中美医疗器械标准研讨会

U.S.–China Medical Device Standardization Workshop

主办单位：
中国食品药品检定研究院（国家药品监督管理局医疗器械标准管理中心）
美国先进医疗技术协会
美国国家标准化机构

支持单位：
美国贸易发展署

Organized by:
National Institute for Food and Drug Control (Center for Medical Device Standardization Administration, NMPA)
Advanced Medical Technology Association(AdvaMed)
American National Standard Institute(ANSI)

Sponsored by:
U.S.Trade and Development Agency (USTDA)

2019年3月15日 北京

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Agenda

会议议程

AGENDA

U.S.-China Medical Device Standardization Workshop

March 15th, 2018 | Beijing, China

8:30 Registration

Morning session moderated by Yu Xinhua, CMDSA

9:00 Welcome Remarks
Li Jun, CFDA
Steven Winkates, USTAD
Yu Xinhua, CMDSA
Xu Fang, ANSI
Guo Ning, AdvaMed

9:15 Overview of China Standardization System in Medical Devices
Li Jun, NMPA

9:35 New Development in Chinese Medical Device Standardization
Yu Xinhua, CMDSA

10:00 Role of Voluntary Standards in the U.S. FDA Review and Approval Process
Bill Sutton, USFDA

This presentation will provide a first-hand account for CFDA of the interplay between voluntary standards and market approval in the United States.

10:45 Coffee Break

11:00 Introduction of IMDRF's Technical Document "Optimizing Standards for Regulatory Use"
Zheng Jia, Ph.D. CMDSA

This presentation will discuss "Optimizing Standards for Regulatory Use," a document aims to offer recommendations to standards developing organizations (SDOs), regulatory authorities (RAs) and other stakeholders for improving standards for use in medical device regulatory activities.

11:25 Introduction on the U.S. Standardization System
Xu Fang, ANSI

This presentation will provide a high-level overview of the U.S. standardization system.

11:45 International Best Practices: Conformity Assessment Testing

Yan Huaguo, Siemens Healthineers

The presentation will touch on how other countries/regions test products, identify best practices, and recommendations for China to consider as they develop their own policy in this regard.

12:30 Lunch

Afternoon session moderated by Zach Helzer, AdvaMed

1:30 International Best Practices: Mandatory Versus Voluntary Standards

Jamie Zhang, Stryker

This presentation will outline the differences and impact on manufacturers and patients in terms of voluntary versus mandatory standards for medical devices and diagnostics.

2:15 ISO Standards Development Process

Dr. Yiping Ma, BD

This presentation will outline the standards development and implementation process utilized by U.S. and international SDOs and hone in on areas for where China-based technical committees (TCs) can improve, e.g. the need for broader participation of foreign companies and transition periods that both standard editions can be used during transition.

3:00 Coffee Break

3:15 Recent Progress of International Standards Development for Robotics

Yang Shuping, China National Technical Committee for Automation Systems and Integration Standardization

This presentation will introduce recent progress of standards development for medical robotics around the world.

4:00 Recent progress of international standards development for AI and MedTech

Dr. Ren Haiping, NIFDC

This presentation will introduce recent progress of standards development for AI and medical technology around the world.

4:30 Q&A Discussion

Zach Helzer, AdvaMed

4:55 Closing Remarks

Steven Winkates, USTDA

Yu Xinhua, CMDSA

5:00 Adjourn

中美医疗器械标准研讨会日程

时间：2018 年 3 月 15 日 8：30 - 17：00
地点：北京中关村南大街 36 号湖北大厦 3 楼东湖厅

8:30 **会议签到**

上午主持：中国食品药品检定研究院医疗器械标准管理研究所副所长余新华

9:00 **欢迎致辞**

李军	*国家药品监督管理总局医疗器械注册管理司*
温凯时	*美国贸易发展署东亚区项目管理主任*
余新华	*中国食品药品检定研究院医疗器械标准管理研究所副所长*
许方	*美国国家标准化机构中国首席代表*
郭宁	*美国先进医疗技术协会*

9:15 **医疗器械标准管理体系介绍**
李军，国家药品监督管理总局医疗器械注册管理司处长

9:35 **概述：中国医疗器械标准工作动态**
余新华，中国食品药品检定研究院医疗器械标准管理研究所副所长

10:00 **自愿性标准在 FDA 审批流程中的角色**
Bill Sutton，美国食品药品管理局(FDA)驻华办公室助理主任

10:45 **茶歇**

11:00 **概述：IMDRF 技术文件 – 优化医疗器械监管所用标准**
郑佳，中国食品药品检定研究院医疗器械标准管理研究所，副研究员

11:25 **美国标准化体系介绍**
许方，美国国家标准化机构中国首席代表

11:45 **国际最佳实践：合格评定检测**
严华国，西门子医疗设备公司

12:30 **午餐**

下午主持：美国先进医疗技术协会 Zach Helzer

1:30 **国际最佳实践：强制性标准与自愿标准**
张海明，Stryker

2:15 **国际标准化组织标准制定流程**
马亦平博士，BD

3:00 **茶歇**

3:15 **机器人领域国际标准研究的最新进展**
杨书评，全国自动化系统与集成标准化技术委员会

4:00 **人工智能和医疗技术国际标准发展的最新进展**
任海萍，中国食品药品检定研究院医疗器械检定所光机电室 主任

4:30 **提问解答**
Zach Helzer，美国先进医疗技术协会

4:55 **闭幕辞**
温凯时，美国贸易发展署东亚区项目管理主任
余新华，中国食品药品检定研究院医疗器械标准管理研究所副所长

5:00 **结束**

Hosts and Supporting Agencies Overview

主办单位介绍

U. S. Trade and Development Agency (USTDA)

The U.S. Trade and Development Agency (USTDA) has the mutually beneficial mission of linking U.S. businesses to export opportunities by funding project preparation and partnership building activities which develop sustainable infrastructure and foster economic growth in partner countries.

USTDA promotes economic growth in emerging economies by facilitating the participation of U.S. businesses in the planning and execution of priority development projects in host countries. The Agency's objectives are to help build the infrastructure for trade, match U.S. technological expertise with host country development needs, and help create lasting business partnerships between the United States and emerging economies.

USTDA's Program Activities

Project Development

Project identification and investment analysis generally involves technical assistance, feasibility studies and pilot projects which support large investments in infrastructure contributing to host country development. USTDA's program in China includes the transportation, energy, agriculture, and healthcare sectors.

Trade Capacity Building and Sector Development

Trade capacity building and sector development assistance supports the establishment of industry standards, rules and regulations, market liberalization and other policy reform. In China, USTDA has supported activities to enhance the protection of intellectual property rights, fair and transparent government procurement practices, science-based agricultural biotechnology regulations, and standards across a range of sectors.

Cooperation Programs

USTDA's success in China is due in large part to the public-private cooperation programs that the Agency supports in country. These programs provide a forum for government agencies and private companies from both countries to share technical, policy, and commercial knowledge to advance shared goals. USTDA has successfully established programs based on this model in the aviation, energy, healthcare, and agriculture and food sectors.

By adapting to the evolving needs of China's market and closely coordinating with decision-makers in both countries, these public-private partnerships have achieved long-term success, providing continued trade opportunities.

Reverse Trade Missions

Through the Agency's reverse trade missions (RTMs), USTDA has increased its support for programs designed to bring procurement officials to the United States to witness U.S. technologies, equipment, and ingenuity firsthand. These visits also facilitate new partnerships with U.S. companies needed to spur commercial cooperation. Related, USTDA also supports technology demonstrations, training, and specialized sector-specific workshops and conferences.

美国贸易发展署 (USTDA)

美国贸易发展署(USTDA) 致力于在新兴经济体推动经济发展和美国的商业利益。美国贸易发展署通过对项目前期，试点项目以及反向代表团赴美考察等形式的资金资助，达到在合作伙伴国家推动可持续性基础设施和经济增长的同时帮助美国企业寻找出口机会。

美国贸易发展署鼓励美国公司积极参与新兴经济体项目所在国重点发展领域里的项目规划和实施过程中的机会。目的是帮助美国有技术优势的公司配合项目所在国的发展寻求契机，并建立长期持久合作关系。

美国贸易发展署的项目活动

项目开发

美国贸易发展署支持的项目确认和投资分析通常为了支持项目所在国大型基础设施项目投资决策前以所需要的技术援助，可行性研究分析和试点项目等。在中国的项目集中在交通，能源和医疗卫生领域。

能力建设和行业发展

能力建设和行业发展是为了帮助推动建立行业标准，法规等相关政策需求的活动。在中国，美国贸易发展署支持过的项目内容涉及知识产权，公平透明政府采购，以科学为基础的农业生物技术规范，以及涉及其他更宽泛领域涉及行业标准的内容。

国际商业伙伴关系项目

通过国际商业伙伴关系项目，美国贸易发展署加大资金投入力度，组织更多灵活多样的赴美考察团，技术交流/研讨会和培训等，选择特定的一些行业，帮助中方人员了解美国技术，掌握第一手资料，加深对美国企业的了解并能推动潜在的商务合作。

政府企业合作平台

美国贸易发展署在中国取得成功的部分原因是与其他相关机构共同支持了政府企业合作项目的平台。在这个平台上，美国和中国的政府机构和私营企业均可以共享在特定领域的技术、政策和商业知识。美国贸易发展署已经成功地在航空、标准合格评定、能源和医疗保健等行业推动了该模式。

通过适应中国市场变化的需求，和中国决策者的密切配合，这些公私伙伴关系企业积累了一些长期合作的成功经验，提供持续的贸易机会，并推动中国支柱产业的发展。

U.S.-China Standards and Conformance Cooperation Program

Sponsored by the U.S. Trade Development Agency (USTDA) and coordinated by the American National Standards Institute (ANSI), the **U.S.-China Standards and Conformance Cooperation Program** (SCCP) provides a forum through which U.S. and Chinese industry and government representatives can:

- Cooperate on issues relating to standards, conformity assessment, and technical regulations;
- Foster the relationships necessary to facilitate U.S.-China technical exchange on standards, conformity assessment, and technical regulations; and
- Exchange up-to-date information on the latest issues and developments relating to standards, conformity assessment, and technical regulations.

Beginning in 2013, ANSI will coordinate 20 workshops over a 3-year period in China under the SCCP. The workshops will cover a wide range of sectors, as proposed by interested U.S. private-sector organizations. Workshop topics will be chosen in coordination with relevant industry associations, ANSI, and USTDA.

To learn more about the U.S.-China SCCP or to express interest in sponsoring or participating in a workshop, please visit our website at:

www.standardsportal.org/us-chinasccp

FOR MORE INFORMATION
Henry Yuan
Program Manager
American National Standards Institute (ANSI)
1899 L St. NW – Eleventh Floor
Washington, DC 20036

T: 202.331.3624
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E: us-chinasccp@ansi.org

美中标准与合格评定合作项目

由美国贸易发展署 (USTDA) 提供资助、 美国国家标准协会 (ANSI) 负责协调的美中标准与合格评定合作项目 (SCCP) 在以下几个方面为美国和中国相关行业和政府代表提供了一个论坛：

- 在标准、合格评定以及技术法规等领域的合作;
- 为促进美中在标准、合格评定以及技术法规等领域的技术交流建立必要的联系;
- 及时交流关于标准、合格评定以及技术法规等领域的 最新议题和发展情况的相关信息

根据 SCCP 项目规定，从 2013 年开始的三年内，ANSI 将在中国协调举办20场研讨会。根据美国私营业界相关组织的建议，研讨会内容将覆盖不同的行业和领域。研讨会的主题将由相关行业组织、ANSI 以及 USTDA 协调选定。

欲了解该项目的更多情况或有意赞助或参与该项目，请访问下列网站：

www.standardsportal.org/us-chinasccp

了解其他信息，请联系

Henry Yuan

项目经 理

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American National Standards Institute (ANSI)

As the voice of the U.S. standards and conformity assessment system, the American National Standards Institute (ANSI) empowers its members and constituents to strengthen the U.S. marketplace position in the global economy while helping to assure the safety and health of consumers and the protection of the environment.

The Institute oversees the creation, promulgation and use of thousands of norms and guidelines that directly impact businesses in nearly every sector: from acoustical devices to construction equipment, from dairy and livestock production to energy distribution, and many more. ANSI is also actively engaged in accrediting programs that assess conformance to standards – including globally-recognized cross-sector programs such as the ISO 9000 (quality) and ISO 14000 (environmental) management systems.

ANSI has served in its capacity as administrator and coordinator of the United States private sector voluntary standardization system for the past hundred years. Founded in 1918 by five engineering societies and three government agencies, the Institute remains a private, nonprofit membership organization supported by a diverse constituency of private and public sector organizations.

Throughout its history, ANSI has maintained as its primary goal the enhancement of global competitiveness of U.S. business and the American quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems and promoting their integrity. The Institute represents the interests of more than 270,000 companies and organizations and 30 million professionals worldwide through its office in New York City, and its headquarters in Washington, D.C.

美国国家标准协化机构（ANSI）

作为美国标准和合格评定体系的发言人，美国国家标准化机构授权其会员强化美国市场在全球经济中的地位，同时协助保障消费者的安全和健康以及环境保护事宜。

机构对数以千计的标准和指导方针的制定、颁布、实施进行监督，而这些标准和指导方针几乎直接影响商业的每个领域：从声呐设备到建筑设备，从乳制品及家禽产品到能源分配等等。 美国国家标准化机构也积极参与评估合格到标准的委托项目——包括诸如 ISO9000（质量）和 ISO14000（环境的）管理系统等全球认可的跨领域项目。

在过去的一个世纪中，美国国家标准化机构担任美国私营部门自愿性标准化体系的管理者及协调者。自 1918 年由五家工程师协会和三个政府部门成立以来，本机构一直是一个民间、非营利性质的会员制组织，得到来自私营和公共部门的多元化支持。

纵观历史，美国国家标准化机构的首要目标一直是强化美国商业的全球竞争力，通过推进自愿性标准及合格评定体系并对它们进行完善从而提高美国人民的生活质量。机构总部设在华盛顿特区，并在纽约设有办公地点，代表全球超过 27 万家公司及组织和三千万专家的利益。

Advance Medical Technology Association (AdvaMed)

AdvaMed advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation.

The Advanced Medical Technology Association (AdvaMed), is a trade association that leads the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world. AdvaMed’s membership has reached nearly 300 members and more than 80 employees with a global presence in countries including Europe, India, China, Brazil, and Japan. AdvaMed's member companies range from the largest to the smallest medical technology innovators and companies.The Association acts as the common voice for companies producing medical devices, diagnostic products and health information systems.

AdvaMed promotes competitive policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets. While the policies advocated by AdvaMed are tailored to the specific issues facing the device industry, the need for strategic government policies is applicable to all the high technology, high value sectors in which America must compete effectively if it is to assure robust economic growth and a high standard of living for the American people.

美国先进医疗技术协会(AdvaMed)

美国先进医疗技术协会(AdvaMed)是世界领先的医疗技术行业协会，总部设在美国，代表全球医疗器械及诊断设备制造商，成员公司规模不一，同时包括了大型集团和小规模企业，在全球包括中国、日本、印度、巴西和欧洲等地设有办事机构或专职人员。AdvaMed 关注和推动政策的制定，以加大医疗技术投资、发展医疗技术创新及帮助患者获得诊疗机会为宗旨，从而在中国以及世界各地促进更健康的生活和更良好的经济发展。

美国先进医疗技术协会(AdvaMed)在中国积极推动最高标准的行业道德行为规范准则、帮助患者及时获得安全有效的产品，并推动有关价值创新的经济政策制定。2014 年，AdvaMed 在上海开设中国办事处，扩大了在中国的影响力，加强了我们与行业有关方的合作——包括制造商、患者群体、医疗卫生服务单位以及中国政府部门——以推动医疗技术创新和高品质的医疗保健服务的发展。

Speaker Biographies

演讲人介绍

Jun LI

Director of the Division of Registration Research, Department of Medical Device Registration, National Medical Products Administration

Former Deputy Director of the Medical Device Standards Management Research Institute, National Institutes for Food and Drug Control (Center for Medical Device Standards Management, National Medical Products Administration). He is mainly taking in charge of the standards, classification, naming and coding of medical devices.

李军

国家药品监督管理局医疗器械注册管理司注册研究处处长

曾任中国食品药品检定研究院（国家食品药品监督管理总局医疗器械标准管理中心）医疗器械标准管理研究所副所长。主要负责医疗器械标准、分类、命名、编码等相关工作。

Xinhua YU

Senior editor, holds the post of Deputy Director of Institute for Medical Device Standardization Administration, National institutes for Food and Drug Control

He is mainly responsible for standardization and management of medical device, studies of classification of medical device standards, studies of coding of medical device standards and so on. He has participated in the amendment to Measures for the Administration of the Standards for Medical Devices and taken charge of amending works of Management Regulations on Formulation and Amendment to the Standards for Medical Devices. He has taken charge of and participated in formulations of multiple medical device standards at the national levels and researches on standard system construction. He has organized compilation and writing of standards such as Interpretation of YY0505-2012 Standards, Interpretation of GB9706.1 Standards, Inspection Procedure of Safety Standards for Medical Electrical Equipment, Knowledge about Medical Device Standards and so on.

余新华

编审，现担任中国食品药品检定研究院医疗器械标准管理研究所 副所长（主持工作）。主要负责医疗器械标准管理、医疗器械标准分类研究、医疗器械标准编码研究等工作。参与修订《医疗器械标准管理办法》，主持《医疗器械标准制修订工作管理规范》修订工作。主持或参与多个国家级医疗器械标准制定及标准体系建设研究课题。组织《YY0505-2012 标准解读》、《GB9706.1 标准解读》、《医用电气设备安全标准检验规程》、《医疗器械标准知识》等标准书籍编写。

Fang XU
Chief Representative
American National Standards Institute China Office

Xu Fang has been working with American National Standards Institute (ANSI) as the Chief Representative of ANSI China Office since 2012. In this position, he has primary responsibility for overall liaison of ANSI's activities with Chinese government agencies, standard development organizations and various industry groups.

Prior to working with ANSI, Mr. Xu served for American Forest & Paper (AF&PA) China Office as the main contact point for US government, industry and Chinese government for all of aspect of AF&PA China Program. As the representative of US forest industry, he worked with Chinese Ministry of Housing and Urban Rural Development (MoHURD) and State Administration of Forestry on developing and revising a serial of codes and standards pertaining to design, construction and inspection of wood constructions. He has made numerous presentations among Chinese developers, design professionals, importers and consumers and introduced applications of US wood products. Prior to joining in AF&PA, Mr. Xu worked with an engineering firm as the Chief Structural Engineer for more than 13 years.

Mr. Xu holds his Bachelor of Engineering degree from Tongji University.

许方
美国国家标准化机构(ANSI)中国代表处的首席代表

许方先生自 2012 年起担任美国国家标准化机构(ANSI)中国代表处的首席代表，负责 ANSI 在中国的相关工作和业务。在此之前，许先生于 1999 年起担任美国林业及纸业协会中国代表处首席代表，负责美国林产品的贸易政策以及市场推广。在此期间，许先生作为美国林产工业的代表，参与制订了中国数本关于木结构建筑设计、施工、验收以及产品的标准和法规的编写工作，为中国木结构建筑标准的应用和发展起了积极的作用。许先生毕业于同济大学结构工程专业，在加入美国林业及纸业协会之前，曾从事十多年的建筑工程设计与咨询业务，撰写过多篇学术论文。

Steven Winkates
Director of Program Management, East Asia Region
U.S. Trade and Development Agency (USTDA)

Steven Winkates is the Director of Program Management for the East Asia Region at USTDA, based at the U.S. Embassy in Beijing, China. He is responsible for managing USTDA's activities in China and Mongolia, directing business development efforts,coordinating with relevant stakeholders in both the region and the United States, and marketing USTDA services to potential partners in both countries.

Prior to this position, Mr. Winkates worked in Beijing for a consulting firm which specializes in developing transportation infrastructure projects. He also previously served as a Country Manager at USTDA, covering China and Southeast Asia during his tenure, and as a Policy Analyst at the U.S. Department of Commerce.

Mr. Winkates holds a Master of Public Policy from Georgetown University and a Bachelor of Arts from Rhodes College.

温凯时
美国贸易发展署东亚区项目主任

Steven Winkates 是美国贸易发展署东亚地区项目管理主任，常设办公地在美国驻中国大使馆。他负责管理美国贸易发展署在中国和蒙古区域的项目，包括指导业务发展工作、协调该地区和美国利益相关方的关系、并向两国的潜在合作伙伴推广美国贸易发展署的活动及相关服务。

在此之前，Winkates 先生曾任职于一家专门从事交通基础设施项目开发的咨询公司。他曾担任美国贸易发展署中国和东南亚地区发展负责人和美国商务部政策分析师等相关职位。

Winkates 先生先后获得罗德学院的文学学士学位和乔治城大学的公共政策硕士学位。

Ning GUO

RA&QA associate director of Advamed

Guo Ning is RA&QA associate director of Advamed, he takes the responsibility from May 2018. He focuses on the medical device RA and QA in China, to help members communicate post market and pre-market regulatory issues. Before join AdvaMed, Guo Ning worked for RB as a Sr. manager, in charge of life cycle risk management for all the product lines. And Guo Ning also worked for Medtronic as RA manager, lead the Compliance & Operation team to resolve AE, FCA, Labeling, CFDA inquiry and Registration Process optimizations. Before 2014, Guo Ning was one of the Beijing FDA officials, and responsible for market surveillance among pharmaceutical, medical device, cosmetics and health food.

Guo Ning got master's degree of MBA from Tsinghua University and has a bachelor's degree of pharma from Peking University.

郭宁

AdvaMed 中国区法规事务副总监

他从 2015 年 5 月起开始负责协助会员企业进行医疗器械法规事务和质量管理方面的法规分析和沟通。在此之前，郭宁曾担任利洁时（中国）投资有限公司高级经理，负责全产品线的生命周期风险管理，并曾在美敦力（上海）有限公司担任法规事务经理的职务，带领团队负责不良事件，召回，产品标签管理，CFDA 事件处理以及注册流程优化。2014 年以前，郭宁曾就职于北京市食品药品监督管理局，从事“三品一械”（药品，化妆品，保健食品和医疗器械）的稽查和综合协调工作。

郭宁毕业于北京大学医学部药学院，并在清华大学获得 MBA 学位。

William M. Sutton
FDA Assistant Country Director, China

William (Bill) Sutton is an Assistant Country Director in the Office of International Programs (OIP) at the United States Food and Drug Administration (FDA) China Office where he serves as the International Program and Policy Analyst (IPPA) for medical devices. Before being named Assistant Country Director of the FDA China Office, Mr. Sutton was the Deputy Director of the Division of Industry and Consumer Education (DICE) at FDA's Center for Devices and Radiological Health (CDRH) where he led the Division in the strategic development of regulatory education on medical device topics spanning premarket and postmarket policy.

