th of December, 2018. Meanwhile the feedback deadline for the other 16 national standards listed below is 11th February, 2019.

- “Information Security Technology- Entity Authentication Assurance Framework ”
- “Information Security Technology- Certificate Request and Application Protocol Based on Multiple Channels”
- “Information Security Technology- XML Digital Signature Syntax and Processing Specification ”
- “Information Technology- Security Techniques- Message Authentication Codes (MACs)- Part 1 Mechanisms using a block cipher”
- “Information Security Technology- Light Weight Authentication and Access Control Mechanism”
- “Information Security Technology- Security Protection Technical Requirements and Testing and Assessment Approaches for Industrial Control Systems”
- “Information Security Technology- Security Techniques Requirement and Evaluation Criteria for Server”
- “Information Techniques- System Security Engineering Capability Maturity Model”
- “Information Security Technology-Cybersecurity Vulnerability Identification and Description Specification”
- “Information Security Technology- Guidelines for the Category and Classification of Cybersecurity Vulnerability”
- “Information Security Techniques-Cybersecurity Vulnerability Management Specification”
- “Information Security Techniques- Terminology”
- “Information Technology- Security Techniques- Information Security Incident Management- Part 2: Guidelines to plan and prepare for incident response”
- “Information Technology- Security Techniques- Guidelines for Information Security Management Systems Auditing”
- “Information Security Technology- Guide for Health Information Security ”
- “Information Security Technology- Requirements for Data Security Technology of the Government Information Sharing”

19. CAC released “Measures on Financial Information Services”

On 26th December, CAC (Cyberspace Administration of China) released officially the “Measures on Financial Information Services”

SESEC sorts pertinent explanation and analyses as follow:

- The definition of “financial information services” complies with WTO’s related agreements;
- The measures if specification document aiming at detailed management and requirements;
- The services online need to be qualified inspected by authority;
- The measures are supplements to “Measures on Foreign institutions’ financial information services in China”.

20. TC260 published 27 national standards on cyber security

On 28 December 2018, TC 260 (National Information Security Standardization Technical Committee) published 27 national standards on cyber security that will come into force on the 1st of July 2019. The standards are listed as below:

- GB/T 15851.3-2018 "Digital Signature Scheme for Message Recovery in Information Technology Security Belt Part 3: Mechanisms Based on Discrete Logarithm" Replaces Standard Number: GB/T 15851-1995
- GB/T 28449-2018 "Information Security Technology Network Security Grade Protection Evaluation Process Guide" Replaces GB/T 28449-2012
- GB/T 36629.3-2018 "Information Security Technology Civic Network Electronic Identity Identification Security Technical Requirements Part 3: Authentication Service Messages and Their Processing Rules"
- GB/T 36950-2018 "Information Security Technology Smart Card Security Technical Requirements (EAL4+)"
- GB/T 36951-2018 "Information Security Technology Requirements for Application Security of Internet of Things Perception Terminal"
- GB/T 36957-2018 Information Security Technology Disaster Recovery Service Requirements
- GB/T 36958-2018 Technical Requirements for Network Security Grade Protection and Safety Management Center of Information Security Technology
- GB/T 36959-2018 "Specification for Capacity Requirements and Assessment of Network Security Level Protection Assessment Institutions for Information Security Technology"
- GB/T 36960-2018 "Information Security Technology Authentication and Authorized Access Control Middleware Framework and Interface"
- GB/T 36968-2018 "Information Security Technology IPSec VPN Technical Specification"
- GB/T 37002-2018 "Information Security Technology E-mail System Security Technical Requirements"
- GB/T 37024-2018 Security Requirements for the Perception Layer Gateway of the Internet of Things
- GB/T 37025-2018 "Technical Requirements for Data Transmission Security of Information Security Technology Internet of Things"
- GB/T 37027-2018 "Information Security Technology Network Attack Definition and Description Specification"
- GB/T 37033.1-2018 "Information Security Technology Radio Frequency Identification System Password Application Technical Requirements Part 1: Password Security Protection Framework and Security Level"
- GB/T 37033.2-2018 "Information Security Technology Requirements for Password Applications in Radio Frequency Identification Systems Part 2: Technical Requirements for Electronic Labels and Readers and Their Communication Password Applications"
- GB/T 37033.3-2018 "Information Security Technology Requirements for Password Applications in Radio Frequency Identification Systems Part 3: Key Management Technical Requirements"
- GB/T 37044-2018 "Information Security Technology Internet of Things Security Reference Model and General Requirements"
- GB/T 37046-2018 Guidelines for Assessment of Disaster Recovery Service Capability of Information Security Technology
- GB/T 37076-2018 Technical Requirements for Fingerprint Identification System of Information Security Technology
- GB/T 37090-2018 "Technical Requirements and Testing and Evaluation Method for Safety of Information Security Technology Virus Prevention and Control Products"