Mr. Sutton began his career at FDA in 1983, and has held positions in CDRH, the Office of Device Evaluation (ODE), and the Office of Communication and Education (OCE). During his tenure at the FDA he served as an administrative reviewer at ODE and as a Supervisory Consumer Safety Officer at the mandated industry and international assistance program in OCE. In both roles he worked on domestic and international compliance issues, and served as Chairman of FDA's Third Party Recognition Board (TPRB), which administered both the Accredited Persons (AP) for 510(k) review and AP for Inspection programs. For over 21 years he has educated the worldwide medical device community about Federal medical device regulations and policies. Mr. Sutton received a Bachelor of Science in Management Studies from the University of Maryland University College.

萨盾
美国食品药品管理局驻华办公室助理主任

萨盾是在美国食品药品管理局（USFDA）国际项目办公室下属的 FDA 驻华办公室助理主任，他负责医疗器械的国际项目和政策分析。在被任命为 FDA 驻华办公室助理主任之前，萨盾先生是医疗器械和放射健康中心（CDRH）的行业与消费者教育处（DICE）副处长。他主要负责该处在医疗器械上市前和上市后相关法规教育工作的战略发展。

萨盾先生 1983 年起开始在 FDA 工作，曾在医疗器械评审办公室（ODE）和交流教育办公室（OCE）工作。在 FDA 工作期间，曾在 ODE 担任行政评审员，在 OCE 的企业和国际协助项目中担任消费者安全官主管。在这两项工作中，他负责国内和国际合规事务，并担任 FDA 第三方认可委员会（TPRB）主席，管理 510(k)评审的认可人员（AP）和现场检查的 AP。在过去的 21 年中，他参与了多国大量医疗器械相关联邦法规政策的培训。萨盾先生获得马里兰大学大学学院分校的科学管理学士学位。

Jia ZHENG

Doctor Zheng works for Institute for Medical Device Standardization Administration, National institutes for Food and Drug Control. He is mainly responsible for the standardization and management of active medical device. He serves as Secretary-general of Quality Management and Corresponding General Aspects for Medical Devices (TC221) and President of Working Team of Medical Robot Standardization of IEEE. He is one of main draftsmen of *Management Regulations on Formulation and Amendment to the Standards for Medical Devices.* He has published more than ten academic papers pertaining to the standardization and management of medical device.

郑佳

博士，工作于中国食品药品检定研究院医疗器械标准管理研究所。主要负责有源医疗器械标准管理。担任全国医疗器械质量管理和通用要求标准化技术委员会（TC221）秘书长，IEEE 医用机器人标准化工作组主席。《医疗器械标准制修订工作管理规范》主要起草人之一。发表医疗器械标准管理相关学术论文十余篇。

Huaguo YAN

Senior Test Lab Manager, Siemens Healthineers Ltd

Mr. Yan has been worked in the field of active medical device certification for 14 years. He is responsible for product testing in Siemens Healthcare involved in product safety, EMC and radiation protection. He also participated in SAC TC10 standardization work such as IEC 60601 3rd edition transition in China and relevant training material draft.

He was a Biomedical Engineering major at Southeast University. Before joining Siemens, he worked in UL and TUV Rheinland for medical device certification.

严华国

西门子医疗系统有限公司测试实验室高级经理

具有 14 年医用电气产品测试与认证经验，负责西门子医疗产品测试工作，主要为产品安全，电磁兼容与辐射防护，并参与 SAC TC10 标准化工作，如 IEC60601 系列标准第三版标准转化及培训教材编写工作。

毕业于东南大学生物医学工程专业。在加入西门子前，曾先后在第三方检测机构 UL，TUV 莱茵从事医疗器械认证工作

Zachary Helzer

Vice President, Global Strategy and Analysis at AdvaMed

Zach is responsible for the AdvaMed Greater China portfolio in Washington, DC, and works closely with the AdvaMed team in China to maximize member company market access by advocating for policies that improve the regulatory and payment environment, and minimize trade barriers through interaction with US and foreign governments, stake holder groups as well as the Chinese government directly.

Prior to joining AdvaMed, Zach worked for Siemens Healthcare coordinating international trade, regulatory and standards advocacy. Before that, Zach was International Director at the Medical Imaging and Technology Alliance(MITA). Zach earned his Master's Degree in International Studies with a concentration in International Politics from the Josef Korbel School of International Studies at the University of Denver and has a Bachelor's Degree in History with a minorin Political Science from Metropolitan State University of Denver.

Zachary Helzer

美国先进医疗技术协会全球战略与分析副总裁

Zach Helzer是AdvaMed全球战略与分析副总裁。Helzer先生负责美国先进医疗技术协会(AdvaMed)大中华地区的项目，并与中国团队密切合作，通过倡导围绕改善监管和支付环境的政策，从而减少医疗企业的市场准入技术性贸易壁垒。其同时也与中国政府、外国政府和相关利益相关团体保持合作关系。

在加入美国先进医疗技术协会之前，Helzer 先生曾在西门子医疗集团工作，协调国际贸易、监管和标准等领域工作。在此之前，他曾担任医学影像与技术联盟（MITA）的国际主任。他先后获得丹佛大都会大学政治学学士学位、历史学学士学位及约瑟夫科贝尔国际研究学院国际政治学硕士学位。

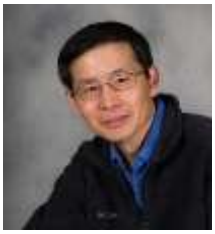
Jamie ZHANG
Senior RA Scientific Officer of Stryker China

He joins in Stryker on Dec. 2017 aim to meet following needs in the facing of China profound regulatory requirements and company's ultimate goal of global design and manufacture. He worked in Tianjin Medical Device Testing And Supervision Center(TMDT) for 7 years before Stryker. In TMDT he developed several China standards and also was convener of ISO and IEC. He has rich experience on standardization field of Medical device in China or international.

张海明
史赛克（北京）医疗器械有限公司资深注册技术主管

他于 2017 年 12 月加入史赛克。主要致力于满足匹配中国法规要求与公司产品设计、生产最终结果的需求。加入史赛克之前，他曾在天津市医疗器械质量监督检验中心任职 7 年。期间制定了多个中国行业标准，同时他还曾担任 ISO 和 IEC 的工作组召集人。在中国及国际医疗器械标准化领域积累了较多经验。

Yiping MA, Ph. D
Principle Engineer, R&D, Becton and Dickson



Dr. MA is a mechanical engineer with 20+ years of broad experience in new product design and development of complex high technology products and medical device products. Expertise is in solving challenging technical problems and evaluating new technologies. Extensive experience in mechanical design and analysis, system and component level failure analysis, designing experiments, and cross functional technical leadership.

He currently holds over 50 issued U.S. patents across both high tech and medical device industries and many pending U.S. and International patent applications. He is also the member of Member, ISO/TC 84/WG 9.

马亦平博士
Becton and Dickson 研发部首席工程师

马博士是一名资深的机械工程师，在处理复杂的高科技产品和医疗设备产品的新产品设计和开发方面拥有 20 多年的经验，其中包括机械设计和分析、系统和组件级故障分析、设计实验和跨职能技术等。

他目前在高科技和医疗设备行业领域中拥有 50 多项美国专利。他同时也也是国际标准化组织/84 技术委员会/第 9 工作组成员。

Shuping YANG

Key Roles:

- Professor of Beijing Research Institute of automation for machinery industry
- Secretary general of ISO/TC299 mirror committee (SAC/TC159/SC2) in China
- ISO/TC299/WG6 co-convener of modularity for service robot (2015-2019)
- ISO/TC299/SG1 WG3 JWG35 member

Yang has been working on robotics standardization research for more than 12 years, mainly responsible for domestic SAC/TC159/SC2 standardization work management and international standard coordination.

杨书评

研究员级高工

硕士研究生，北京机械工业自动化研究所研究员

- 现任全国自动化系统与集成标准化技术委员会机器人及机器人装备分技术委员会（SAC/TC159/SC2）秘书长
- ISO/TC299/WG6 服务机器人模块化工作组副组长
- ISO/TC299/SG1 WG3 和 JWG35 成员

长期从事机器人标准化研究工作，主要研究方向为机器人技术及标准化，负责国内 SAC/TC159/SC2 标准化工作管理和国际标准跟踪。

Haiping REN

Doctor Ren, Head of Optical-electromechanical Medical Device Inspection Office of National institutes for Food and Drug Control, and she has engaged in registration & inspection and national supervision and sampling work for more than 10 years. Her main research interests include active medical device and medical software testing and quality control, and she has rich experience in inspection.

The scientific researches that she is currently participating or participated, taking charge of or took charge of are found by National Supported Program, NSFC (Natural Science Foundation of China), National Key R&D Projects and so on. She has published more than 100 papers in the journals at home and abroad. She serves as President of Artificial Intelligence Medical Device Working Group, member of National Committee of Technicalization of Medical Electric Equipment and member of National Medical Measurement Technique Committee.

任海萍

博士，中国食品药品检定研究院光机电医疗器械检验室主任，从事十余年注册检验和国家监督抽验工作。主要研究方向为有源医疗器械、医用软件的检测及质量控制，检验经验丰富。正在或曾主持和参加国家支撑项目、国家自然科学基金、国家重点研发计划课题等多项科学研究，在国内外期刊上共发表论文 100 余篇。IEEE 人工智能医疗器械工作组主席、全国医用电器技术化委员会委员、全国医学计量技术委员会委

Presentations

演讲材料

国家药品监督管理局 NMPA

医疗器械标准管理体系介绍

Overview of China Standardization System in Medical Devices

国家药品监督管理局
医疗器械注册管理司
2019年3月 北京

Department of Medical Device Registration
National Medical Products Administration
March,2019 Beijing

国家药品监督管理局 NMPA

医疗器械 Medical Devices

- 标准管理体系现状 Overview of Standardization System
- 面对形势和下布工作 Challenges and Next Steps

医疗器械标准管理——法规体系结构

Standards Management of Medical Devices – Legal Framework

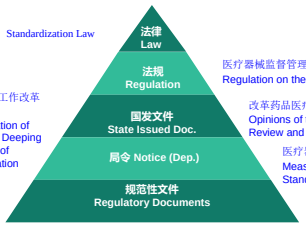
NMPA

通法 Common Law

专法 Specialized Law

Standardization Law

深化标准化工作改革方案
Implementation of the Plan for Deeping the Reform of Standardization Work



医疗器械监督管理条例
Regulation on the Supervision and Administration of Medical Devices

改革药品医疗器械审评审批制度的意见 （国发〔2015〕44号）
Opinions of the State Council on Reform of the System of Evaluation, Review and Approval of Drugs and Medical Devices (No.44 [2015])

医疗器械标准管理办法
Measure for the Administration of the Standards for Medical Devices

- 医疗器械标准制修订工作管理规范 (Amendments to the Measure for the Administration of the Standards for Medical Devices)
- 医疗器械标准报批发布工作细则 (Standardized Notification and Reporting Work Plan for Medical Devices)

医疗器械标准管理体系

Standards Management System of Medical Devices

NMPA

国务院标准化行政主管部门
State Council's administrated administrations and bureaus

国家药监局 NMPA （行业标准）
Sectoral Standards

国标委SAC （国家标准）
National Standards

国务院行业主管部门
Sectoral supervision office at the State Council

总局医疗器械标准管理中心
Medical Devices Management Center

标准化技术归口单位
Standards/ Technical Intuitions

TC

SC

WG

WG

标准化技术委员会
Standardization Administration of China

医疗器械标准管理体系—专业标委会（24个）

Standards Management System of Medical Devices – 24 Technical Committees

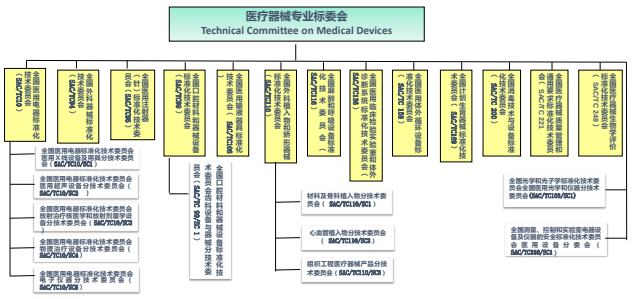
NMPA

- 目前，共成立24个医疗器械专业标准化技术委员会。
  Currently, there are 24 technical committees are formed to cover medical devices
- 24个医疗器械标委会均与国际标准化机构对口，与国际电工委员会（IEC）对口的技委会共有7个，与国际标准化组织（ISO）对口的技委会有17个。
  The 24 medical device-related technical committees are all in line with the international standardization bodies, there are 7 technical committees correspond to IEC, and 17 technical committees correspond to ISO.
- 标准化技术归口单位 3个。
  There are 3 corresponding standardization and technical agencies.

医疗器械标准管理体系—专业标委会（24个）

Standards Management System of Medical Devices – 24 Technical Committees

NMPA



医疗器械标准管理体系—专业标委会（24个）
Standards Management System of Medical Devices – 24 Technical Committees

与国际电工委员会（IEC）的对应关系 Correspondence with IEC Standards

总标技委名称、SAC/TC号	IEC代号	分标技委名称、SAC/TC号	IEC代号
全国医用电器标准化技术委员会（SAC/TC10）	IEC TC62/TC87	全国医用电器标准化技术委员会医用X射线设备及用具分技术委员会（SAC/TC10/SC1）	IEC:TC 62/SC 62B
		全国医用电器标准化技术委员会医用超声设备分技术委员会（SAC/TC10/SC2 ）	IEC:TC 87
		全国医用电器标准化技术委员会放射治疗核医学和放射剂量学设备分技术委员会（SAC/TC10/SC3）	IEC:TC 62/SC 62C
		全国医用电器标准化技术委员会物理治疗设备分技术委员会（SAC/TC10/SC4）	IEC:TC 62/SC 62D
		全国医用电器标准化技术委员会电子仪器分技术委员会（SAC/TC10/SC5）	IEC:TC 62/SC 62D

医疗器械标准管理体系—专业标委会（24个）
Standards Management System of Medical Devices – 24 Technical Committees

与国际标准化组织（ISO）的对应关系 Correspondence with ISO Standards

总标技委名称、SAC/TC号	ISO代号	分标技委名称、SAC/TC号	ISO代号
全国外科器械标准化技术委员会（SAC/TC94）	ISO:TC 170	/	/
全国医用注射器（针）标准化技术委员会（SAC/TC95）	ISO:TC 84	/	/
全国口腔材料和器械设备标准化技术委员会（SAC/TC99）	ISO:TC 106	齿科设备与器械分技术委员会（SAC/TC 99/SC 1）	ISO:TC 106/ SC 4/SC 6
全国医用输液器具标准化技术委员会（SAC/TC106）	ISO:TC 76	/	/
全国外科植入物和矫形器械标准化技术委员会（SAC/TC110）	ISO: TC150	材料及骨科植入物分技术委员会（SAC/TC110/SC1）	ISO:TC 150/SC 1/SC 4/SC 5
		心血管植入物分技术委员会（SAC/TC110/SC2）	ISO:TC 150/SC 2
		组织工程医疗器械产品分技术委员会	ISO:TC 150/SC 7
全国麻醉和呼吸设备标准化技术委员会（SAC/TC116）	ISO:TC 121	/	/
全国医用临床检验实验室和体外诊断系统标准化技术委员会（SAC/TC136）	ISO:TC 212	/	/

医疗器械标准管理体系—专业标委会（24个）
Standards Management System of Medical Devices – 24 Technical Committees

与国际标准化组织（ISO）的对应关系 Correspondence with ISO Standards

总标技委名称、SAC/TC号	ISO代号	分标技委名称、SAC/TC号	ISO代号
全国医用体外循环设备标准化技术委员会（SAC/TC 158）	ISO:TC 150/ SC 2 IEC:TC 62/SC 62D	/	/
全国计划生育器械标准化技术委员会（SAC/TC169）	ISO:TC 157	/	/
全国视听技术与设备标准化技术委员会（SAC/TC 200）	ISO:TC 198	/	/
全国医疗器械质量管理和通用要求标准化技术委员会（SAC/TC221）	ISO:TC 210	/	/
全国医疗器械生物学评价标准化技术委员会（SAC/TC248）	ISO:TC 194	/	/
		全国光学和光子学标准化技术委员会全国医用光学和仪器分技术委员会(SAC/TC103/SC1)	ISO:TC 172/SC 7/SC 5 IEC:TC 76/WG4

医疗器械标准技术体系—分类
Standards Management System of Medical Devices – Classification

- 按规范对象分类，医疗器械标准可以分为基础标准、产品标准、方法标准和管理标准； Medical Devices Standards are classified as: basic standards, product standards, methodology standards, and management standards
- 按标准性质分类，医疗器械标准分为强制性标准和推荐性标准。 In terms of standardization type, medical devices standards include both mandatory and recommended standards.

◆ 国家标准
National Standards

标准性质分为强制性国家标准(GB)和推荐性国家标准（GB/T）

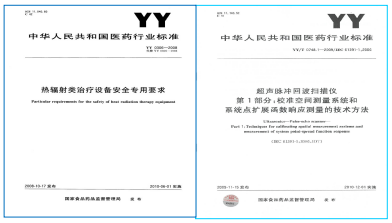
Categorized into mandatory national standards (GB) and recommended national standards (GB/T)

医疗器械标准技术体系—分类
Standards Management System of Medical Devices – Classification

◆ 行业标准：
Industry Standards

标准性质分为强制性行业标准（YY)和推荐性行业标准(YY/T)

Categorized as mandatory industry standards (YY) and recommended industry standards (YY/T)

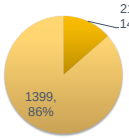


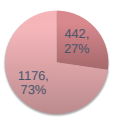
标准化法第十条：法律、行政法规和国务院决定对强制性标准的制定另有规定的，从其规定。
Article 10 of the Standardization Law: For technical requirements necessary to meet the basic requirements, for supporting compulsory national standards, and leading the relevant industries, recommended national standards can be formulated. The recommended national standards shall be formulated by the standardization administrative department under the State Council.

医疗器械技术标准体系—标准数量
Standards Management System of Medical Devices – Number of Standards

医疗器械标准发布数量
Total Number of Standards Developed around Medical Devices

标准类型 Standards Type		数量 Amount	合计 Total
GB	强制性标准 Mandatory	86	219
	推荐性标准 Recommended	133	
YY	强制性标准 Mandatory	356	1399
	推荐性标准 Recommended	1043	
合计 Total		1618	1618





国家药品监督管理局

NMPA

医疗器械 Medical Devices

标准管理体系现状
Overview of Standardization System

面对形势和下布工作
Challenges and Next Steps

国家标准化工作改革
Overview of Standardization Reform

NMPA

深化标准化工作改革方案
2015.3
Implementation of the Plan for Deeping the Reform of Standardization Work

标准化法
2017.11
Standardization Law

团体标准管理规定（试行）
2017.12
Management Regulation of Association Standards (Trial)

医疗器械监管
Supervision of Medical Devices

NMPA

最严谨的标准
Rigorous Standards

最严格的监管
Restricted Supervision

最严厉的处罚
Severe Punishment/ Penalty

最严肃的问责
Serious Accountability

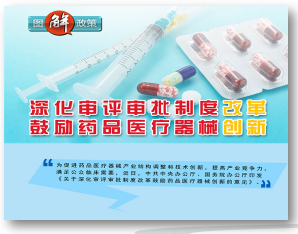
医疗器械审评审批改革
Reform of the System of Evaluation, Review and Approval of Drugs and Medical Devices

NMPA

2017年10月，为进一步鼓励创新，深化审评审批制度改革鼓励药品医疗器械创新的中办、国办（关于意见）
In October 2017, the General Office of the CPC Central Committee and the General Office of the State Council released *the Opinions on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation of Drugs and Medical Devices* to encourage technological innovation in the drug and medical device industries.

以提高医疗器械质量为核心；
Core mission is to improve the quality of medical devices
以满足人民群众需求为目标；
Key objective is to meet new needs of the general public
进一步优化审评审批流程。
Continue to optimize the evaluation and approval process

深入贯彻落实中办国办《意见》精神，积极落实审评审批改革措施，制定改革任务分工表，明确十四项重点任务、63项具体措施。
To thoroughly implement the objectives set by the CPC Central Committee and the State Council, the "Opinion" proposed 14 key tasks and 63 reform measures, and a reform role and coordination matrix had been formulated.



NMPA

顶层设计 Top-Level Design/Framework

1 完善标准体系
Optimize Standardization System

◆构建结构合理、规模适度、内容科学的医疗器械标准体系
Build a feasible, scalable and scientific standardization system for medical devices

◆实施标准提高计划，着力推进基础性通用标准的制修订工作，突出创新医疗器械领域标准工作
Implement standard improvement plan and promote the revision of basic and common standards, with a special emphasis on the standardization in innovative medical devices

NMPA

供给侧改革 Supply-side Structural Reform

2 推动供给侧改革
Promote supply-side structural reform

◆鼓励依法成立的社会团体制定团体标准，更好地响应医疗器械领域创新和市场对标准的需求，增加了医疗器械标准的有效供给。
Encourage the establishment of association standards by legal social organizations to meet new market needs in innovative medical devices market; sufficiently provide standards to the industry

◆激发市场活力，有效引导
Stimulate market vitality and effectively guide the standardization work

职责划分
Clarification of Roles

3 落实各方职责

Confirm Roles of Relevant Stakeholders

◆理顺参与标准化工作各部门及相关单位等的关系，明确各方标准化职责和工作内容 Streamline the coordinating relationship among administrative offices and standardization organizations; clarify the roles and responsibilities of all involved stakeholder

◆突出“总局医疗器械标准管理中心”的职责，对其拟定医疗器械标准规划、组织标准体系研究、标准制修订管理、标委会管理以及标准实施协调等职能进行了细化，有利于充分发挥总局标管中心的作用。Highlight the role and duties of the “Medical Device Standards Management Center”, and refine the functions of medical device standard planning, organization standard system research, standard revision and management, standard committee management and coordination

提速增效
Increasing speed and efficiency

4 加强精细化管理

Strengthen and refine management

◆强化对立项、起草、征求意见、技术审查、批准发布、复审，各环节的要求

Strengthen and tighten requirements for each step of the standardization work, including proposal, drafting, public comment solicitation, technical validation, approval and publication, and review.

◆加强医疗器械标准精细化管理

Strengthen and refine management of medical devices standards.

全周期
Full lifecycle

可及性
Reachability

4 实现闭环管理

Realize the closed loop management system

◆进一步强化了标准的跟踪评价及实施评估，实现对医疗器械标准的闭环管理

Further strengthening the mechanism of monitoring and implementation evaluation; conduct closed loop management on medical devices standards

5 提高标准可及性

Increase reachability of standards

◆加大了标准公开力度，提高了标准可及性

Enhance the transparency and to increase the reachability and application of standards

强化实施
Strengthen Implementation

6 强化标准实施

Strengthen Implementation of Standards

◆强调了强制性标准在医疗器械监管中的地位

Emphasis of role of mandatory standards in supervising medical devices

◆强调推荐性标准一旦被法律法规、规范性文件及经注册或者备案的产品技术要求引用的内容应当强制执行

Emphasize that the recommended standards should be enforced once they are cited and referenced by laws and regulations, regulatory documents, and technical requirements for filed and registered products

国际合作
International Cooperation

7 深度开展国际合作

Deepen international cooperation

◆深度参与IMDRF标准化协调工作 Increase participation in coordinating IMDRF standardization work

◆继续加强与美国国家标准学会（ANSI）、德国电工委员会、美国电气和电子工程师协会（IEEE）等国际标准化组织的深度合作

Continue to strengthen in-depth cooperation with international standardization bodies and organizations, such as ANSI, DKE, IEEE

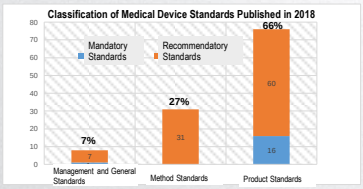
New Developments in Chinese Medical Device Standardization

National Institutes for Food and Drug Control
(Institute for Medical Device Standardization Administration, National Medical Products Administration)
Yu Xinhua
March 15, 2019

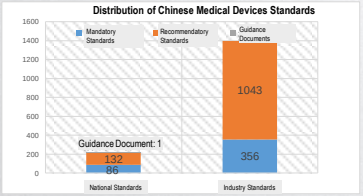
CONTENTS

I. Development and Revision of Medical Device Standards

- Having effectively implemented plans to improve medical device standards and completed tasks of standard development and revision of 2018:
  - Having organized and completed the development and revision of 97 standards, which are published for soliciting opinions from the general public
  - Having cooperated in publishing 115 standards in the industry of medical devices and 4 amendments to industry standards



- As of March 2019, there are totally 1,618 medical device standards currently effective in China
- Have basically covered all technical fields of medical devices like electrical medical devices, surgical instruments and implants for surgery
- The conversion rate of the international standards reaches 90.4%

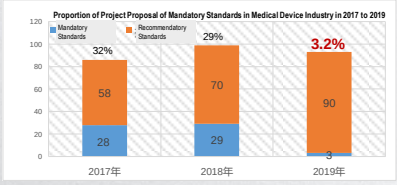


Distribution of Standards in Different Technical Fields of Medical Devices

No.	Technical Field	Number of Standards
1	Medical electrical equipment	328
2	Surgical instruments	59
3	Injectors for medical purpose (needles)	34
4	Dental materials, instruments and equipment	160
5	Birth control	30
6	Anaesthetic and breathing equipment	54
7	Medical optics	114
8	Infusion apparatus	138
9	Implants for surgery and orthopedic instruments	202
10	Clinical examination laboratory and in vitro diagnosis	230
11	Extracorporeal circulation equipment	40
12	Disinfection technology and equipment	85
13	Quality Management	21
14	Biological assessment of medical devices	57
15	Safety of electrical equipment for medical laboratory	2
16	Hygienic materials and dressings	49
17	Biological protection for medical purpose	12
18	Assisted reproduction	3

II. Integration and Simplification of Medical Device Standards

- Having made sustained efforts to integrate and simplify mandatory standards, the proportion of which has already reduced to 27%:
  - In principle, product standards, method standards and management standards are not developed as mandatory standards
  - The proportion of planned projects of mandatory standards in medical device industry has declined for 3 years in a row and became 3% in 2019



III. Project Proposals of Medical Device Standards

- Multiple measures are taken simultaneously to normalize the project proposal of standards and strictly control the sources of the development of medical device standards:

Focus on supervision demands

•Solicit project proposal demands from relevant bureaus and departments of NMPA, Center for Medical Device Evaluation NMPA and all provincial supervision departments in a targeted way

Be strict in project proposal procedures

•Voting by Technical Commission: Name, nature, scope and first drafter of project proposed
•Seek for opinions: seek for public opinions on the website of Institute for Medical Device Standardization Administration for 1 month
•Expert demonstration: full demonstration of necessity and feasibility

Expand sources of project proposals

•More convenient operation: information-based declaration of standard project proposals
•More universal participation: encouraging all sectors of society and individuals to make project proposals

Improve priority ordering of project proposals

•Priorities are given to project proposals of revised standards, adoption of latest international standards and major, fundamental and general standards as well as those listed in National Science and Technology Major Projects

IV. Progress of the Development and Revision of GB9706 Series Standards

➢ Impact of the frequent revision of International Standard IEC60601-1 on the progress of the revision of GB9706.1:

- The project proposal of revising National Standard GB9706.1 was formally approved
- Planned to convert IEC60601-1 Edition 3.1

- Kobe Meeting on IEC/TC62 approved further revision of IEC60601-1
- Planned to publish Edition 3.2 in January 2019

- Annual Meeting on IEC/TC62 was canceled, delaying the work
- Planned publication of Edition 3.2 was postponed to the end of 2019

2014.9 — 2015.11 — 2015.12 — 2016.10 — 2017

Postponed the submission of GB9706. 1 new edition for approval

- Completed the examination and authorization according to the plan of project proposal
- Prepared for the submission for approval

- Received more than 300 suggestions on the problems existed in Edition 3.1 from different countries
- Decided by voting, totally 107 suggestions were included in Edition 3.2

➢ To promote the publication and implementation of GB9706.1 and take into full consideration voices from the industry, the revision of GB9706.1 new edition was initiated again:

2017
- Pay close attention to the progress of the revision of edition 3.1
- Give positive feedback of China

2017.12
- Revise GB9706.1 new edition by reference to the draft of Edition 3.2
- Completed the examination and authorization again

2018.6
- Completed the materials to be submitted for GB9706. 1 new edition

2018.9
- The National Center of Standards Evaluation and the Institute for Medical Device Standardization Administration carried out preliminary review

Materials will be submitted for approval after further examination and authorization in March 2019

➢ The project proposals of 66 collateral standards and special standards have been approved.

- The procedures of submission for approval have been completed for 28 projects and planned to be carried out in 2019
- Except 3 recommendatory standards (usability, closed-loop control and listening devices), all others are mandatory standards

➢ No plan to convert 3 standards by far:

Item	Number	Name of Standard	Reasons not to convert
1	IEC60601-1-9	Medical Electrical Equipment Part 1-9: General Requirements for Basic Safety and Essential Performance Collateral Standard: Requirements for Environment Conscious Design	Inconformity with Chinese laws and regulations
2	IEC60601-2-23	Medical Electrical Equipment Part 2: Particular Requirements for Basic Safety and Essential Performance of Transcutaneous Partial Pressure Monitoring Equipment	No similar products in China
3	IEC 80601-2-59-2008	Medical Electrical Equipment Part 2-59: Particular Requirements for Basic Safety and Essential Performance of Screening Thermographs for Human Febrile Temperature Screening	No similar products in China
4	ISO80601-2-67	Medical Electrical Equipment Part 2-67: Particular Requirements for Basic Safety and Essential Performance of Oxygen Conserving Equipment	Not subject to management as medical devices in China

V. Implementation of Medical Device Standards

➢ Actively trace the implementation of standards and gradually realize the full-life-cycle closed-loop management of medical device standards:

Actively investigate problems existed in the implementation of standards

- Send letters to 110 units like supervising, evaluating and inspecting organizations and industry associations, investigate problems existed in the implementation of prevailing standards, and give feedback advices on over 100 standards:
  - 6 standards will be revised in 2019
  - For some problems, explanatory documents have already been published on websites of relevant technical committees
  - The publicizing and implementation of some standards will be organized again in 2019

Systematically evaluate the implementation of mandatory standards

- Evaluate the implementation of 26 mandatory standards in the medical device industry like YY 0505-2012:
  - Technical indexes: applicability, advancement, coordination
  - Effect of implementation: popularization of standard, implementation of standard, quotation of standard

VI. Training on the Publicizing and Implementation of Medical Device Standards

➢ Carry out systematic planning, make efforts to strengthen the training on the publicizing and implementation of medical device standards, guide supervisors and manufacturers to fully understand and grasp the standards, and promote the implementation of standards:

- 2018-2019 plan of training on the publicizing and implementation of medical device standards are available for the public on the website of the Medical Device Standardization Administration and reproduced by several public accounts like those of industry associations.
- In 2018, totally 24 training sessions on the publicizing and implementation of standards were carried out and attracted 2,289 participants
- In 2019, it is planned to organized over 20 training sessions on the publicizing and implementation, which involve 97 standards

VII. Information Disclosure of Medical Device Standards

➢ Further promote the information disclosure of medical device standards, improve services:

- Publicize 122 project applications and 87 draft standards for comment
- Publicize the texts of 382 mandatory medical device standards
- 100% publicize the catalog information about 1,618 medical device standards
- Establish a public communication platform to gather questions on the implementation of standards and answer questions

Website of Medical Device Standardization Administration: http://www.nifdc.org.cn/qxbgzx/CL0482/

VIII. Organizational Structure of Medical Device Standards

- In the emerging fields strongly supported by the national scientific and technological development, actively explore and promote the preparation and establishment of new standardization technical committees or centralized units;

1. Technical Committee of the Biological Evaluation Standardization of Nanometer Medical Devices
   National Institutes for Food and Drug Control
2. Technical Committee of Active Implant Standardization
   Shanghai Testing & Inspection Institute for Medical Devices
3. Centralized Technical Unit of Medical Device Standardization
   Jiangsu Testing & Inspection Institute for Medical Devices
4. Centralized Technical Unit of Additional Medical Materials Manufacturing Technologies and Medical Devices Standardization
   National Institutes for Food and Drug Control
5. Centralized Technical Unit of Artificial Intelligence Medical Device Standardization
   National Institutes for Food and Drug Control

The number of technical committees of medical device standardization will be increased from 24 to 26.

The number of centralized technical units of medical device standardization will be increased from 3 to 6.

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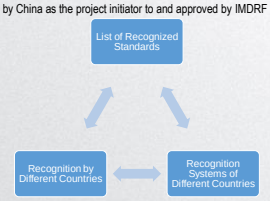
IX. International Exchange and Cooperation

- In March 2018, the new project "Updated List of International Standards Recognized by IMDRF Member States" proposed by the Medical Device Standardization Administration on behalf of China was approved by the Management Committee of IMDRF
- The first project proposed by China as the project initiator to and approved by IMDRF



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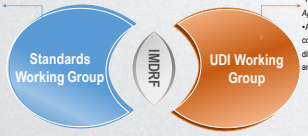
- Deep participation in the drafting of IMDRF standards and technical documents of coding
- Chinese experiences on the management of medical device standards have been effectively promoted in the international community.

•IMDRF *Optimizing Standards for Regulatory Use* was published in December 2018.
•China has preliminarily completed the conversion



•Have completed the translation of IMDRF *UDI Application Guidelines* (Draft for Comment)
•Amending advices on relevant term definition, composition of production identifiers and duties of different parties have been universally recognized and accepted by UDI Working Group.

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- Actively participate in international standardization activities and steadily increase its influence on international standardization:

- Recommended **58** registered experts to the International Standard Organization
- Put forward new proposals for **5** international standards
  - *Air Filter - Aerosol Bacteria Interception Test Methods*
  - *DEHP Analysis Method*
  - *Shading Infusion Set ...*
- Played a leading role in developing **2** international standards:
  - *Water Sound, Hydrophone and Hydrophone Calibration Part 2: Low Frequency Sonic Pressure Field Calibration Procedures*
  - *Cardiovascular Implants - Heart Occluders*
- Gave feedback to and voted on **554** international standards

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- Further deepen the communication and cooperation with foreign advanced standardization organizations:

Established substantial cooperative relationship with IEEE and made positive progress

- In March 5, 2018, the National Institutes for Food and Drug Control signed a Memorandum of Understanding with IEEE in Beijing.;
- Established IEEE Medical Robots Standardization Working Group, and Artificial Intelligence Medical Devices Standardization Working Group, and acted as chairman
- Project proposals of 3 IEEE standards were approved.

Active involvement in AHWP

- Actively participated in the work of AHWP UDI Working Group
- Cooperated with the Medical Device Registration Division in the drafting of AHWP UDI questionnaires

Continued to carry forward discussions on Chinese and American systems of medical device standards

- Organized seminars between Chinese and American experts on an irregular basis based on Sino-US Memorandum of Understanding , on medical device standards.

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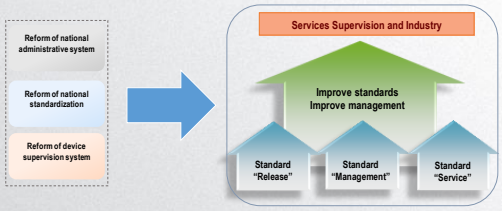
Future Working Ideas on Standards Management

- In 2019, the medical device standards management will comply with the requirements for reform and development, face up to challenges arising from the reform, satisfy demands for medical device supervision and industry demands, set up new ideas and explore new models:



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I. Standard "Release"

- Further deepen the integration and simplification of mandatory medical device standards, accelerate the implementation of the Conclusions on the Integration and Simplification of Mandatory Standards, and gradually optimize the system of mandatory medical device standards

40 mandatory standards in the medical device industry will be converted to recommendatory standards

Accelerate the research on and give priority to the proposals of integration and revision projects

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Ⅱ. Standard "Management"

- Further strengthen the fine management of standards and ensure the justice, equity, publicity and transparency of the process of development and revision

- Be strict in procedures
- Insist on quality-oriented principle
- Conduct researches on the guiding opinions on the implementation of mandatory standards
- Strengthen the training on the publicizing and implementation of standards
- Assess the performance of 4 technical committees
- Key aspects to be assessed include completion rate of revising tasks, quality of submitted materials and schedule management

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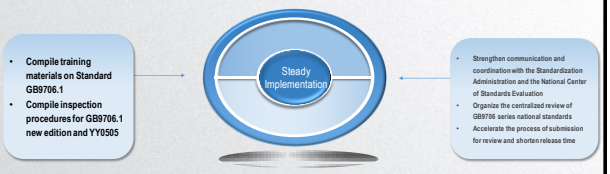
III. Standard "Services"

- Make sufficient preparations for the release and implementation of GB9706.1 new edition and serve the supervision and industry:



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谢 谢

THANK YOU

中国医疗器械标准工作动态

中国食品药品检定研究院
（国家药品监督管理局医疗器械标准管理中心）
余新华
2019.3.15

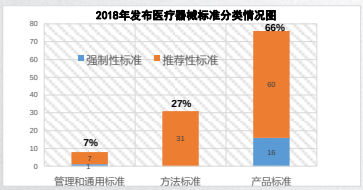
CONTENTS

Part1/ 最新工作动态

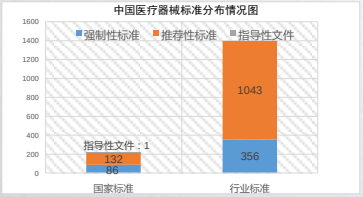
Part2/ 近期工作计划

一、医疗器械标准制修订

- 有效实施医疗器械标准提高计划，顺利完成2018年度制修订任务：
  - 组织完成医疗器械行业标准制修订97项，均向社会公开征求意见
  - 配合发布医疗器械行业标准115项，行业标准修改单4项



- 截止到2019年3月，中国现行有效的医疗器械标准共1618项
- 基本覆盖了医用电气设备、手术器械、外科植入物等医疗器械各技术领域
- 国际标准转化率达90.4%

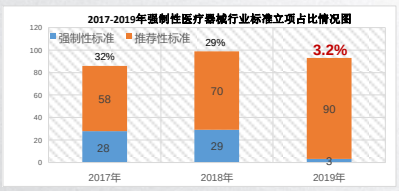


医疗器械各技术领域标准分布情况

序号	技术领域	标准数量
1	医用电器	328
2	外科器械	59
3	医用注射器（针）	34
4	口腔材料和器械设备	160
5	计划生育	30
6	麻醉和呼吸设备	54
7	医用光学	114
8	输液器具	138
9	外科植入物和矫形器械	202
10	临床检验实验室和体外诊断	230
11	体外循环设备	40
12	消毒技术与设备	85
13	质量管理	21
14	医疗器械生物学评价	57
15	医用实验室电器设备安全	2
16	卫生材料及敷料	49
17	医用生物防护	12
18	辅助生殖	3

二、医疗器械标准整合精简

- 持续推进强制性标准整合精简，强制性标准占比已下降为27%：
  - 原则上，产品标准、方法标准、管理标准不制定为强制性标准
  - 强制性医疗器械行业标准计划项目占比连续3年持续下降，2019年仅占3%



三、医疗器械标准立项

- 多措并举规范标准立项，把好医疗器械标准制定源头关：

聚焦监管需求
•向国家局相关司局、国家器审、各省监管部门定向征集立项需求

严格立项程序
•技委会表决：立项名称、性质、范围、第一起草单位
•征求意见：在标管中心网站公开征求意见1个月
•专家论证：对必要性和可行性充分论证

扩大立项来源
•操作更便捷：信息化申报标准立项提案
•参与更广泛：鼓励社会各方、个人均可提出立项

完善优先立项原则
•对修订标准、采用最新版国际标准、重大基础通用标准、列入国家重大科技专项的的立项项目予以优先立项

四、GB9706系列标准制修订进展

➢国际标准IEC60601-1的频繁修订影响了GB9706.1修订进展：

- 修订GB9706.1国标项目正式立项
- 计划转化IEC60601-1第3.1版

- IEC/TC62神户会议批准对IEC60601-1第3.1版再次修订
- 计划2019年1月发布第3.2版

- IEC/TC62年会因故取消，工作滞后
- 第3.2版发布计划推迟到2019年底

2014.9 → 2015.11 → 2015.12 → 2016.10 → 2017 → 暂缓新版GB9706.1报批

- 按立项计划完成审定
- 准备报批

- 收到各国对3.1版存在问题的意见多达300多项
- 经表决，列入第3.2版共计107项

➢为推动GB9706.1的发布实施，充分考虑业界呼声，新版GB9706.1修订工作再次启动：

2017
- 密切关注第3.1版修订进展
- 积极反馈中国意见

2017.12
- 参考3.2版草案修改新版GB9706.1
- 再次审定通过

2018.6
- 完成新版GB9706.1报批材料

2018.9
- 国标审评中心和标管中心正开展标准前置审核

2019年3月将二次审定后报批

➢ 66项并列及专用标准已获批立项

- 28项已完成报批，其余计划在2019年报批
- 除3项（可用性、闭环控制、听力设备）推荐性外，其余均为强制性

➢ 暂不计划转化3项:

序号	编号	标准名称	暂不转化的原因
1	IEC60601-1-9	医疗电气设备 第1-9部分:基本安全和基本性能 通用要求 并列标准:环境意识设计的要求	和中国法规不一致
2	IEC60601-2-23	医用电气设备 第2部分：经皮局部压力监护设备基本安全和基本性能专用要求	中国没有类似产品
3	IEC 80601-2-59-2008	医疗电气设备,第2-59部分:人类发热检查用检查温度记录仪的基本安全和基本性能用特殊要求	中国没有类似产品
4	ISO80601-2-67	医用电气设备 第2-67部分：氧气保存设备基本安全和基本性能专用要求	在中国不按医疗器械管理

五、医疗器械标准实施

➢积极跟踪标准实施情况，逐步实现医疗器械标准全生命周期闭环管理：

主动调研标准实施问题

- 向监管、审评、检测、行业协会等110家单位发函，调研现行标准实施存在的问题，反馈意见涉及100余项标准：
  - 6项将在2019年修订
  - 部分问题已在相关技委会网站发布解释性文件
  - 部分标准将在2019年再次组织宣贯

系统开展强标实施评价

- 对YY 0505-2012等26项强制性医疗器械行业标准开展实施评价工作:
  - 技术指标：适用性、先进性、协调性
  - 实施效果：标准推广、标准执行、标准被引用

六、医疗器械标准宣贯培训

➢系统规划、着力加强医疗器械标准宣贯培训，指导监管、生产企业充分理解和掌握标准，促进标准实施：

- 2018-2019年医疗器械标准宣贯培训计划，在标管中心网站对公众公开，并在行业协会等多个公众号转载
- 2018年累计开展标准宣贯培训共24场次，参与培训人数达2289人
- 2019年将计划组织宣贯20余场次，涉及97项标准

七、医疗器械标准信息公开

➢进一步推进医疗器械标准信息公开，提升服务水平：

- 对外公开了122项立项申请和87项标准征求意见稿
- 对外公开382项医疗器械强制性标准文本
- 100%对外公开医疗器械1618项标准目录信息
- 建立公众交流平台，随时收集标准实施问题，答疑解惑

标管中心网站：http://www.nifdo.org.cn/qxbgzx/CL0482/

八、医疗器械标准组织架构

- 在国家科技发展重点支持的新兴领域，积极探索和推动筹建新的标准化技术委员会或归口单位：

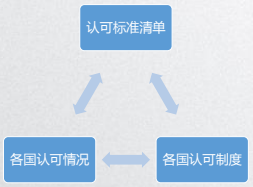
1. 纳米医疗器械生物学评价标准化分技委 中检院
2. 有源植入物标准化分技委 上海市医疗器械检测所
3. 医用电声设备医疗器械标准化技术归口单位 江苏省医疗器械检验所
4. 医用增材制造技术医疗器械标准化技术归口单位 中检院
5. 人工智能医疗器械标准化技术归口单位 中检院