- GB/T 37091-2018 "Safety Technical Requirements for Information Security Technology and Safety Office U Disk"
- GB/T 37092-2018 Security Requirements for Cryptographic Modules of Information Security Technology
- GB/T 37093-2018 "Security Requirements for Internet of Things Perception Layer Accessing Communication Network"
- GB/T 37094-2018 Requirements for Security Management of Information Security Technology Office Information System
- GB/T 37095-2018 "Basic Technical Requirements for Security of Information Security Technology Office Information System"
- GB/T 37096-2018 "Information Security Technology Office Information System Security Test Specification"

General Products Safety

21. SAMR and CNCA published notice on innovation of CCC catalogue

On 6th December, SAMR and CNCA jointly published the notice on innovation of CCC catalogue jointly issued by SAMR. 12 products are excluded from the CCC catalogue and do not require compulsory certification from the date of promulgation of the notice. And at the same time, 4 kinds of products' CCC are transferred to self-declaration management.

Products deleted from CCC catalogue: reciprocating saw, internal Concrete vibrators, Electric routers and Edge trimmer, Electric stone cutters, Electrode holders, TIG welding blow lamp, MIG/MAG welding torches, Wire feeder for welder, Duplicators, Retro reflectors device for motor vehicles, Burglary resistant safes(cabinet), Burglary resistant safes

Products apply self-declaration: Radio receivers, indirect visual field device for vehicles, retro-reflective markings, vehicle travelling data recorder.

Medical Devices

22. SESEC webinar: Progress of IEC 60601 transformation in China

On 24th January, SESEC held the 4th webinar on "Progress of IEC 60601 transformation in China" in Beijing's office. Dr. Zheng Jia, senior researcher of China food and drug testing and research institute, was invited to deliver a substantial presentation in English. As GB 9706 (IEC 60601) plays a very important role in China's medical device supervision and industry, Dr. Zheng introduced the progress of IEC 60601-1 transformation and progress of IEC 60601-1-x, IEC 60601-2-x transformation. Over 50 European partners and stakeholders joined the 2 hours' webinar and discussed together with Dr. Zheng a series of popular common concerns.

23. NMPA released annual plan on medical device standards

On 15th December, NMPA (National Medical Products Administration) released the 2019 revision and development plan on ministerial level standards of medical device. 94 standards are involved regarding evaluation methods, medical appliances, test and technical requirements.

24. SAMR published draft measures on inspection of imported medical devices agency

On 25th December, SAMR published the draft of “measures on inspection of imported medical devices agency” and called for public comments. The feedback and advice could be delivered by <http://www.chinalaw.gov.cn> before the 23rd of January, 2019.

Energy Management and Environmental Protection

25. MEE published five new national standards on self-monitoring technology

On 4th December, MEE (Ministry of Ecology and Environment) published five new national standards on self-inspection technology for special industrial manufacturers.

- HJ 985-2018 Self-monitoring technology guidelines for pollution sources— Electroplating industry
- HJ 986-2018 Self-monitoring technology guidelines for pollution sources — Farm and sideline food processing industry
- HJ 987—2018 Self-monitoring technology guidelines for pollution sources—Pesticide manufacture
- HJ 988-2018 Self-monitoring technology guidelines for pollution sources— flat glass industry
- HJ 989-2018 Self-monitoring technology guidelines for pollution sources— Non-ferrous metal metallurgy industry
- These mandatory national standards shall be put into force from the 1st March, 2019

www.mee.gov.cn/xxgk2018/xxgk/xxgk01/201812/t20181207_680840.html

26. MIIT updated “Green-design Products List”

On 17th December, 2018 the department of energy conservation and comprehensive application of MIIT released the latest updated green-design products list covering 59 technical specifications. In order to meet requirements of the “Green Manufacturing System Construction 2016-2020” and facilitate green-design product assessment, the list is expected to cover over 10.000 products by 2020.

27. CNCA Published Draft Measures on Labels of Green Products Certification

On 20th December, CNCA published the draft measures on labels of green products certification and called for public comments. The feedback deadline is the 28th of December.

http://www.chinagreenproduct.cn/gzdt/201812/t20181219_57004.shtml

28. NEA Approved the Establishment of Extinguishing and Protection Working Group

On 29th December 2018, NEA (National Energy Administration) approved to set up extinguishing and protection working group of the nuclear power standardization technical committee for general design and safety analysis.

29. NEA Released Yearly Work Plan on English Version of Energy Sector Standards

On 25th January, NEA released yearly work plan on English version of energy sector standards and called for public comments. The deadline is February 22, 2019.

SESEC assesses: the plan deems to develop standard in energy sector and urgent for overseas energy projects and equipment export. The needs mainly focus on international trade, international capacity cooperation, overseas projects or service projects, and economic and technological communication.

30. SESEC IV collected all China medical devices standards bibliography data with 1406 standards

SESEC IV have the list of all China medical devices standards, totally 1406 China Medical Devices standards bibliography data.

If you need the list, please contact assistant@sesec.eu

31. SESEC IV translated the “Association Standards Management Rules” and annexed with this Newsletter

See the annex

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