医疗器械标准化技术委员会将由24个增长到26个

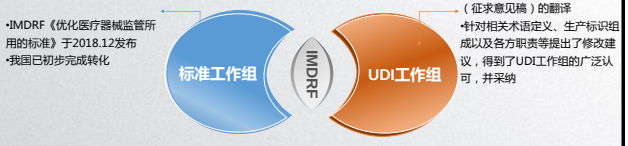
医疗器械标准化技术归口单位将由3个增长到6个

九、国际交流与合作

- 2018.3，标管中心代表我国提出的《更新IMDRF成员国认可国际标准清单》新工作项目获IMDRF管委会通过
- 我国加入IMDRF以来首个作为项目发起人向大会提出并获通过的工作项目



- 深度参与IMDRF标准、编码技术文件的编写工作
- 我国在医疗器械标准管理方面取得经验在国际社会得到有效推广



- 积极参与国际标准化活动，对国际标准化工作的影响力稳步提升：

- 进一步深化和国外先进标准化组织沟通合作：

与IEEE建立实质性合作关系并取得积极进展

- 2018年3月5日，中检院和IEEE在京签署了谅解备忘录；
- 成立IEEE医用机器人标准工作组，人工智能医疗器械标准工作组，担任主席
- 3项IEEE标准立项获批

积极参与AHWP

- 积极参与AHWP UDI工作组相关工作
- 配合器械注册司起草了AHWP UDI调查问卷

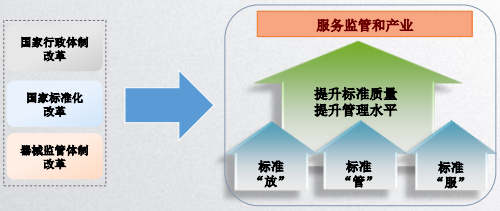
持续推进中美医疗器械标准体系研讨

- 基于中美医疗器械标准合作备忘录，不定期组织中美专家进行交流研讨

CONTENTS

标准管理下一步工作思路

➢ 2019年，医疗器械标准管理工作将顺应改革发展要求，直面改革带来的挑战，面向医疗器械监管和产业需求，树立新理念，探索新模式：



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一、标准“放”

➢ 进一步深化强制性医疗器械标准整合精简，加快落实《强制性标准整合精简结论》，逐步优化强制性医疗器械标准体系

40项强制性医疗器械行业标准将转化为推荐性

对整合、修订的项目将加快研究、优先立项

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二、标准“管”

➢ 进一步加强标准精细化管理，保证制修订过程公平公正、公开透明：

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三、标准“服”

➢ 做好新版GB9706.1发布实施的配套准备工作，服务监管和产业：

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谢 谢

THANK YOU

U.S. FOOD & DRUG ADMINISTRATION

Role of Voluntary Standards in the U.S. FDA Review and Approval Process
自愿性标准在美国FDA审批流程中的作用

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国际项目和政策分析师（医疗器械）
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U.S. Embassy, Beijing
美国大使馆，北京

March 15, 2018
2018年3月15日
Beijing, China
中国北京

Presentation Outline
陈述要点

- Why Are Standards Important?
- 标准为何重要？
- Definition & types of standards
- 标准的定义和类型
- Introduction to CDRH Standards Program
- CDRH标准项目介绍
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices
- 自愿性共识标准在医疗器械上市前申报中的合理使用
- Resources for You
- 可供您使用的资源

Why Are Standards Important?
标准为何重要？

Consistency 一致性 + **Predictability 预见性** + **Credibility 可信性**

= Science Based Decisions基于科学的决策

The National Technology Transfer and Advancement Act (NTTAA)
《国家技术转让与推动法案》（NTTAA）

- 1996 Congress passed the NTTAA
- 1996年，美国国会通过NTTAA
- Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment
- 通告A-119，联邦政府参与自愿性共识标准的制定和使用以及符合性评估
- To use voluntary standards in lieu of government-unique standards
- 使用自愿性标准代替政府特有的标准

The FDA Modernization Act and 21st Century Cures Act
FDA《现代化法案》和《21世纪治愈法案》

- Congress enacted the FDA Modernization Act (FDAMA) and the 21st Century Cures Act
- 美国国会颁布FDA《现代化法案》和《21世纪治愈法案》
  - Amended section 514(c) of the FD&C Act
  - 修订了《药品和化妆品法案》第514(c)节
  - Shall publish in the *Federal Register* recognized all or part of an appropriate standard established by a nationally or internationally recognized standards development organization*; and*
  - 应在《联邦公报》中公布，由国家或国际公认的标准制定组织制定的全部或部分适当标准
  - Declaration of Conformity for Premarket Submissions
  - 上市前申报的符合性声明

Regulations vs Standards
法规与标准

Regulations法规	Standards标准
• Authority to issue from laws (statues) enacted by Congress. • 由国会颁布的法律（成文法）产生的发布权利。 • Agency issues proposed rule in *Federal Register*. • 由机构在《联邦公报》中发布的指导性规则。 • Public comments received by the Agency. • 机构收到的公众意见。 • Final Rule published in *Federal Register*. • 在《联邦公报》中发布的最终规则。 • Final Rule is ***enforceable!*** • 最终规则是***强制性的！***	• Authority to recognize/use from (statues) enacted by Congress. • 由国会赋予的（成文法）认可/使用权利。 • Agency follows a process to recognize standards. • 机构按照流程来认可标准。 • FDA publishes in the Federal Register once per year a list of recognized standards. • FDA每年在《联邦公报》中发布一次公认标准清单。 • Use of any consensus standards is voluntary. • 任何共识标准的使用都是自愿的。

Definitions
定义

- The term "standard," or "technical standard" as cited in the National Technology Transfer and Advancement Act of 1995 (NTTAA):
- 术语“标准”或“技术标准”引用自《国家技术转让与推动法案（1995）》（NTTAA）

"Common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices."

“规则、条件、产品或相关流程和生产方法的指南或特征，以及相关管理系统实践的共同和重复使用。”

"The definition of terms; classification of components; delineation of procedures; specification of dimensions, materials, performance, designs, or operations; measurement of quality and quantity in describing materials, processes, products, systems, services, or practices; test methods and sampling procedures; or descriptions of fit and measurements of size or strength."

“术语的定义；部件分类；程序描述；尺寸、材料、性能、设计或操作规范；在描述材料、流程、产品、系统、服务或实践时质量和数量的测量；试验方法和采样步骤；或尺寸或强度的适合度和测量值的描述。”

Voluntary Consensus Standard
自愿性共识标准

- Voluntary consensus standards are standards developed or adopted by voluntary consensus standards bodies, both domestic and international using agreed-upon procedures.
- 自愿性共识标准是指由国内和国际自愿性共识标准机构使用商定程序制定或通过的标准。
- A voluntary consensus standards body is defined by the following attributes:
- 自愿性共识标准机构具有以下属性：
  - Due Process
  - 正当程序
  - Openness
  - 公开
  - Balance
  - 平衡
  - Consensus
  - 共识

Consensus, which is defined as general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties.

*共识的定义是大体同意，但不一定是一致同意，包括试图解决有关各方的反对意见的过程。

Types of Standards
标准类型

- Basic standard (broad ranging effects)
- 基本标准（具有广泛的影响）
- Terminology standards
- 术语标准
- Test and measurement standards
- 测试和测量标准
- Product specific (or related group of products) standards
- 产品特定（或相关产品种类）标准
- Process management standards
- 流程管理标准
- Interface and data communication standards
- 界面和数据通讯标准
- Performance standards
- 性能标准
- Design standards
- 设计标准

→**Note**: The NTTAA encourages the Executive Branch to use voluntary consensus standards in lieu of writing government specific standards where possible and on mission.

注： NTTAA鼓励行政部门在可能的情况下和执行任务时，使用自愿性共识标准，而不是制定政府特定的标准。

Other Types of Standards
其他标准类型

- International standards such as
- 国际标准，例如：
  - International Organization for Standardization (ISO)
  - 国际标准化组织（ISO）
  - International Electrotechnical Commission (IEC)
  - 国际电工技术委员会（IEC）
  - ASTM International (ASTM)
  - 美国材料与试验协会（ASTM）
- Harmonized standards, e.g., CEN/CENELEC (Annex Za Essential Principles)
- 协调标准，例如CEN/CENELEC（附录Za 基本原则）
- Country-specific standards
- 特定国家标准
- Country-specific mirror adoptions of international standards
- 国际标准在特定国家的镜像应用
- Industry standards
- 行业标准
- Government-unique standards
- 政府特有的标准

Center for Devices and Radiological Health (CDRH)Mission
器械与放射健康中心（CDRH）的使命

- Protect and promote the public health
- 保护和促进公共健康
- Patients and providers have timely & continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products.
- 患者和医疗服务提供者能够及时和持续地获得安全、有效和高质量的医疗器械和安全的射线产品。
- Facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.
- 通过以下手段促进医疗器械创新：推进监管科学，为行业提供可预测、一致、透明和有效的监管途径，并确保消费者对在美国销售的器械的信任

CDRH Standards Involvement
CDRH标准构成

- 660+ Committees and Working Groups
- 660+委员会和工作小组
- 350+ Employees
- 350+职员
- 1255 Recognized Standards
- 1255个公认标准
- 758 International Standards
- 758个国际标准
- 19 Specialties
- 19个专业
- 47 Federal Register Notices
- 47个《联邦公报》通知

Priorities:
优先次序：

•How effective is the scope of the standard in addressing/mitigating a potential health hazard?

•标准的适用范围在解决/减轻潜在健康危害方面的有效性

•How useful is it in managing CDRH's workload?

•其在管理CDRH工作量方面的有用性

•What would be the consequences of non-participation?

•不参与的后果

Horizontal Device Standards
卧式器械标准

- Quality Management (e.g., ISO 13485)
- 质量管理（例如ISO 13485）
- Risk Management (e.g., ISO 14971)
- 风险管理（例如ISO 14971）
- General Safety & Design (e.g., AAMI HE75, IEC 62366, etc.)
- 一般安全与设计（例如AAMI HE75、IEC 62366等）
- Industrial Sterilization (e.g., ISO 11135, ISO 11137, etc.)
- 工业灭菌（例如ISO 11135、ISO 11137等）
- Aseptic Processing (e.g., ISO 13408 series)
- 无菌加工（例如ISO 13408 系列）
- Biological Evaluation (e.g., ISO 10993 series)
- 生物学评价（例如ISO 10993 系列）
- Electrical Safety (e.g., AAMI ES60601-1, etc.)
- 电气安全（例如AAMI ES60601-1等）
- Medical Device Software (e.g., IEC 62034, IEC 80001, etc.)
- 医疗器械软件（例如IEC 62034、IEC 80001等）
- Medical Device Connectors (e.g., ISO 80369, etc.)
- 医疗器械连接件（例如ISO 80369 等）
- MRI Safety (e.g., ASTM F2503, ASTM F2052, ISO/TS 10974, etc.)
- MRI安全（例如ASTM F2503、ASTM F2052、ISO/TS 10974等）

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Vertical Device Standards
立式器械标准

- Medical devices for therapy & surgery (e.g., ESUs, etc.)
- 治疗和手术用医疗器械（例如ESU等）
- Patient monitoring (e.g., ECG, blood pressure, oximetry, etc.)
- 患者监测（例如ECG、血压、血氧测量等）
- Protective barriers (e.g., gloves, gowns, drapes, masks, etc.)
- 防护措施（例如手套、隔离衣、消毒被单、口罩等）
- Dialysis equipment (e.g., dialyzers, water for dialysis, etc.)
- 透析设备（例如透析器、透析用水等）
- Cardiovascular implants (e.g., heart valves, pacemakers, etc.)
- 心血管植入物（例如心脏瓣膜、起搏器等）
- Transfusion, infusion and injection devices
- 输血、输液和注射器械
- Hip, knee, joint implants
- 髋关节、膝关节、关节植入物
- Cochlear implants
- 耳蜗植入物
- Intraocular implants
- 眼内植入物

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Guidance for Industry and Food and Drug Administration Staff
行业和食品和药品管理局工作人员指南

Contains Nonbinding Recommendations
包含不具约束力的建议

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices
自愿性共识标准在医疗器械上市前申报中的合理使用
Guidance for Industry and Food and Drug Administration Staff
行业和食品和药品管理局工作人员指南

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本文件草案发布日期：2014年5月13日

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IV. Use of Consensus Standards in Premarket Process
IV. 共识标准在上市前流程中的应用

- Declaration of Conformity
- 符合性声明
  - Section 514(c)(1)(B) of FD&C Act
  - 《药品和化妆品法案》第514(c)(1)(B) 节
- General Use
- 一般应用

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IV. A. Use of Declaration of Conformity (DOC)
IV.A 符合性声明（DOC）的应用

- Purpose is to declare conformance with a consensus standard the FDA has recognized to meet certain premarket requirements.
- 目的是声明符合FDA认可的共识标准，满足特定的上市前要求。
- Manufacturer has met consensus standard at time of submission.
- 制造商在申报时已符合共识标准。
- DOC elements consistent with ISO/IEC 17050-a and ISO 17050-2
- DOC内容与ISO/IEC 17050-a和ISO 17050-2一致

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IV. A. Use of Declaration of Conformity (DOC)
IV. A. 符合性声明（DOC）的使用

Type of Consensus Standard for which a DOC might be provided in a premarket submission **可能在上市前申报中提供的DOC的共识标准类型**		**Should submission include complete test report?** **申报中是否应包含完整的测试报告?**	**Should submission include supplemental documentation per ISO/IEC 17050-2?** **根据 ISO/IEC 17050-2，申报中是否应包含补充文件?**
Design Standard 设计标准		No否	No否
Standard Includes标准包括— *Test Method(s) or Procedure(s)* *测试方法或程序*	*Acceptance Criteria* *可接受标准*		
Included 包含	Not included 不包含	No否	Yes, criteria/summary results 是，标准/汇总结果
Not included 不包含	Included 包含	No否	Yes是
Included 包含	Included 包含	No否	No是
Not included 不包含	Not Included 不包含	Yes是	Yes, complete test report 是，完整的测试报告

What if my device is not included in scope of a consensus standard?
器械不包含在共识标准的适用范围内时的应对措施

•Submitter should explain why standard is appropriate for device in question
•申报提交人应解释标准适用于相关器械的原因

•In most circumstances, the scope of the standard defines what is to be tested
•在大多数情况下，标准的适用范围规定了要测试的内容

•FDA recommends testing on “Finished device”
•FDA建议对“成品器械”进行测试

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Who is required to test my device?
由谁对我的器械进行测试？

- The submitter may base a DOC on testing and analysis performed;
- 提交人可根据所执行的检测和分析出具一份DOC：
  - In-house; or
  - 内部；或
  - Third party, e.g. testing lab or certification body.
  - 第三方，例如检测实验室或认证机构。
- If using a third party, please include name and address of each testing laboratory or certification body.
- 如采用第三方，请给出每个检测实验室或认证机构的名称和地址。

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Elements of a Declaration of Conformity (DOC)
符合性声明（DOC）的内容

- Format described in ISO/IEC 17050-1 *Conformity Assessment – Supplier's declaration of conformity – Part 1: General requirements.*
- *格式要求参见ISO/IEC 17050-1符合性评估 – 供应商符合性声明 – 第1部分：一般要求。*
- Examples include:
- 示例包括：
  - Name and address of applicant/sponsor responsible for DOC
  - 负责DOC的申请人/发起人的名称和地址
  - Product/device identification, e.g. product codes
  - 产品/器械标识，例如产品代码
  - Statement of conformity
  - 符合声明书
  - A list of standards for which the DOC applies
  - DOC适用的标准清单

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Elements of DOC (cont.)
DOC的内容（续）

- The FDA recognition number for each standard
- 每个标准的FDA识别码
- The date and place of issuance of the DOC
- DOC的发布日期和地点
- Signature, printed name, and function of the sponsor responsible for the DOC
- 负责DOC的发起人的签名、打印姓名和职能
- Any limitation on the validity of the DOC
- DOC有效性的限制

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Supplemental Documentation
补充文件

- Not all consensus standards recognized by the FDA are appropriate for DOC without supporting documentation
- 并不是所有获得FDA认可的共识标准均适用于没有支持文件的DOC
- Consensus standard may satisfy only a portion of premarket submission
- 共识标准可能仅满足部分上市前申报
- Consensus standard is too general and broad in scope
- 共识标准范围过于笼统和宽泛
- ISO/IEC 17050-2 *Part 2: Supporting Documentation*
- ISO/IEC 17050-2 *第2部分：支持文件*

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FDA Review of DOC and Supplemental Documentation
FDA对DOC和补充文件的评审

- The elements of ISO/IEC 17050-1, or equivalent, of a DOC are present;
- 包含ISO/IEC 17050-1的内容，或DOC的同等内容；
- DOC has (have) a recognition number;
- DOC有识别码；
- No deviations made to consensus standard(s);
- 共识标准无偏差；
- Consensus standard(s) is (are) applicable to the medical device
- 共识标准适用于医疗器械

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FDA Review (cont.)
FDA评审（续）

- The supportive documentation, if determined to be necessary, is provided as per ISO/IEC 17050-2 or equivalent;
- 如确定必要，根据ISO/IEC 17050-2或同等标准提供支持性文件；
- Data or information is submitted to support DOC; and
- 提交数据或信息以支持DOC；以及
- DOC does NOT include a promissory statement.
- DOC不包括承诺性声明。

IV. B. General Use of Consensus Standards
IV.B 共识标准的一般应用

- General Use of Consensus Standards, submitter conforms to standard in part or in whole;
- 共识标准的一般应用，提交人符合部分或全部标准；
- Submitter does NOT submit a DOC, examples:
- 提交人未成功提交DOC，示例：
  - Chooses not to submit DOC
  - 选择不提交DOC
  - Submitter made changes to methodology
  - 提交人更改了方法
  - Using consensus standard without recognition number
  - 使用无识别码的共识标准

General Use of Consensus Standards
共识标准的一般应用

- When citing general use we recommend the basis of such use be included with underlying information or data that supports how the standard was used
- 在引用一般应用时，我们建议提供此类应用的依据，包括支持如何使用该标准的基本信息或数据

Transition Period
过渡期

- When Standards Change Prior to Review of a Premarket Submission
- 在上市前申报评审前，标准发生变化时
- When Standards Change During Active Review of a Premarket Submission
- 在上市前申报审查过程中，标准发生变化时
- Transition Period Expiration
- 过渡期到期

Promissory Statement
承诺性声明

- Statement that device is not yet known to be in conformance with consensus standard
- 尚不知晓器械是否符合共识标准的声明
- FDA believes the use of promissory statement indicating future conformance is NOT appropriate
- FDA认为，使用暗示未来符合性的承诺性声明是不合适的
- FDA expects the conformance to consensus standard prior to premarket submission
- FDA要求在上市前申报提交前符合共识标准

Other Factors to Consider
需要考虑的其他因素

- Limitations of Consensus Standards
- 共识标准的局限性
  - Specific device may raise issues not addressed by consensus standard
  - 特定器械可能会产生共识标准未涉及的问题
  - May require animal testing or clinical study
  - 可能需要动物试验或临床研究

- When Devices or Standards Change After Marketing Authorization
- 如器械或标准在上市许可后变更
  - Changes do NOT retroactively affect a product's clearance or approval
  - 变更不会反过来影响产品的许可或批准
  - FDA actively assesses the impact of changes
  - FDA主动评估变更的影响

Internet Resources
网络资源

- National Institute of Standards and Technology:
- 国家标准与技术研究院：
- https://www.nist.gov/standardsgov

- CDRH Standards Program:
- CDRH标准项目：
- https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

- FDA Standards Database:
- FDA标准数据库：
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

- Device Advice: Comprehensive Regulatory Assistance:
- 器械建议：综合监管协助：
- www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

- CDRH Learn:
- CDRH学习
- https://www.fda.gov/Training/CDRHLearn/default.htm

- FDA SMG 9100.1:
- https://www.fda.gov/aboutfda/reportsmanualsforms/staffmanualguides/ucm193332.htm

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Contact Information
联系方式

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Optimizing Standards for Regulatory Use
IMDRF Technical Document

National Institutes for Food and Drug Control
(Institute for Medical Device Standardization Administration,
National Medical Products Administration)
Zheng Jia
March 15, 2019

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I. IMDRF Profile

➢Formally established in 2011, the International Medical Device Regulators Forum (IMDRF) is now the most important cooperative association in the field of international medical device regulation. Its main objective is to accelerate international medical device regulatory harmonization, promote the establishment of a high-efficiency and convenient medical device regulation mode and accordingly protect public health and safety to the greatest extent:

- Including China, IMDRF now has 10 full member states.
- By establishing research working groups in hot fields in which regulators of all member states are interested and developing and publishing IMDRF guideline documents, IMDRF guides and stimulates the global regulatory convergence.
- By far, it has published 26 Technical documents and 17 Information documents.

II. IMDRF Standards Working Group Profile

In March 2016, IMDRF Management Committee approved the establishment of "International Standards Research Working Group", which aims to investigate how to enable international standards to better satisfy regulatory demands:

1. International standards play a very important role in promoting global medical device regulatory synergy
2. International standards jointly recognized by regulators of member states only account for a small percentage. Great difference exists between different states.
3. The transformation of international standards from "index measurement" to "risk analysis" brings challenges and impacts to the regulatory systems of member states

- The convener is Scott Colburn from the US FDA.
- The working group has totally 21 full members:
  - Representatives of 10 countries, namely China, Germany, USA, Canada, Russia, Brazil, Japan, Singapore, Korea and Australia
  - Representatives of EU and WTO
  - Representatives of medical device industry associations, DITTA and GMTA

- Overall objective: to improve international standards

Phase III (March 2018 to September 2019)
- ✓ Update the list of IMDRF international standards
- ✓ Analyze the policies on the recognition of standards and technological disparity of member states

Phase II (Deferment was approved in September 2017. October 2017 to September 2019)
- ✓ Compile IMDRF technical document *Optimizing Standards for Regulatory Use;*
- ✓ Facilitate the signature of memorandum of understanding between IMDRF and IEC/ISO;

Phase I (March 2016 to September 2017)
- ✓ Summarize main problems of international standards;
- ✓ Investigate regulators of member states for their degree of involvement in international standards
- ✓ Discuss with IEC/ISO and put forward possible improvement measures

III. Main Achievements

(1) Summarize common problems encountered by regulators during the adoption of international standards and involvement in international standardization:

01 Except for FDA, in other states, only a small percentage of supervisors are IEC/ISO registered experts

02 Regulators have no obvious influence in the voting for international standards

03 Process documentation of international standards cannot be effectively obtained and traced

04 The introduction of risk analysis into international standards makes it hard to unify the standards of supervision

05 The requirements and test methods of some international standards are not clearly defined

06 Some international standards use obscure language and tend to cause ambiguity

(2) In November 2018, IMDRF technical document *Optimizing Standards for Regulatory Use* (IMDRF/Standards WG/N51 FINAL:2018) was officially published:

(3) Cooperation with the International Organization for Standardization

- IMDRF signed memorandum understanding between ISO/TC210 and IEC/TC62
- Act as Grade A Liaison Man

1 Exchange visits of representatives to attend high-level meetings and to take part in the drafting of important policy documents

2 IEC/ISO provides information about forthcoming international standards meetings

3 Adequately consult IMDRF before approving the project proposal of international standards

4 IMDRF is entitled to obtain relevant working documents and draft standards of IEC/TC62 and ISO/TC210

5 IMDRF is entitled to send representatives to take part in the activities of IEC/ISO technical committees and working groups

IV. Basic Information about IMDRF New Projects

- In March 2018, the project proposal of *Update the List of International Standards Recognized by IMDRF* made by China was approved with unanimous approval of IMDRF Management Committee.

Recognition of Standards

Update the list of international standards recognized by IMDRF and member states' recognition and adoption of such standards

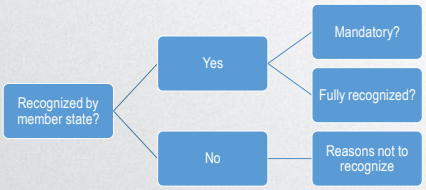
Similarities and differences of different IMDRF member states in the recognition of international standards

Compare and analyze policies on the recognition and adoption of standards implemented by medical device regulators of different member states

Recognition Policies

- Issued questionnaires to IMDRF member states to investigate how their medical device regulators adopt standards:

- Update the list of recognized standards by IMDRF, including 1,069 standards from 75 IEC and ISO technical committees and branch technical committees



➢ In total, 10 member states and 2 non-member states Indonesia and New Caledonia gave feedback:

V. Preliminary Survey Result of New Project

➢ Policies on the recognition of standards of member states

- 11 states have official procedures for the recognition of standards (except Brazil)
- 8 states have independent standards management departments

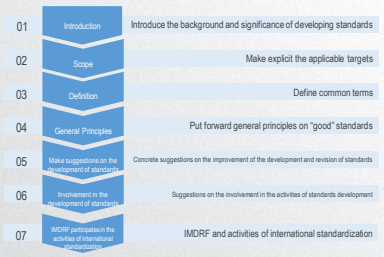
- 11 states have developed relevant regulations and directives on medical devices (except Canada)
- Stipulate that manufacturers should or can use medical device standards to prove its compliance with regulations

10 states have mandatory standards (except Australia and Russia)

- 10 states make the list of recognized standards available to the public for free (except Brazil and New Caledonia)

CONTENTS

I. Overall Structure



II. Background

➢ IMDRF has reached the consensus below:

- Standards developed on international consensus are based on science, technologies and experiences and reflect the best experiences in relevant fields as a whole.
- Relying on standards developed on international consensus is the key factor to establish and perfect regulatory system

Accelerate international medical device regulatory convergence

➢ However, regulators of member states discover that: the development direction of standards is now weakening its role in regulation and supervision of medical devices

➢ IMDRF compiled the *Optimizing Standards for Regulatory Use*: make explicit suggestions to medical device regulators, standards developing organizations and other stakeholders to improve standards and to enhance the regulators' confidence in the adoption and evaluation of standards

To regulators

Attach importance to the supervision of the progress of science and practices

To manufacturers

The harmonization of standards will accelerate the product launching and promote international trade

To International Organization for Standardization

More standards will be adopted and promoted by the international community

To the public

Obtain safer and more effective medical devices and therapies

III. Definition

- Definition of consensus:

General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments.

Note 1: Consensus does not mean unanimity.

Note 2: source ISO/IEC Guide 2: 2004,1.7

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IV. Core Concepts

- IMDRF's expectation of "good" standards. Being "good" means it can be adopted by the regulators:

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V. General Principles of Developing "Good" Standards

(1) Meet one or several **basic principles of IMDRF:**

A The scope related to the standards corresponds to one or several basic principles of IMDRF

B The level required to be reached in the standards can objectively meet the requirements of relevant IMDRF basic principles

C There are specific methods and steps to test whether each requirement in the standards is met and specific indexes and inspection methods to evaluate the conformity

(2) Performance principles:

Some circumstances and products clearly reflect that it is necessary to define design requirements (such as interoperability), but considerations shall be given to the performance principle instead of the designing characteristic of specific devices to the greatest extent to stimulate the development of innovative and healthy technologies.

Example: Table standards

Design requirements: a table should have four wooden legs.

Performance requirements: a table should remain stable despite of the impact of external forces.

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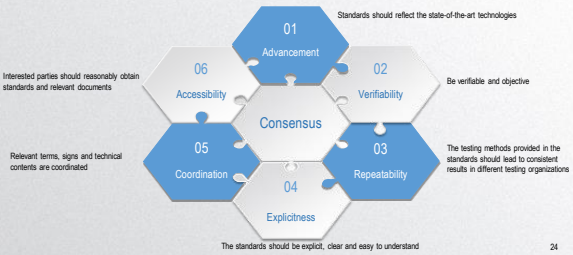
(3) While developing standards, follow the consensus process and consider interests of all stakeholders through consultation

(4) "Good" standards should also have the following features:



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VI. Specific Suggestions on the Improvement of Standards

(1) Totally 12 suggestions on the improvement of standards, mainly include four aspects:

Increase content
- Whether the increased range of application corresponds to a certain IMDRF basic principle and which one.
- Add appendix to compare the terms of standards with corresponding IMDRF basic principles.
- Add appendix to explain the requirements of standards and the principles of testing methods
- Add appendix to illustrate the difference between the old edition and new edition

Quantitative Requirements
- The requirements of standards should define the acceptance conditions in a quantitative way, including required clinical performance
- If there are no explicit acceptance conditions, define other methods to prove the conformity.

Feasible method
- Describe the testing methods in details to ensure the success and consistent results of tests

Exceptions
- Explain why some reasonable and predictable risks are not included in the standards
- When certain danger is clearly pointed out but no specific requirements on risk reduction are provided in the standards, guidance on how to properly dissolve such risks shall be provided.
- If the standards allow the declaration of conformity when certain acceptance condition or requirement is not met, explain why such acceptance condition is not mandatory.

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(2) For all key processes of the development of standards, make suggestions on the improvement of standards development:

- On each phase of standards development, the standards developing organizations should think over how relevant standards are used by regulators

1. Advanced research on project proposal
2. Seeking for opinions
3. Review
4. Training

- Conduct comprehensive analysis of demands for standards to avoid the development of unnecessary or hardly used standards for regulators;
- The evaluation of the effect of standards implementation shall be included to take into account the practicability of such standards in supervision.
- In the questionnaires for opinions, add information about the classification of opinions: besides general opinion, technical opinion and editing opinion, two additional categories shall be included, namely regulatory opinions and clinical opinions.
- Identification of regulatory opinions and clinical opinions will add perspectives of value to the development of standards.
- Attach importance to the information after product launching while revising the standards.
- Trace and evaluate the performance of relevant technologies after launching.
- Trainings on relevant standards and procedures of standards development shall be organized on a regular basis.

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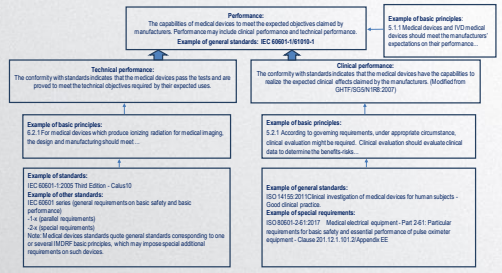
(3) Use standards to meet the IMDRF's basic principles of safety and effectiveness:



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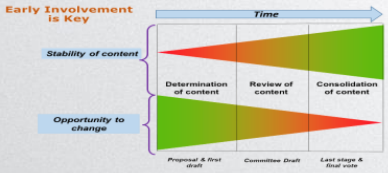
VII. Enhance Regulators' Involvement in Standardization Activities

- Establish professional standards management departments to effectively involve supervisors in international standardization activities
- Give effective feedback to enable their opinions to be better understood and adopted by drafters
- Early involvement in the development of international standards



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Conclusion

Optimizing Standards for Regulatory Use

Having passed through the procedures of in-depth discussions among IMDRF members states, seeking public opinions and reaching consensus, it conveys the appeals and expectations on international standards of regulators of all member states. Based on cooperation and collective commitment to use the consensus standards, it is expected that all standards developing organizations and medical and regulatory institutions will join hands in "enhancing the applicability of standards to regulators and improving regulators' effective involvement in all phases of standards development."

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谢 谢

THANK YOU

《优化医疗器械监管所用的标准》IMDRF技术文件

中国食品药品检定研究院
（国家药品监督管理局医疗器械标准管理中心）
郑佳
2019.3.15

CONTENTS

一、IMDRF概况

➢国际医疗器械监管机构论坛（IMDRF）于2011年正式成立，是目前国际医疗器械监管领域最重要的合作组织，其主要目标是从战略层面加速国际医疗器械的法规协调，促进建立高效、便捷的医疗器械监管模式，从而最大限度地保护公众健康和安全：

- 包括中国在内，IMDRF目前已有10个正式的成员国。
- 通过成立各成员国监管机构感兴趣的热点领域的研究工作组，制定并发布IMDRF指南文件，指导并促进全球监管趋同发展。
- 目前已发布26个技术文件（Technical document）和17个信息文件（Information document）。

二、IMDRF标准工作组概况

2016年3月，IMDRF管理委员会批准成立“国际标准研究工作组“，研究如何使国际标准更好地满足监管需求：

1. 国际标准对于推动全球医疗器械协同监管非常重要
2. 各国监管机构对国际标准的共同认可率偏低，且差异较大
3. 国际标准从“指标检测“转变”风险分析“，给各国监管带来挑战和冲击

➢ 召集人是美国FDA的思考特·科尔伯恩

➢ 工作组正式成员共计21人：

- 中国、德国、美国、加拿大、俄罗斯、巴西、日本、新加坡、韩国、澳大利亚等10个国家代表
- 欧盟和WHO代表
- DITTA和GMTA医疗器械行业协会代表

➢ 总体目标：改进国际标准以更好地为监管所用

第三阶段（2018年3月-2019年9月）
- ✓ 更新IMDRF国际标准清单；
- ✓ 分析各国认可标准的政策及技术差异。

第二阶段（2017年9月批准延期，2017年10月-2019年9月）
- ✓ 编写IMDRF技术文件《优化医疗器械监管所用的标准》；
- ✓ 推动IMDRF和IEC/ISO 签署合作备忘录；

第一阶段（2016年3月-2017年9月）
- ✓ 梳理国际标准的主要问题；
- ✓ 调查各国监管机构在国际标准的参与程度；
- ✓ 和IEC/ISO共同讨论，提出可能的改进措施。

三、主要工作成果

（一）梳理监管机构在采用国际标准和参与国际标准化活动碰到的共性问题：

01 除FDA，其他国家监管人员作为IEC/ISO注册专家总体比例偏低

02 监管机构在国际标准投票中的影响力不明显

03 国际标准过程文件无法有效获取和跟踪

04 国际标准中引入风险分析使监管尺度难于统一

05 部分国际标准的要求和试验方法不明确

06 部分国际标准使用语言晦涩难懂，容易引起歧义

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（二）2018年11月，IMDRF技术文件《提升医疗器械监管所用的标准》（IMDRF/Standards WG/N51 FINAL:2018）正式发布：

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（三）和国际标准化组织合作

- IMDRF和ISO/TC210、IEC/TC62签署合作备忘录
- 作为A级联络员

1 互派代表参加高层会议，参与重要政策文件起草

2 IEC/ISO提供即将召开国际标准会议的信息

3 国际标准立项前将充分征求IMDRF意见

4 IMDRF有权获取IEC/TC62、ISO/TC210的有关工作文件、标准草案等

5 IMDRF有权选派代表参加IEC/ISO技术委员会、工作组等活动

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四、IMDRF新项目基本情况

➢ 2018年3月，中国提出的《更新IMDRF认可国际标准清单》获IMDRF管委会一致通过，批准立项：

对比、分析各成员国医疗器械监管机构认可和使用标准的政策

认可政策

IMDRF各成员国认可国际标准异同

认可标准

更新IMDRF认可国际标准情况以及各国认可和使用情况

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➢ 向IMDRF成员国发放调查问卷，调研各国医疗器械监管如何使用标准：

监管部门是否有专门的标准管理部门？

是否接受公众提出的认可标准需求？

是否有标准认可程序？

是否有认可标准清单？是否公开？

符合性评价中标准的作用？

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➢ 更新IMDRF认可清单，包含1069个国际标准，来自75个IEC和ISO的技术委员会、分技术委员会

各国认可情况

认可

强制？

全部认可？

不认可

不认可的原因

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➢ 共10个成员国和印度尼西亚、新喀里多尼亚等2个非成员国反馈了意见:

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五、新项目初步调查结果

➢ 各国认可标准政策：

- 11个国家有官方的认可标准程序（除巴西）
- 8个有独立的标准管理部门

- 11个国家都已制定相关医疗器械法规指令（除加拿大）
- 规定制造商应该或可以使用医疗器械标准来证明符合法规要求

10个国家有强制性标准（除澳大利亚和俄罗斯）

- 10个国家向公众免费公开认可标准清单（除巴西、新喀里多尼亚）

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Part1/ IMDRF标准工作进展

Part2/ 优化医疗器械监管所用的标准

15

一、整体结构

01	简介	提出编制背景和意义
02	范围	明确适用的对象
03	定义	定义常用语
04	通用原则	提出“好”标准的通用原则
05	标准研制建议	改进标准制修订的具体建议
06	参与标准制定	参与标准制定活动的建议
07	IMDRF参与国际标准化活动	IMDRF和国际标准化活动

二、背景

➢ IMDRF拥有以下共识：

- 国际共识标准以科学、技术和经验为基础，总体上反映了相关领域的最佳经验
- 依靠共识标准是建立健全监管体系的关键因素

简化审评流程 提升效率 | 客观评价 安全有效性 | 建立有效对话

加速国际医疗器械监管趋同

➢ 但各国监管部门发现：标准发展方向正削弱其在医疗器械监管中发挥作用

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➢ IMDRF组织编写了《优化医疗器械监管所用的标准》：向医疗器械监管机构、标准制定组织以及其他利益相关方提出明确的建议，以提升标准质量，从而提升监管机构以及合格评定时使用标准的信心

对监管机构
将重视监管科学和实践的进步

对生产企业
标准协调一致将有助于加快产品上市并促进国际贸易

对国际标准化组织
更多地标准将被国际社会使用、推广

对公众
获得更安全有效的医疗器械和治疗方法

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三、定义

➢ 共识的定义：

普遍同意，其特征是任何重要的利益相关方不存在对实质性问题的持续反对，并通过一个程序寻求考虑各方意见并协调争论。

注1：共识并不意味着全体一致同意。

注2：来源自ISO/IEC 指南2:2004,1.7。

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四、核心思想

➢ IMDRF对“好”标准的期望，“好”即能为监管部门所用：

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五、研制“好”标准的通用原则

（一）应该满足一个或多个**IMDRF基本准则**：

A 标准涉及的范围与IMDRF一个或多个基本准则相对应

B 标准中所包含的需要达到的水平可以客观地满足相关IMDRF基本准则的要求

C 标准中每一项要求是否达到的测试方法和步骤是明确的，并有明确的符合性判定的指标和检验方法

（二）性能原则：

虽然某些情况和产品明显反映出有必要明确设计要求（例如互操作性），但尽可能考虑性能原则而非具体器械设计特征，以促进创新和健康的技术发展。

举例：‘桌子标准

设计要求：桌子应该有四条木质的腿。

性能要求：桌子在受到...外力冲击时仍保持稳定。

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（三）标准研制时，应遵循共识程序、协商考虑各相关方的利益：

（四）“好”标准还应当满足以下特点：

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六、提升标准质量的具体建议

（一）完善标准内容的建议共12条，主要内容包括四个方面：

增加内容
- 适用范围增加是否对应以及对应哪一条IMDRF基本准则。
- 增加附录，供标准条款和对应的IMDRF基本准则的对照表。
- 增加附录，对标准要求、试验方法的原理说明。
- 增加附录，说明新旧版本的差异。

定量要求
- 标准要求应尽可能以定量方式明确验收条件，包括需要规定的临床性能。
- 如果没有明确验收条件，则应明确用于证明符合性的其他方法。

方法可行
- 应对试验方法进行详细描述，以确保能成功地开展测试并得到一致的结果。

特例情况
- 说明部分合理可预见的风险没有包含在标准的原因。
- 当标准明确指出某种危险但却无法给出降低危险的具体要求时，标准应就如何适当解决由此产生的风险提供指导。
- 如果标准条款允许不符合某项验收条件或要求时仍能宣称符合性时，则应说明验收条件不是强制性的原因。

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（二）针对标准制定各个关键环节，提出完善标准制定程序的建议：

➢ 在标准制定的每一个阶段，标准制定组织应认真考虑标准如何为监管机构所用

1 预研立项 → 2 征求意见 → 3 复审 → 4 培训

- 对标准需求全面分析，避免起草监管部门不必要或几乎不用的标准。
- 还应包括标准实施影响的评估，明确考虑该标准对监管的实用性。
- 在征求意见表中加入关于意见分类的信息：除了对意见按通用、技术或编辑性进行分类外，意见表还应包括两个额外的意见分类，即来自监管或临床的意见。
- 识别出监管或临床所提的意见将为标准研制过程增加有价值的视角。
- 应在标准修订时重视产品上市后信息。
- 跟踪和评估相应技术上市后的表现。
- 应定期组织并提供有关标准和标准制定程序的培训。

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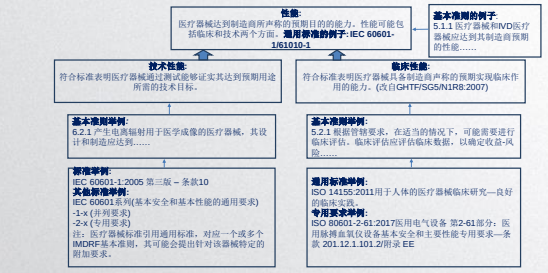
（三）用标准来满足IMDRF安全有效基本准则：



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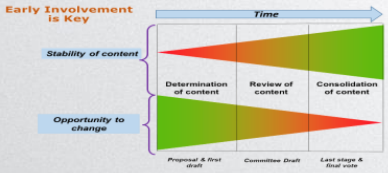
七、提升监管部门在标准化活动的参与度

➢成立专业的标准管理部门，有效组织监管人员参与国际标准化活动

➢有效反馈意见，以便意见能被起草人更好地理解和采纳

➢尽早参与国际标准制定工作



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结语

《优化医疗器械监管所用的标准》

经过了IMDRF各成员国深入讨论、公开征求意见、形成共识，传达了各国监管机构对国际标准的期望和诉求，通过合作以及对使用共识标准的集体承诺，希望各标准制定组织和医疗且监管机构合作推进，“提高标准对监管机构的适用性以及监管机构在标准制定各阶段的有效参与“

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谢 谢

THANK YOU

An Introduction:

American National Standards Institute
United States Standards System

ANSI
American National Standards Institute

Key Terms

- **Standards**
  - **Market-driven** product and service specifications (e.g., technical requirements, management systems, etc.)
- **Regulations**
  - **Mandatory** technical specifications, which may include particular standards or conformity assessment procedures
- **Conformity Assessment**
  - **Processes and systems** used to verify the compliance of a product, person, process or system to either a standard or a regulation (e.g., testing, certification)

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ANSI
American National Standards Institute

- **The American National Standards Institute leads standards, conformity assessment, and related activities in the United States of America.**
- Founded in 1918, ANSI is a private, non-profit organization.
- ANSI is not a government agency or a standards developer.

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ANSI
American National Standards Institute

- Represents U.S. globally
- Ensures integrity of the standards and conformity assessment system
- Offers neutral forum
- Accredits standards developers and conformity assessment organizations
- Coordinates partnership between U.S. public and private sectors

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ANSI
American National Standards Institute

- U.S. member of ISO
- U.S. member of the IEC, via ANSI's U.S. National Committee
- a U.S. member of IAF and ILAC
- member of regional forums in the Pacific Rim and the Americas
- liaison with groups in Europe, Africa and the Middle East
- bilateral agreements with other national standards bodies

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Snapshot: ANSI International, Regional, and Bilateral Activities

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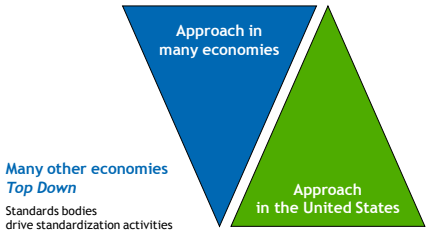
The ANSI Federation represents more than **125,000 companies and organizations** and **3.5 million professionals** worldwide

Members of the ANSI Federation include . . .

- Academia
- Individuals
- Government
- Manufacturing
- Trade Associations
- Professional Societies
- Service Organizations
- Standards Developers
- Consumer and Labor Interests
- and many more

U.S. Standards and Conformity Assessment System
comparison with many other economies



Many other economies
Top Down
Standards bodies drive standardization activities

United States
Bottom Up
Standards users drive standardization activities

U.S. Standards and Conformity Assessment System
comparison with many other economies

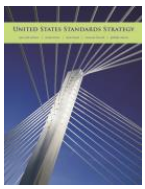
- Emphasizes private-sector **standards solutions**
- Relies on private-sector **compliance verification** for both regulatory and non-regulatory functions
- Provides a strong voice and greater authority to standards users and individual stakeholders

U.S. Standards and Conformity Assessment System
the public-private partnership

- No single government agency has control over standards
  - Each agency determines which standards meet its needs
- **National Technology Transfer and Advancement Act (NTTAA)** — Public Law 104-113
  - Encourages each government agency to seek existing private-sector standards that are appropriate for its purpose and mission

U.S. Standards and Conformity Assessment System
reliable – flexible – responsive

- Market driven
- Flexible and sector-based
- Industry-led and government-supported



This system is designed to . . .
- **Support** a broad range of stakeholder engagement
- **Address** emerging priorities and new technologies
- **Allow** stakeholders to find the solutions that best fit their respective needs

As defined in the *United States Standards Strategy*
www.us-standards-strategy.org

U.S. Standards System
a market driven approach

- In the U.S. alone, there are more than 100,000 standards
- These documents are being developed by:
  - standards developing organizations (SDOs)
  - over 500 consortia
  - thousands of committees
- Over 9,500 approved American National Standards

U.S. Standards System
guiding principles

- Standards should meet societal and market needs and should not be developed to act as barriers to trade
- The U.S. endorses the globally accepted standardization principles of the World Trade Organization Technical Barriers to Trade Agreement
  - Transparency
  - Openness
  - Impartiality
  - Effectiveness and relevance
  - Consensus
  - Performance-based
  - Coherence
  - Due process
  - Technical Assistance
  - Flexible
  - Timely
  - Balanced

WORLD TRADE ORGANIZATION

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U.S. Standards System
different tools for globally relevant standards

National Participation (one country one vote)	Direct Participation	Consortia
▪ Treaty Organizations ▪ Non-Treaty Organizations	▪ Nationally Accepted ▪ Internationally Accepted	
Examples ISO, IEC, ITU, CODEX, etc.	Examples ASTM International, ASME, SAE, etc.	Examples IGRS, W3C, etc.

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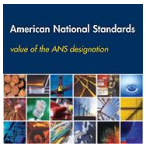
American National Standards (ANS)

- Currently there are approximately 225 ANSI-accredited standards developers
  - Not all standards developed by these organizations are submitted for consideration as ANS
- There are approximately 10,000 American National Standards
- Learn more: www.ansi.org/ansvalue



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U.S. Standardization System
examples of ANSI-accredited SDOs and U.S. TAGs

ASTM International	American Society of Mechanical Engineers	International Code Council
American Dental Association	National Electrical Manufacturers Association	National Fire Protection Association
SAE International Society of Automotive Engineers	IEEE Institute of Electrical and Electronics Engineers	Underwriters Laboratories Inc. Underwriters Laboratories Inc.
American Society of Civil Engineers	American Petroleum Institute	And more than 200 additional organizations

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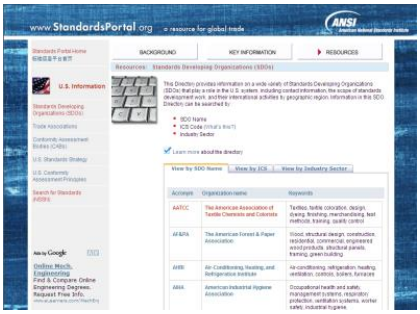
Getting Involved in U.S.-Based SDOs

Getting Involved in U.S.-Based SDOs (2)



U.S. Standards System

examples of roles and responsibilities

	ANSI	Standards Developers	Companies	Consumers	Government	NIST
Coordinates U.S. system and policy development	✓					
Independently runs standards development activities		✓				
Coordinates and monitors USG use of and participation in VCS activities						✓
Legal metrology and WTO-TBT enquiry point						✓
Provides technical input for standards development			✓	✓	✓	✓
Participates in U.S. policy development	✓	✓	✓	✓	✓	✓

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简介:

美国国家标准化机构
美国标准体系

ANSI
American National Standards Institute

关键词

- **标准**
  - **以市场为导向**的产品和服务规范
    (例如：技术要求，管理系统，等等)
- **法规**
  - **强制性**技术规范，可能包含特定标准或合格评定程序
- **合格评定**
  - 用来证明产品、人员、过程或系统符合标准或技术法规（例如测试，认证）等的**过程和系统**

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ANSI
American National Standards Institute

- **美国国家标准协会(ANSI)领导美国的标准、合格评定以及其它相关活动。**
- 成立于1918年，是私营非盈利机构。
- ANSI既不是政府机构，也不是标准制定机构。

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ANSI
American National Standards Institute

- 在全球代表美国
- 确保标准与合格评定系统的完整性
- 提供中立的平台
- 对标准制定机构与合格评定组织进行认可
- 协调美国政府与私营业界的合作

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ANSI
American National Standards Institute

- 代表美国参加ISO
- 通过ANSI全国委员会参加IEC
- 代表美国参加IAF 和ILAC
- 代表美国参加太平洋周边和每周地区性论坛
- 与欧洲、非洲和中东相关组织的联络人
- 负责与其他国家标准机构之间的双边协议

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Snapshot: ANSI International, Regional, and Bilateral Activities

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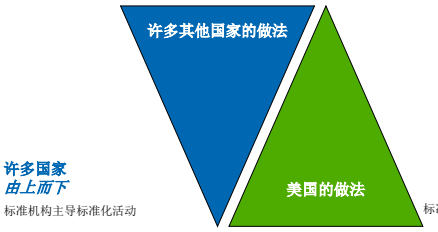
ANSI联盟代表**125,000 公司和组织**以及全球**350万专业人士。**

ANSI联盟包括 . . .

- 学术团体
- 个人
- 政府
- 制造商
- 行业协会
- 专业机构
- 服务性组织
- 标准制定机构
- 消费者及劳动者利益组织
- 其他

美国标准及合格评定系统
与其他国家之间的比较



许多国家
由上而下
标准机构主导标准化活动

美国
由下而上
标准使用者主导标准化活动

美国标准及合格评定系统
与其他国家之间的比较

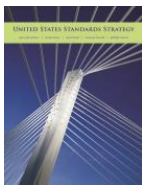
- 强调私营产业标准解决方案。
- 在监管与非监管方面，依靠私营产业**符合性验证。**
- 为标准使用者和个别利益相关方提供有力支持和更大的授权。

美国标准及合格评定系统
政府-私营产业之间的伙伴关系

- 没有任何一家政府机构能够控制标准
  - 每个政府机构确定哪些标准满足其要求。
- **《国家技术转让与促进法案》(NTTAA) –公共法104-113**
  - 鼓励每个政府部门从现有私营行业的标准中寻找适合其目的和宗旨的标准。

美国标准及合格评定系统
可信 - 灵活 - 及时

- 以市场为导向
- 灵活并且按Flexible and sector-based
- 行业领导，政府支持



这个体系是为了 . . .
- **支持广大利益相关方共同参与**
- **强调新出现的轻重缓急以及新的技术**
- **允许利益相关方探寻适合其需求的解决方案**

As defined in the *United States Standards Strategy*
www.us-standards-strategy.org

美国标准体系
以市场为导向

- 单在美国，有超过100,000个标准
- 这些标准由下列机构制定:
  - 标准制定机构(SDOs)
  - 500多个联盟
  - 数千个委员会
- 超过9,500被批准为美国国标。

美国标准体系
指导原则

- 标准应满足社会和市场需求而不应成为贸易的壁垒。
- 美国支持全球公认的世界贸易组织技术性贸易壁垒协定中的标准化原则
  - 透明
  - 公开
  - 无偏见
  - 有效相关
  - 协商一致
  - 以性能为基础
  - 一致性
  - 法律程序公正
  - 技术帮助
  - 灵活
  - 及时
  - 平衡

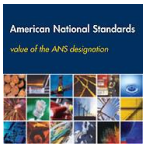
WORLD TRADE ORGANIZATION

美国标准系统
参与全球相关标准的不同工具

国家参与 (一国一票)	直接参与	联盟
▪ 公约组织 ▪ 非公约组织	▪ 国家认可 ▪ 国际认可	
例如 ISO, IEC, ITU, CODEX, etc.	例如 ASTM International, ASME, SAE, etc.	例如 IGRS, W3C, etc.

美国国家标准(ANS)

- 目前有约225个经ANSI认可的标准制定机构
  - 不是所有由这些标准制定机构制定的标准都申报美国国家标准。
- 目前大约有10,000多个美国标准。
- 欲知更多详情：www.ansi.org/ansvalue

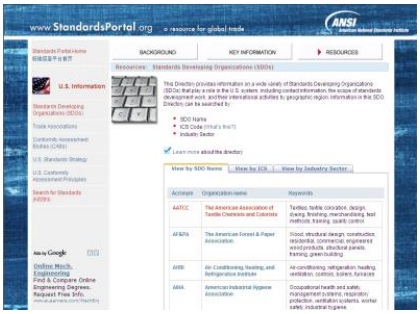


美国标准化系统
ANSI认可的部分标准制定机构和美国技术顾问小组

ASTM International	American Society of Mechanical Engineers	International Code Council
American Dental Association	National Electrical Manufacturers Association	National Fire Protection Association
SAE International Society of Automotive Engineers	IEEE Institute of Electrical and Electronics Engineers	Underwriters Laboratories Inc.
American Society of Civil Engineers	American Petroleum Institute	And more than 200 additional organizations

欲参与美国标准制定机构（1）

欲参与美国标准制定机构（2）



美国标准体系
角色与责任

	ANSI	SDO	公司	消费者	政府	NIST
协调美国的体系以及政策发展	✓					
独立开展标准制定工作		✓				
协调监督政府使用和参与自愿性规范活动						✓
法定计量以及 WTO-TBT 咨询点						✓
为标准制定提供技术建议和意见			✓	✓	✓	✓
参与美国政策发展	✓	✓	✓	✓	✓	✓

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International Best Practices: Conformity Assessment Testing

Yan Huaguo, Siemens Healthineers
2019-03-15, Beijing

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Conformity assessment testing

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Conformity assessment

- Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled

Note: The subject field of conformity assessment includes activities defined elsewhere in this International Standard, such as testing , inspection and certification, as well as the accreditation of conformity assessment bodies. (ISO/IEC17000:2004)

Conformity assessment testing

- Determination of one or more characteristics of an object of conformity assessment, according to a procedure
- An element of conformity assessment, also known as compliance testing, or type testing
- Testing or other activities that determine whether a process, product, or service complies with the requirements of a specification, technical standard, contract, or regulation.

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Conformity assessment testing and certification

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- **ILAC**
  International Laboratory Accreditation Cooperation
- **CB**
  Certification Bodies' Scheme
- **CCC**
  China Compulsory Certification
- **NRTL**
  Nationally Recognized Testing Laboratory
- **INMETRO**
  Itituto Nacioal de Metrologia, Qualidade e Tecologia
- **Others**

Note: IECEE -The IEC System for Conformity Testing and Certification of Electrical Equipment

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ILAC: International Laboratory Accreditation Cooperation

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Regional Accreditation Bodies signed mutual recognition agreement (MRA) which came in force on 31th January 2001:

APLAC	Asia Pacific Laboratory Accreditation Co-Operation
EA	European Co-Operation for Accreditation
IAAC	InterAmerican Accreditation Cooperation

ILCA Member:102 Accredited Body till Feb, 2019

CNAS	China National Accreditation Service for Conformity Assessment	CHINA, Peoples Republic of	
A2LA	American Association for Laboratory Accreditation	UNITED STATES OF AMERICA	
DAkkS	Deutsche Akkreditierungsstelle GmbH	GERMANY	

Accreditation is the independent evaluation of conformity assessment bodies against recognized standards to carry out specific activities to ensure their impartiality and competence.

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ILAC: International Laboratory Accreditation Cooperation

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The goal of ILAC：
1) Research laboratory accredited procedures and specifications
2) Promote the development of laboratory accreditation and promote international trade
3) Help developing countries establish laboratory accreditation systems
4) Promote mutual recognition of laboratories worldwide and avoid unnecessary duplication of reviews

Role of ILAC Mutual Recognition Arrangement (MRA):
By establishing a mutual peer review system, the ILAC forms an international multilateral mutual recognition mechanism and promotes the use of recognized laboratory results through multilateral agreements, thereby reducing technical barriers. As of March 2019, 100 laboratory accreditation bodies including China have become members of the ILAC and signed Mutual Recognition Arrangement to gradually end the history of repeated testing in international trade and realize products. The goal of “accredited once, accepted everywhere” has laid the foundation.

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Testing & Standard

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Example: Electrical Medical Devices Safety

IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance	
IEC 60601-1-X Collateral Standards*	Part 1-2: Electromagnetic Compatibility
	Part 1-3: Radiation Protection
	Part 1-6: Usability
	Part 1-8: Alarms
	Part 1-9: Environment
	Part 1-10: Physiological Closed-Loop Controllers
	Part 1-11: Home Healthcare Environment
IEC 60601-2-X Particular Standards	**Medical Electrical Equipment** **Part 2: Particular requirements for basic safety and essential performance** e.g. MR-, endoscopic-, ultrasonic equipment

- -1-1: Medical electrical systems and
- -1-4: Programmable medical electrical systems is integrated in IEC 60601-1 Ed.3

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Standards for Conformity Assessment Testing

IEC 60601-1

INTERNATIONAL STANDARD

GB

中华人民共和国国家标准

ANSI/AAMI ES60601-1:2005/(R)2012

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-1/A1

October 2013

CAN/CSA-C22.2 No. 60601-1:14

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Conformity Assessment Testing & Product Market Access

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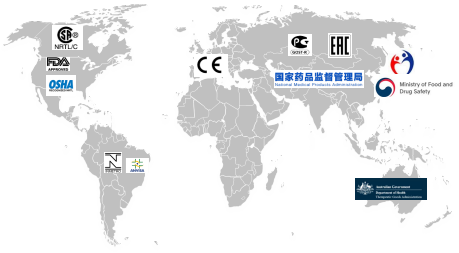
Market Access to Global Regions



Large diversity of legal requirements for market placement of medical products in different areas, but most of them are technically based on the IEC 60601-x-xx standard family

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Test report for approval in different Countries/Regions

- **North America (USA/Canada)**
  - → **NRTL 3rd party lab approvals with factory inspections**
    - → **CTL descriptive reports, submitted to UL, SCA, SGS or TÜV,…**
- **Brazil**
  - → **IMMETRO Certification**
    - → **ILAC* reports, submitted to IMMETRO certified labs, e.g. SGS, TÜV Rheinland, TÜV SÜD … with factory inspections**
- **China**
  - → **NMPA approval**
    - → **With NMPA recognized 3rd party labs such as LMTI, CMTC**

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Test report for approval in different Countries/Regions

- **Korea**
  - → **Recognition by Kolas**
    - → **ILAC reports accepted, but on-site inspections needed**
    - → **Provision of CB* reports/certificates speeds up the approval process**
- **Rest of the World (Europe, Japan, MEA,…)**
  - → **Reports with ILAC accreditation sufficient**
    - → **Alternatively CB reports with 3rd party labs**

* The need for CB reports for Korea is not completely clarified and understood yet.

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Test report for approval in different Countries/Regions

Country/Region	Market Access Approve	Test report
China	NMPA	Test report by NMPA Recongized Testing Lab (eg, BIMT, CMTC, LMTI…)
USA	• FDA • OHSA NRTL	• No specific requirement for test report, ILAC reports highly accepted • NRTL test report and certification
Canada	• Health Canada • SCC	• No specific requirement for test report, ILAC reports highly accepted • NRTL test report and certification
EU	CE	No specific requirement for test report, ILAC report highly accepted
Brazil	• ANVISA • INMETRO	• ILAC report or • CB report (CTF Level 3&4 not acceptable)
Japan	PMDA	ILAC report
Korea	KFDA	ILAC report or CB report
Rest of the world	-	ILAC reports accepted widely

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Summary of test report for market access

- **The ILAC report is very helpful and has been widely accepted**
- **NRTL reports and certificates are mandatory in the US/Canada**
- **CB report is helpful but not mandatory**

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Practice in Siemens Healthineers

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Standard application and Testing during design and development

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Product Engineering Process X-ray products

Angiography

*** C-arms**
*** Tube assembly**
*** Collimator**
*** Image detector**

*** Patient support**
*** User interface**

*** Display**

*** High voltage generator**
*** Image system**
*** System control**

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Standard application and Testing during design and development

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Product Engineering Process X-ray product

Typical components and their correspondence to standards

High voltage generator	**IEC 60601-1 / 60601-2-54**
Tube assembly	**IEC 60601-1 / 60601-1-3 / 60601-2-28**
C-arms / Basic Unit / Wall stand	**IEC 60601-1 / 60601-2-54**
Ceiling stand	**IEC 60601-1**
Collimator	**IEC 60601-1 / 60601-1-3 / 60601-2-28**
Image detector	**IEC 60601-1**
User interface	**IEC 60601-1**
Patient table	**IEC 60601-1**
Image system	**IEC 60950-1 / IEC 62368-1**
Display system	**IEC 60601-1**
X-ray Angiography System	IEC 60601-1 / 60601-1-2 /60601-1-3 / 60601-2-43 / 60601-2-54

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Standard application and Testing during design and development

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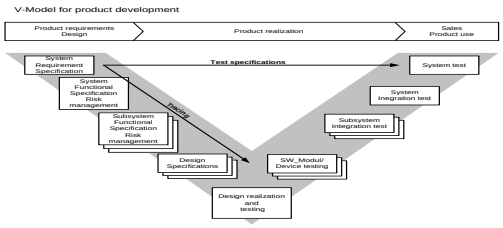
Product Engineering Process



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Standard application and Testing during design and development

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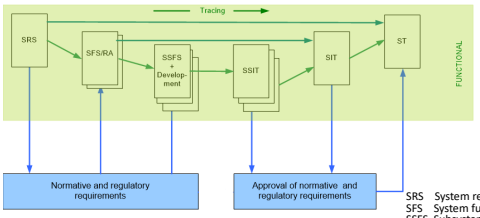
Product Engineering Process



SRS System requirements specification
SFS System functional specification
SSFS Subsystem functional specifications
SSIT Subsystem integration tests
SIT System integration test
ST System test

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Comformity Testing in Siemens Healthineers

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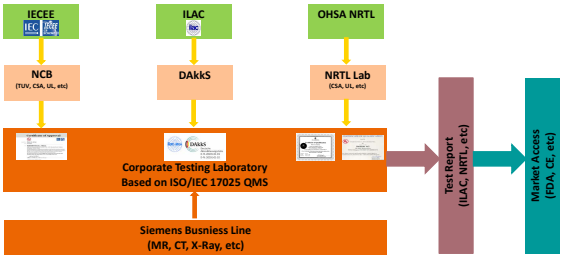

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Corporate Testing Laboratory – Creating test reports for worldwide market access

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Qualified personnel

Established Quality Management System according IEC 17025

Accepted in person by 3rd parties

Safety Standards	Equipment	Product Documentation	ILAC Test Reports	NRTL*-Product approval
• General standards • Collateral standards • Particular standards • National standards and deviations	• Equipment under test • Measuring equipment with extended calibration requirements • Test methods • Test sites within the laboratory or a customer site	Review for completeness and adequacy of accompanying documents like • Risk analyses • User manuals • Component certificates	• Electrical safety • Mechanical safety • Product-related radiation protection • Electromagnetic compatibility	• 3rd-party approval to serve the US- and Canadian market • Long-term cooperation's with 3rd parties like UL, CSA and TÜV PS

* NRTL – Nationally Recognized Testing Laboratories by United States Department of Labor Occupational Safety & Health Administration (OSHA)
** IE CEE – International Commission on the Rules for the Approval of Electrical Equipment

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Conclusion

the inspection reports could be the self-inspection reports of the registration applicants, or inspection reports issued by qualified medical device inspection institutions".

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Thank you!

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BACK UP

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Certification, Testing, Inspection

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Certification

Certification is the provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements. Certification is also known as third party conformity assessment.

Testing

Testing is the determination of one or more of an object or product's characteristics and is usually performed by a laboratory.
For example, many people have their blood tested which involves analysing the blood against a number of characteristics such as whether it shows the presence of a disease, or genetic disorder.

Inspection

Inspection describes the regular checking of a product to make sure it meets specified criteria.
Fire extinguishers, for example, need regular inspections to ensure they are safe for use.

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国际最佳实践: 合格评定检测

严华国, 西门子医疗系统有限公司
2019-03-15, 北京

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合格评定检测

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合格评定 (conformity assessment)

- 与产品（包括服务）、过程、体系、人员或机构有关的规定要求得到满足的证实。
  注：合格评定的专业领域包括**检测**、检查和认证，以及对合格评定机构的认可活动。（GB/T27000—2006，ISO/IEC17000:2004）

合格评定检测 (conformity assessment testing)

- 按照程序确定合格评定对象的一个或多个特性的活动。
- 合格评定(conformity assessment)的一个组成部分，也称为符合性检测(compliance testing), 或型式检测(type testing)。
- 确定其过程、产品或服务是否符合相应规范、技术标准、合同或法规的测试或其他活动。

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合格评定检测与认证

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- **ILAC**
  International Laboratory Accreditation Cooperation
  国际实验室认可合作组织
- **IECEE CB**
  Certification Bodies' Scheme 认证机构体系
- **CCC**
  China Compulsory Certification中国强制认证
- **NRTL**
  Nationally Recognized Testing Laboratory 国家认可实验室
- **INMETRO**
  Itituto Nacioal de Metrologia, Qualidade e Tecologia 巴西国家质量与技术检测局认证
- **其他机构**

注： IECEE: 国际电工委员会电工产品合格测试与认证组织

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ILAC: 国际实验室认可合作组织

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如下区域认可机构签署互认协议(MRA)，自2001年1月31日起生效:

APLAC	Asia Pacific Laboratory Accreditation Co-Operation 亚太实验室认可合作组织
EA	European Co-Operation for Accreditation 欧洲认可合作组织
IAAC	InterAmerican Accreditation Cooperation 泛美认可合作组织

ILCA 成员: 截止2019年2月，共有102家认可机构

CNAS — CHINA, Peoples Republic of — China National Accreditation Service for Conformity Assessment

A2LA — UNITED STATES OF AMERICA — American Association for Laboratory Accreditation

DAkkS — GERMANY — Deutsche Akkreditierungsstelle GmbH

认证是对符合性评定机构依据公认标准进行的独立评估，证明其执行特定活动的公正性和能力。

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ILAC: 国际实验室认可合作组织

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ILAC目标为：
1）研究实验室认可的程序和规范；
2）推动实验室认可的发展，促进国际贸易；
3）帮助发展中国家建立实验室认可体系；
4）促进世界范围的实验室互认，避免不必要的重复评审。

ILAC多边承认协议（MRA）作用：
ILAC通过建立相互同行评审制度，形成国际多边互认机制，并通过多边协议促进对认可的实验室结果的利用，从而减少技术壁垒。截止2019年3月，包括我国在内的100个实验室认可机构成为国际实验室认可合作组织的正式成员，并签署了多边互认协议，为逐步结束国际贸易中重复检测的历史，实现产品"一次检测、全球承认"的目标奠定了基础。

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检测与标准

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举例: 医用电气设备安全标准

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IEC 60601-1 医用电气设备 **第1部分:** 基本安全和基本性能的通用要求	
IEC 60601-1-X 并列标准*	-1-2部分: 电磁兼容性
	-1-3部分: 辐射防护 (X射线)
	-1-6部分: 可用性
	-1-8部分: 警报
	-1-9部分: 环境意识设计
	-1-10部分: 生理闭环控制器
	-1-11部分: 家庭卫生保健
IEC 60601-2-X 专用标准	**医用电气设备** **第2部分: 基本安全和基本性能的专用要求** 如: 磁共振, 内窥镜, 超声等设备

- -1-1部分: 医用电气系统以及-1-4部分: 可编程医用电气系统（PEMS）已经整合入IEC 60601-1第三版中(14,16章节)。

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合格评定检测标准

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IEC 60601-1

INTERNATIONAL STANDARD

中华人民共和国国家标准

ANSI/AAMI ES60601-1:2005/(R)2012

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-1/A1

October 2013

CAN/CSA-C22.2 No. 60601-1:14

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合格评定检测及产品市场准入

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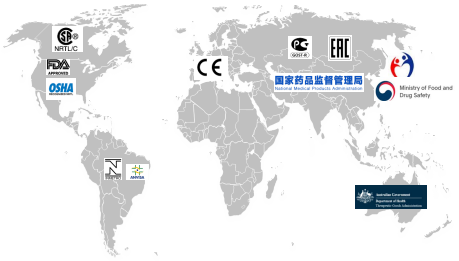
全球市场准入概况



医疗产品在不同地区市场投放的法律要求差异较大，但技术上大多是以IEC 60601-x-xx系列标准为基础的。

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不同国家与地区市场准入检测报告要求

- **北美区域 (美国/加拿大)**
  - → **取得第三方实验室NRTL (北美国家认可实验室)认可并完成工厂检查(Factory Inspections)。**
    - → **CTL撰写描述性报告，提交给UL, SCA, SGS或TÜV等机构,...**
- **巴西**
  - → **IMMETRO(巴西国家质量与技术检测局)证书**
    - → **ILAC(国际实验室认可合作组织) 认可报告提交至IMMETRO认证实验室, 如. SGS, TÜV 莱茵, TÜV SÜD ... 并完成工厂检查。**
- **中国**
  - → **国家药品监督管理局(NMPA)认可。**
    - → **NMPA认可的第三方实验室,如辽宁省医疗器械检验检测院(LMTI), 上海市医疗器械检测所(CMTC)。**

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不同国家与地区市场准入检测报告要求

- **韩国**
  - → **KOLAS(韩国校正·实验机关认证及机验机关认证机构)认可**
    - → **接受ILAC(国际实验室认可合作组织)认可报告，但另需现场检验。**
    - → **提供CB报告*/证书将加快了审批过程。**
- **世界其他地区(欧洲，日本，中东亚地区，...)**
  - → **ILAC(国际实验室认可合作组织)认可报告足够。**
    - → **或者提供第三方实验室的CB报告。**

* 韩国CB报告的必要性尚未完全澄清和理解。

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不同国家与地区市场准入检测报告要求

国家/地区	市场准入	检测报告
中国	国家药品监督管理局(NMPA)	国家药品监督管理局(NMPA)认可的测试实验室出具的检测报告(如北京市医疗器械检验所—BIMT, 上海市医疗器械检测所—CMTC, 辽宁省医疗器械检验检测院—LMTI...)。
美国	• 美国食品和药物管理局(FDA) • 北美国家认可实验室 (OHSA NRTL)	• 对检测报告无特殊要求，接受ILAC认可实验室测试报告 • 提供NRTL 检测报告及证书。
加拿大	• 加拿大健康局(Health Canada) • 加拿大标准委员会(SCC)	• 对检测报告无特殊要求，接受ILAC认可实验室测试报告 • 提供NRTL 检测报告及证书。
欧盟	CE认证	对检测报告无特殊要求，接受ILAC认可实验室测试报告。
巴西	• 巴西国家卫生监督局(ANVISA) • 巴西国家质量与技术检测局 (INMETRO)	• ILAC报告或 • CB 报告 (不接受客户测试设施—CTF等级 3和4)
日本	日本药品和医疗器械管理局 (PMDA)	ILAC认可实验室测试报告。
韩国	韩国食品药品管理局(KFDA)	接受ILAC认可实验室测试报告。 或CB报告
世界其他地区	-	ILAC报告广泛接受

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市场准入检测报告总结

- **ILAC 的报告非常有帮助，并已被广泛接受采纳**
- **NRTL 报告及证书在美国/加拿大被强制**
- **CB 报告有帮助，但非强制性**

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在西门子医疗Siemens Healthineers的实践

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设计和开发过程中的标准应用及测试

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X射线产品的产品工程过程

血管造影机

* C臂
* 射线管组件
* 准直器
* 影像侦测器

* 患者支架
* 用户界面

* 显示

* 高压发生器
* 影像系统
* 系统控制

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设计和开发过程中的标准应用及测试

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X射线产品的产品工程过程

典型组件及其所对应的标准

高压发生器	**IEC 60601-1 / 60601-2-54**
射线管组件	**IEC 60601-1 / 60601-1-3 / 60601-2-28**
C形臂	**IEC 60601-1 / 60601-2-54**
天花板支架	**IEC 60601-1**
准直器	**IEC 60601-1 / 60601-1-3 / 60601-2-28**
影像探测器	**IEC 60601-1**
用户界面	**IEC 60601-1**
病床	**IEC 60601-1**
影像系统	**IEC 60950-1 / IEC 62368-1**
显示系统	**IEC 60601-1**
X射线造影系统	IEC 60601-1 / 60601-1-2 /60601-1-3 / 60601-2-43 / 60601-2-54

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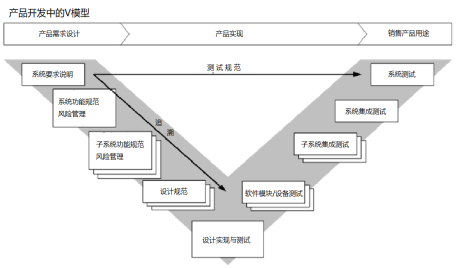
产品工程过程



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设计和开发过程中的标准应用及测试

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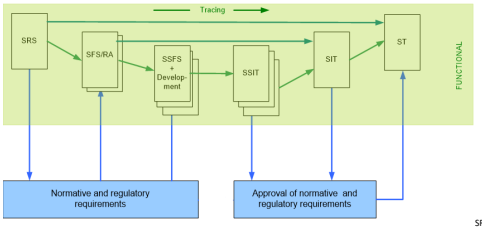
产品工程过程



SRS 系统要求说明
SFS 系统功能规范
SSFS 子系统功能规范
SSIT 子系统集成测试
SIT 系统集成测试
ST 系统测试

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西门子医疗符合性测试流程

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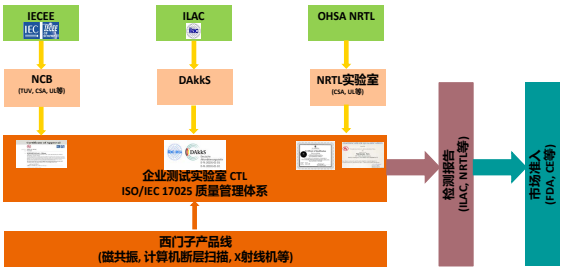

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公司测试实验室 CTL –为全球市场准入创建测试报告

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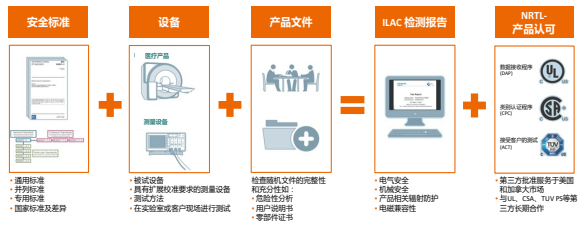
具备有资质的人员　基于IEC 17025建立质量管理体系　由第三方接受



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谢谢!

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备注

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认证, 检测及检验

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认证 Certification

认证是由一个独立的机构提供书面保证(证书)，证明所涉及的产品、服务或系统满足特定的要求。

认证又称第三方合格评定。

检测 Testing

测试是确定一个或多个对象或产品的特性，通常由实验室进行。

例如，许多人进行血液检测，这项检测包括分析血液的一些特征，如是否显示了一种疾病，或遗传性疾病。

检验 Inspection

检验是指定期对产品进行检查，以确保其符合规定的标准。

例如，灭火器需要定期检查以确保其使用安全。

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International Best Practices:

Mandatory Versus Voluntary Standards

Jamie Zhang

Senior RA Scientific Officer of Stryker

March 15th, 2019 Beijing

March 12, 2019

About *Me*

- Join in Stryker in the end of 2017.
- Integrate ***China Standard*** and company's ultimate goal of global design and manufacture.
- Work in ***Tianjin*** Medical Device Testing And Supervision Center for ***7 years***.
- Developed more than ***10*** Chinese Industrial medical device standards.
- ***Convenor*** of ISO/TC249/JWG6 and IEC/SC62D/JWG37.
- Developed ***two*** ISO International Standards.

Definition- Standard & **Mandatory** Standard & Technical **Regulations**

WTO-TBT Agreement

Standards Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is **not mandatory**. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method. ……Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. ……

Technical regulations Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which **compliance is mandatory**. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

11.4
mandatory standard
standard the application of which is made compulsory by virtue of a general law or **exclusive reference** in a **regulation**

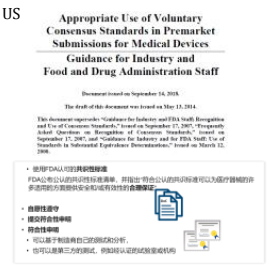
ISO/IEC Guide 2:2004
Standardization and related activities -- General vocabulary

Standard
document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

3

Application- ***Mandatory*** Standard And ***Voluntary*** Standard

US


Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices
Guidance for Industry and Food and Drug Administration Staff

China

Article 6
Medical devices shall meet the **mandatory national standard** or **mandatory industry standard** when there are no relevant mandatory national standard available.
Provisions of Supervision and Administration of Medical Devices (State Order No.680)
May.04,2017

Several clauses from ***Voluntary*** Standards are actually ***mandatory*** when they're referenced by ***mandatory*** standards.

4

Features of different way to apply standards

Feature	China	US
When need to be considered	Must be considered when the mandatory standard be implemented. Only can be reviewed and offer comments during drafting process.	Need to be considered only after recognized by FDA. At least have **two chances** to offer comments.
Mandatory/Voluntary	Mandatory for mandatory standard	Voluntary(Not mandatory)

Weakness of standard(No matter International Standard of National Standard)
- May not consider sufficient comments from different stakeholders
- Only consider current technology
- May have mistakes or unclear descriptions

5

Example- ***Not Considered*** All Technical Implementation Model

ISO 17510-2:2007

ISO 17510:2015

6

Example- *Unclear* Description

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YY 0607-2007(IEC 60601-2-10:1987,IDT)

IEC 60601-2-10:2016

Peak Value or Effective Value?

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Guarantee the product safe and effective when use the standard as voluntary

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Product Development Process

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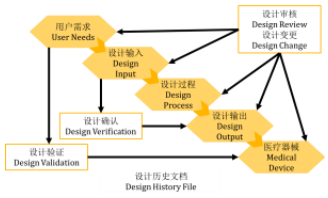
Product Development Process
Design control waterfall model



Basis for Stryker new product development process.

Based on the *FDA design control guidance for medical device manufacturers (11 March 1997)*

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Product Development Process
Stryker design control process

Voice of Customer / User Needs

Design Input

Design & Development

Design Transfer

Verification & Validation

Market Release

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Product Development Process
Project initiation

Internal or Externally initiated

- Clinical needs
- Market opportunities
- Business strategy

Externally initiated projects

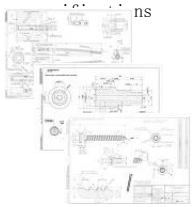
- Idea Management

Product Development Process
Voice of the customer

Gathering voice of the customer: surgeons, nurses, operating theatre staff, regulations…

Product Development Process
Design transfer

Translation of **design** specifications into **manufacturing** ns



Product Development Process
Traceability & change control

Product documentation

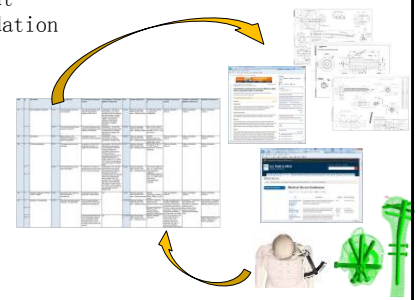
- DHF: Design History File
- DMR: Device Master Record

Change control process

Design input / output verification / validation (DIOVV)

Design input/output verification/validation
Aspects

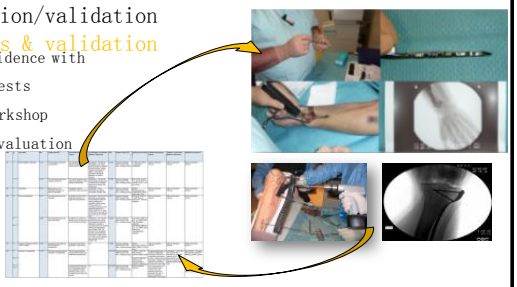
- Technical aspects
- Product benchmarking
  - Similar devices (same indication for use)
  - Predicate devices
- Intended use



Design input/output verification/validation
User needs & validation

Objective evidence with

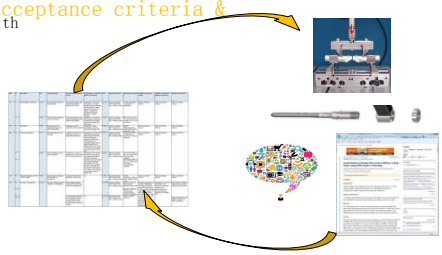
- Handling tests
- Cadaver Workshop
- Clinical evaluation



Design input/output verification/validation

Design input, acceptance criteria & Objective evidence with verification

- Literature
- Standards
- User feedback
- Benchmarking
- Test methods
- Interface analysis



Test Method Selection

Test Method Selection

How to select the right test methods

Test method references

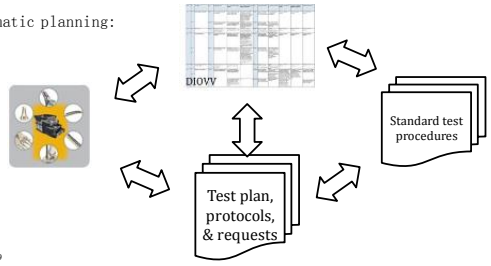
- Internal standard test procedures
- Standards (if suitable)
  - ISO, ASTM, ANSI/AAMI, GB, YY…
- Literature *
- Customized methods *

* e.g. if no suitable standard

Test Method Selection

Planning tools and test triggers

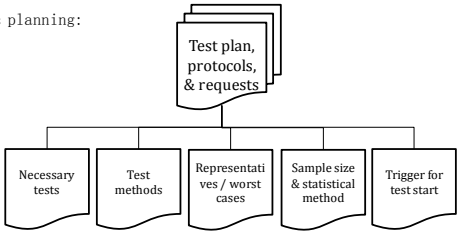
Systematic planning:



Test Method Selection

Planning tools and test triggers

Systematic planning:



Test Method Selection

Standards – limitations & alternatives

Standards (ASTM, ISO) and their limitations for mechanical testing

- May only apply to single components
- Usually do not define acceptance criteria
- May be suitable for «standardized» products
  - e.g. screws as specified in ASTM F543 or ISO 5835, 6475 & 9268
- May not be suitable for «non-standardized» products
  - e.g. screws different from ISO & ASTM specifications
  - e.g. plates that are not straight

Test Method Selection
Standards – limitations & alternatives

Alternatives

- Develop alternative test method
- Some standards mention appropriateness of using different test methods (see examples)
- "Predicate devices" may offer
  - Benchmarks as input for acceptance criteria
- Literature may offer
  - alternative methods (e.g. to consider anatomical situation)
  - input for acceptance criteria

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Test Method Selection
Standards – limitations & alternatives

Excerpts from **ASTM F543**-13e1 Standard Specification and Test Methods for Metallic Medical Bone Screws

- *«1.2 This specification provides performance … measuring mechanical properties in torsion of … bone. These test methods **may** also be applic… dimensions and tolerances are specified here.*
- *«1.5 Multiple test methods are included in this … user is **not** obligated to test using all of the de… **select** test methods that are **appropriate** for … a **subset** of the herein described test methods.»*

Excerpts from **ASTM F382**-14 Standard Specification and Test Method for Metallic Bone Plates

- *«1.3 This do… consider the… application.*
- *«1.6 Multipl… user is **not** o… **select** test … a **subset** of…*

Excerpts from **ASTM F382**-14 Standard Specification and Test Method for Metallic Bone Plates

- …
- *«X2.1.3 This test method is intended to evaluate the cyclic bending fatigue performance of the bone plate, and may not be appropriate for all situations. When the structurally critical region of the bone plate is shown to be located through a non-uniform region of the bone plate (i.e., a peri-prosthetic, contoured plate), it **may be necessary** to evaluate the cyclic bending fatigue performance of this region of the bone plate **using a different test method**. This is because it … o fit the non-uniform region between the loading rollers of a … critical regions may be identified through such methods as hand calculations, Finite … er interlocking features, or contoured regions, may be located at the proximal or … y result in structurally critical regions at these locations.»*

Excerpts from **ASTM F1264**-16 Standard Specification and Test Methods for Intramedullary Fixation Devices

- *«1.3 Multiple test methods are included in this standard. However, the user is **not** necessarily obligated to test using all of the described methods. Instead, the user should **only select**, with justification, test methods that are appropriate for a particular device design. This may be only a subset of the herein described test methods.»*

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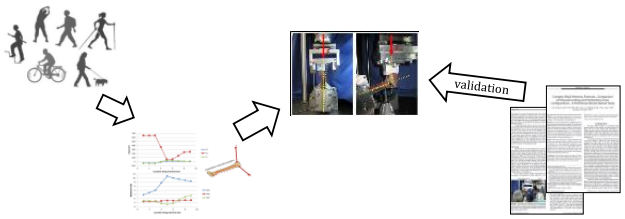
Test Method Selection
Literature based test setup development



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Test Method Selection
Component / assembly / construct

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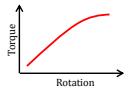
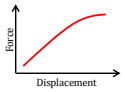
Test Method Selection
Static & dynamic loading

Static Torsion



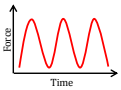
- torsional properties
- driving torque
- torsional yield strength
- maximum torque
- …

Static Force



- stiffness
- yield strength
- ultimate strength
- pullout forces
- …

Dynamic loading



- fatigue strength
- median fatigue limit
- cut-out behavior
- …

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Test Method Selection
Example: Fatigue testing

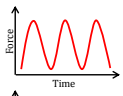
Static loading

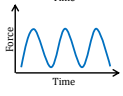
- static pre-test
- define start point for fatigue testing

input

input

Dynamic loading

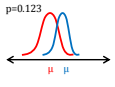




- test to failure
- estimate the *median fatigue limit*

input

Statistical analysis



- compare test groups
- significant different (y/n)

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Test Method Selection

Examples of typical verification tests

Screws	Plates	ExFix	Nails
• Insertion torque • Torsional properties • Pull-out	• Static pre-tests • Fatigue strength (components or constructs) • Locking screw / plate interface	• Components • Interfaces • Construct • Dynamic construct tests • Pin testing	• Static pre-tests • Fatigue strength • Screw / nail interface
Generic			
• Finite Element Analysis	• Biocompatibility • Reprocessing • Sterile Packaging		

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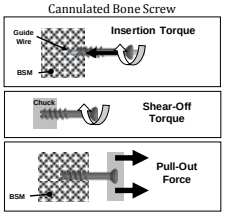
Test Method Selection

Verification test examples: Screws

Cannulated Bone Screw



BSM: Bone Simulation Material

4 point bending test of a nail locking screw

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Test Method Selection

Verification test examples: 4 point bending test

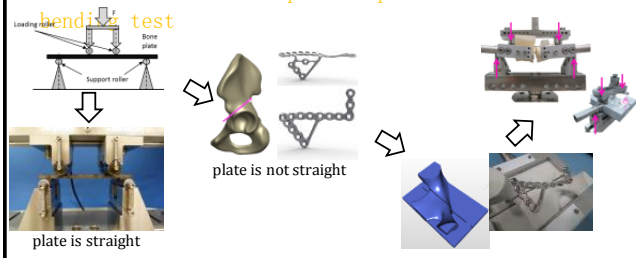

plate is not straight

plate is straight

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Representative Test Samples

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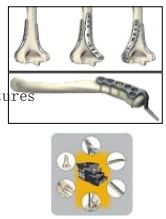
Representative Test Samples

Consider the whole system

- Considerations
  - E.g. same indications, but different **geometries**
  - E.g. same indications, but different **materials**
  - E.g. different **indications**, but same design features
  - E.g. a **whole** instrument set for one system



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Representative Test Samples

Relevance

- Relevance vs. test method
  - Device properties
  - Design features
  - Device geometry
  - Sterile vs non-sterile
- Relevance vs. specifications
  - Process with specified endpoint
- Relevance of existing data
  - Assessments on equivalence

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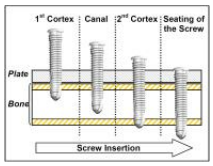
Representative Test Samples
Worst case

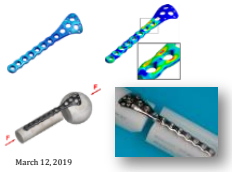
- May be representative for a whole device group
- Rest of the device group: at least as good as the worst case



Representative Test Samples
Worst case identification methods

- Drawings
- Screening tests (e.g. with prototypes)
- Calculations (e.g. finite element analysis)

} Verification testing with worst case samples



Excerpts from **ASTM F382**-14 Standard Specification and Test Method for Metallic Bone Plates

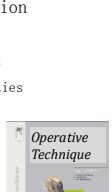
- «**AX.1.1** This test method … … test. *Structurally critical regions may be identified through such methods as hand calculations, Finite Element Analysis, etc. Screw holes or other interlocking features, or contoured regions, may be located at the proximal or distal extremities of a bone plate, and may result in structurally critical regions at these locations.*»

Verification Testing vs. Process Control

Verification testing vs. Process control
Design related

Verification / Validation

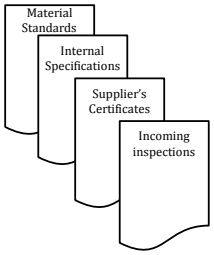
- Design verification
  - e.g. interface analysis
  - e.g. mechanical properties
- Clinical reprocessing
- Biocompatible materials
- Design validation
  - e.g. instructions



Verification testing vs. Process control
Process related

Raw material /
test for mixed-up materials

- Mechanical properties
- Chemistry
- Micro-structure
- Dimensions



Verification testing vs. Process control
Process related

Validated or controlled processes / process stability

- Machining (e.g. dimensions)
- Heat treatments (e.g. hardness)
- Surface finishing
- Final cleaning process
- Final inspection
- Clean room environment
- Sterile packaging

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Risk Management

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Risk Management
Hazard identification & risk evaluation

Identify

Potential hazards

- Foreseen
  (e.g. post market surveilance data on similar devices or literature)
- Unforeseen

Minimize the occurrence

- Design modifications

- Instructions / warnings

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Risk Management
Risk control & clinical evaluation

Clinical evaluation → Risk Control

Critical evaluation of

- relevant scientific literature
- results of clinical investigations
- a combination of both

- Clinical Evaluation
- Post Market Surveillance Plan

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Discussion about Mandatory Standard

Advantage	Disadvantage
Guarantee safe and effective of medical device	Restrictions on innovation
•Reduce the cost of the enterprise	•Not conducive to clear corporate responsibility
Improved approval efficiency	Increase government costs

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Discussion: How could be better

Same objective: To meet people's yearning for a healthy life.

limited field

quality

- More China standards adopt international standards
- More amendment of standard.
- Need foreign companies participate in standard drafting more actively.

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People's yearning for a better life is our goal

Thank you for your attention

You may now ask questions

国际最佳实践:

强制性标准与推荐性标准

张海明

史赛克　资深注册技术主管

2019年***3***月***15***日　北京

March 12, 2019

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关于 我

- 2017年底加入史赛克。
- 致力于整合中国标准与史赛克设计和生产的最终产品。
- 曾在天津市医疗器械质量监督检验中心工作 ***7***年。
- 参与起草了 ***10*** 余份中国医疗器械行业标准。
- 曾为ISO/TC249/JWG6 和IEC/SC62D/JWG37召集人。
- 起草了2份ISO国际标准。

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定义- 标准&强制性 标准& 技术法规

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WTO-TBT 协定

标准 经公认机构批准的、规定非强制执行的、供通用或重复使用的产品或相关加工和生产方法的规则、指南或特性的文件。该文件包括或专门规定用于产品、加工或生产方法的术语、符号、包装、标志或标签要求。在ISO/IEC 指南2中定义的标准可为强制性的也可为推荐性的。在本协定中，标准是推荐性的，技术法规是强制性的。

技术法规 强制执行的规定产品特性或其相应加工和生产方法，包括适用的管理规定的文件。技术法规也可以包括或专门规定用于产品、加工或生产方法的术语、符号、包装、标志或标签要求。

11.4
强制性标准
借助一般法律或法规的排他性引用，使标准在适用时具有强制性

ISO/IEC 指南 2:2004
标准化和相关活动的通用术语

标准：通过标准化活动，按照规定的程序经协商一致制定，为各种活动或其结果提供规则、指南或特性，供共同使用和重复使用的文件。——GB/T 2000.1-2014（与ISO/IEC Guide 2:2004 一致）

3

应用- 强制性 标准和 推荐性 标准

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美国

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

中国

第六条 医疗器械产品应当符合医疗器械强制性国家标准；尚无强制性国家标准的，应当符合医疗器械强制性行业标准。

国务院关于修改《医疗器械监督管理条例》的决定

2017年5月4日

很多推荐性标准中的条款由于被强制性标准引用也成为了事实上的强制性条款。

4

标准不同应用方法的特点

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特点	中国	美国
何时需要符合	• 强制性标准实施后必须符合 • 仅在标准制修订时可以反馈意见	• 仅在被FDA认可后才需要考虑符合 • 在标准制修订和FDA认可时均有机会提出意见
强制/推荐	强制性标准应强制	推荐性

标准的局限性 (无论是国际标准还是国家标准)

- 可能未考虑所有利益相关方的意见
- 仅考虑现存产品的情况
- 可能存在表述不清的情况

5

例子- 未考虑 所有的技术情况

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对于覆盖口部的面罩，应……

YY 0671.2-2011睡眠呼吸暂停治疗第2部分：面罩和应用附件(ISO 17510-2:2007, IDT)

ISO 17510:2015

注：对于仅覆盖鼻部的面罩，在单一故障下患者可以张开口部并正常呼吸。

6

例子- 容易引起歧义的表述

YY 0607-2007(IEC 60601-2-10:1987,IDT)

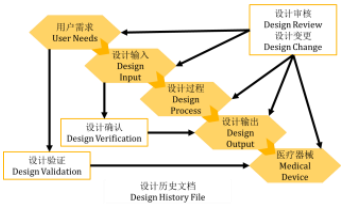
IEC 60601-2-10:2016

峰值还是有效值？

采用推荐性标准时如何保证产品的安全有效

产品开发流程

产品开发流程
设计控制瀑布模型



史赛克开发新产品流程的基础。

依据 FDA 医疗器械制造商的设计控制指南 (1997 年3月11日)

产品开发流程
史赛克设计控制流程

客户声音 / 用户需求

设计输入

设计 & 开发

设计实现

验证 & 确认

市场发布

产品开发流程
项目启动

内部或外部启动

- 临床需求
- 市场机会
- 商务策略

外部发起的项目

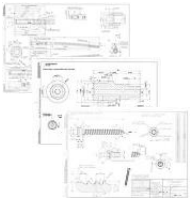
- 创意管理

产品开发流程
客户声音

获取客户的声音:外科医生、护士、手术室工作人员、法规.....

产品开发流程
设计实现

将设计规范转化为制造规范



产品开发流程
可追溯性与变更控制

产品文档

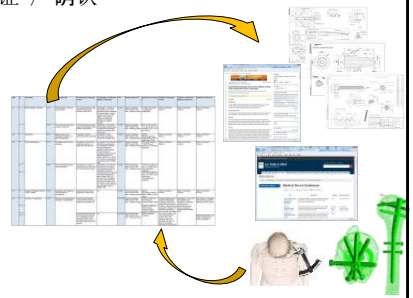
- DHF：设计历史文件
- DMR：设备主记录

变更控制流程

设计输入/输出 验证 / 确认 (DIOVV)

设计输入/ 输出 验证 / 确认
Aspects

- 技术特征
- 产品基准测试
  - 相似产品
    （相同的使用指示）
  - 已上市的同品种产品
- 预期用途



设计输入/ 输出 验证 / 确认
用户需求与验证

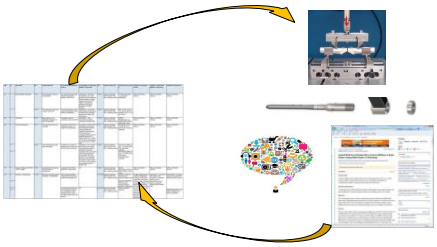
客观证据

- 具体试验
- 尸体实操
- 临床评价

设计输入/ 输出　验证 / 确认
设计输入，验收标准 & 验证

客观证据

- 文献
- 标准
- 用户反馈
- 基准测试
- 测试方法
- 界面分析



测试方法选择

测试方法选择
如何选择正确的测试方法

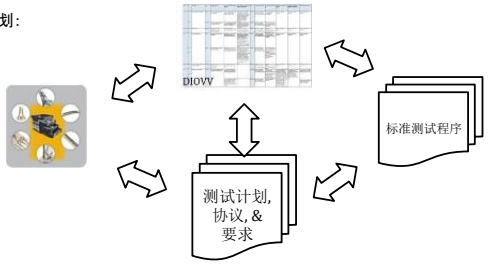
测试方法引用

- 内部标准测试程序
- 标准（若适用）
  - ISO, ASTM, ANSI/AAMI, GB, YY…
- 文献 *
- 定制的方法 *

* 例如：若无合适的标准

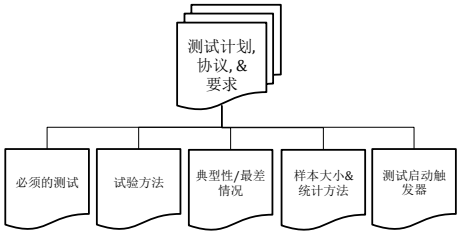
测试方法选择
计划工具和测试触发器

系统规划：



测试方法选择
计划工具和测试触发器

系统规划：



测试方法选择
标准-限制和可替代的选择

标准（ASTM, ISO）及他们在力学试验方面的限制

- 可能只应用于单个组件
- 通常不定义验收标准
- 可能仅适合“标准化”的产品
  - 如ASTM F543或ISO 5835, 6475和9268中规定的螺钉
- 可能不适用于“非标准化产品”
  - 例如：与ISO和ASTM规格不同的螺丝
  - 例如：非直型骨板

测试方法选择
标准–限制和选择

可替代的选择

- 开发替代测试方法
- 一些标准提到了使用不同测试方法的适当性（参见示例）
- “已上市的同品种产品” 可能提供
  - 基准测试作为验收标准的输入
- 文献可能提供
  - 可替代的方法（例如考虑解剖情况）
  - 验收标准的输入

测试方法选择
标准–限制和选择

摘自ASTM F543-13e1金属医用骨螺钉标准规范和试验方法

- «1.2本规范提供了用于测量植入骨[illegible]测试方法也可以适用于除这里规定[illegible]
- «1.3本标准包含多种测试方法。但是[illegible]户应该只选择适合于特定设备设计[illegible]集。»

摘自ASTM F382-14金属骨板标准规范和试验方法

- «1.3本文件可能不适用于所有类型的骨板，使用者被提醒考虑到特定的骨板及其潜在的应用标准的适当性。»
- «1.[illegible]用户[illegible]子集[illegible]
- …

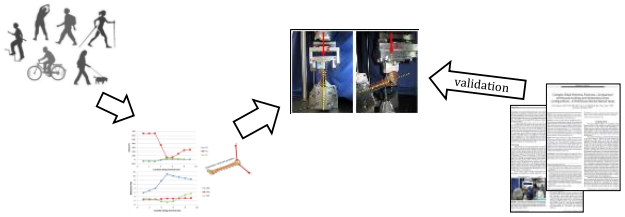
摘自ASTM F382-14金属骨板标准规范和试验方法

- …
- «A2.1.3本试验方法旨在评估骨板的循环弯曲疲劳性能，可能并不适用于所有情况，当骨板的结构临界区通过骨板的非均匀区域时，可能需要使用不同的测试方法来评估骨板这一区域的循环弯曲疲劳性能。这是因为在四点弯曲试验中，可能不可能在物理上拟合加载辊之间的不均匀区域，结构临界区可以通过手工计算、有限元分析等方法确定，螺钉孔或其他联锁特征，或轮廓区域，可能位于锤骨板的近端或远端，并可能导致这些位置的结构关键区域。»

ASTM F1264-16髓内固定装置标准规范和试验方法摘录

- «1.3本标准包含多种测试方法。但是，用户没有必要使用所有描述的方法进行测试。相反，用户应该只选择适合特定设备设计的测试方法，这可能只是本文描述的测试方法的一个子集。»

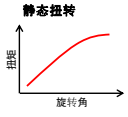
测试方法选择
基于文献的测试设置开发



测试方法选择
组件/组配/构建

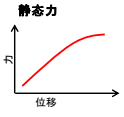
测试方法选择
静态 & 动态 加载

静态扭转



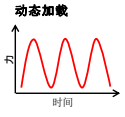
- 抗扭性能
- 驱动扭矩
- 扭转屈服强度
- 最大扭矩
- …

静态力



- 刚度
- 屈服强度
- 极限强度
- 拔出力
- …

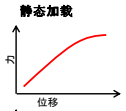
动态加载

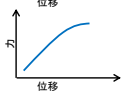


- 疲劳强度
- 中值疲劳极限
- 断裂特性
- …

测试方法选择
例子：疲劳试验

静态加载



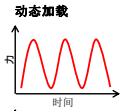


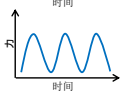
- 前置静态测试
- 定义疲劳试验的起点

输入

输入

动态加载

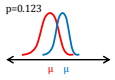




- 测试到失效
- 估计疲劳试验中值

输入

静态分析

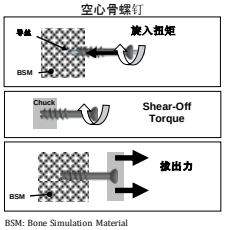


- 对比两组测试
- 显著的不同 (y/n)

测试方法选择
典型验证测试的例子

接骨螺钉	接骨板	外固定支架	髓内钉
• 旋入扭矩 • 抗扭特性 • 拉拔力	• 前置静态测试 • 疲劳强度(部件或构件) • 锁紧螺钉/板接口	• 组件 • 接口 • 构件 • 动态构造测试 • 销测试	• 前置静态测试 • 疲劳强度 • 螺钉/髓内钉界面
通用的			
• 有限元分析	• 生物相容性 • 再加工 • 无菌包装		

测试方法选择
验证测试例子：接骨螺钉



BSM: Bone Simulation Material

4点弯曲试验 a nail locking screw

测试方法选择
验证测试例子：4点弯曲试验

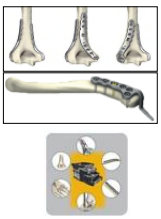
直型板

非直型板

代表性测试样品

代表性测试样品
考虑整个系统

- 考虑的点
  - 相同的适应症，但不同的几何形状
  - 相同的适应症，但不同的材料
  - 不同的适应症，但相同的设计特点
  - 一套完整的器械组成一个系统

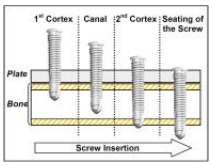


代表性测试样品
相关性

- 相关性 vs. 测试方法
  - 设备属性
  - 设计特点
  - 设备构形
  - 无菌vs 非无菌
- 相关性 vs. 规范
  - 具有特定终点的流程
- 与现有数据的相关性
  - 等效性评估

代表性测试样品
最差情况

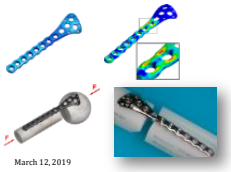
- 是否可以代表整个设备组
- 设备组的其他成员：至少和最坏的情况一样好



代表性测试样品
最坏情况识别方法

- 图纸
- 筛选测试（例如使用原型）
- 计算（如有限元分析）

用最坏情况样本进行验证测试



摘自ASTM F382-14金属骨板标准规范和试验方法

- ***A2.1.3这个测试方法……测试。结构临界区可以通过手工计算、有限元分析等方法确定。螺钉孔或其他获得特征，或轮廓区域，可能位于骨板的近端或远端，并可能导致这些位置的结构关键区域***

验证测试
vs.
流程控制

验证测试 vs. 流程控制
设计相关

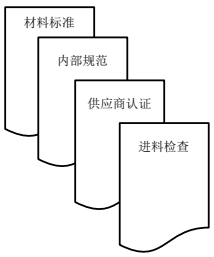
验证 / 确认

- 设计验证
  - 界面分析
  - 机械性能
- 临床后处理
- 生物相容性材料
- 设计验证
  - 说明

验证测试 vs. 流程控制
流程相关

原材料 /
混合材料试验

- 机械性能
- 化学性能
- 微观结构
- 尺寸



验证测试 vs. 流程控制
流程相关

验证或控制过程/过程稳定性

- 加工（如尺寸）
- 热处理（如硬度）
- 表面处理
- 最后的清洗过程
- 最后检查
- 洁净室环境
- 无菌包装

风险管理

风险管理
危险识别& 风险评估

识别

潜在危险

- 可预见的
  （类似设备或文献的市场调查后数据）
- 不可预见的

减少发生的可能性

- 设计变更

- 提示 / 警告

风险管理
风险控制 & 临床评估

临床评估

关键的评估

- 相关的科学文献
- 临床调查结果
- 两者的结合

风险控制

- 临床评价
- 后市场监察计划

关于 强制性 标准的讨论

优点	缺点
保障产品的安全有效	限制创新
•降低企业的开发成本	•不利于明确企业主体责任
增加审批效率	增加了政府财政负担

讨论: 如何可以 更好

监管方和企业的共同目标: 满足人民群众对健康生活的美好向往。

- 更多的中国标准采用国际标准。
- 更多的修标单保证及时更正标准。
- 也要求进口企业能够更积极的参与标准制修订工作。

Thank you for your attention

You may now ask questions

ISO standard development process
国际标准化组织标准制定流程

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Agenda议程

- About ISO
- How are standards developed
- Who develop the standards
- Code of Conduct
- ISO standard are voluntary
- Basic steps
- Revisions
- Implementations
- Enforcement
- Q&A

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- 标准制定方式
- 标准制定人员
- 行为准则
- ISO 标准具有自愿性
- 基本步骤
- 修订
- 执行
- 问答

About ISO ISO 简介

- ISO: International Organization for Standardization
- It is an independent, non governmental international organization with 164 national standards bodies[1].
- It develops voluntary, consensus based, market relevant international standards[1].
- Founded February 23rd 1947[1].
- Headquarter: Geneva Switzerland[1]
- 786 technical committees and subcommittees[1]
- Published over 22500 International Standards[1]

- ISO：国际标准化组织
- ISO 是一个独立的非政府国际组织，拥有 163 家国家标准机构
- ISO 制定了出于自愿、基于共识且与市场相关的国际标准。
- ISO 成立于1947年2月23日。
- 其总部位于瑞士日内瓦
- 拥有 786 个技术委员会及下属委员会
- 共发布了 22,500 余项国际标准

1. https://www.iso.org/about-us.html

How are standards developed标准制定方式

- ISO standards are developed in response to market needs[2].
  - ISO 594-1 (Luer connector) was published in 1986 and adopted by US syringe and IV catheter manufacturers as the standard for connectors. At the time Germany hospitals still uses Record connectors for their devices.
  - Emergency response to 1988 Ramstein Airbase airshow disaster was complicated by the incompatibility of IV devices on the US base and local hospital, which led to the development of ISO 10555-1 which adopted Luer connector as the standard for all IV devices in 1995.
  - However, adoption of Luer connector for enteral feeding, neuraxial, urethral and other devices over the last 20 years has led to some fatal medical errors due to misconnections. Consequently, ISO 80369 series were developed to specify different connector geometries for different applications, minimizing harmful misconnections.
- The standard is based on the opinions of the experts and their consensus[2].
  - When necessary, scientific research, engineering analysis, prototyping and testing are conducted to support the standard.

- ISO 标准根据市场需求予以制定。
  - ISO 594-1（鲁尔接头）发布于 1986 年，美国的注射器和静脉导管制造商们将该标准用作接头标准。在当时，德国医院的设备仍在使用Record接头。
  - 1988 年，拉姆斯泰因空军基地发生航展事故，因美军基地的静脉设备和当地医院的 静脉设备不兼容，致使事故的应急响应变得错综复杂。由此，ISO 于 1995 年制定了 ISO 10555-1，将鲁尔接头用作所有 静脉设备的标准。
  - 但近 20 年来，鲁尔接头在肠内喂养、神经轴、尿道等器械上的应用，导致了一些因错误连接而引发的致命医疗事故。因此，ISO 制定了 ISO 80369 系列标准，旨在为不同的应用指定不同的接头几何结构，从而最大限度地减少有害的误接。
- ISO标准基于专家们的意见和共识。
  - 必要时，应进行科学研究、工程分析、原型设计和测试，以支持该标准。

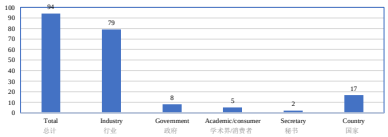
2. https://www.iso.org/developing-standards.html

Who develop the standard标准制定人员

- The new standard is usually delegated to some technical committee, which will in turn assign it to an exiting or new working group.
- The experts in a working group are recommended by national bodies.
  - Ensure wide background, experience, and perspectives
- They represent leading companies in the relevant industry, as well regulatory bodies, academia, and/or consumer groups.

- 新标准的制定任务通常会委托给某一个技术委员会完成，而技术委员会又将该任务分配给现有或新建的工作组。
- 工作组内的专家由国家机构推荐。
  - 以此来确保组内丰富的背景、经验和观点
- 这些专家们代表了相关行业内的领头公司，以及监管机构、学术界和/或消费者团体。

ISO/TC84/WG9 member profile ISO/TC84/WG9 成员概况



ISO standards are voluntary[1] ISO 标准具有自愿性

- ISO standard is not mandatory. Therefore, non-compliance to ISO standard alone does not preclude manufacturers from selling their products.
  - The enforcement of standards is done by regulatory bodies.
- Because of this voluntary nature of the ISO standards, some manufacturers choose to not participate in ISO standard development process for several reasons
  - Fear of disclosing confidential information.
  - Lack of resource to support participation
  - Not aware of the standard being developed
- Therefore ISO standard may have their limitations.
- Care must be taken when countries or regions adopt voluntary ISO standards and make them mandatory without any modifications. That could prevent some existing safe and efficacious products from keep selling in the countries, which was not the intent of ISO standards.

- ISO 标准不具有强制性。因此，即使不符合ISO 标准，制造商也可销售其产品。
  - 标准的执行由监管机构完成。
- 由于 ISO 标准具有自愿性，部分制造商便会出于某些原因而选择不参与 ISO 标准的制定流程，其原因可能有：
  - 担心泄露机密信息
  - 缺乏支持参与的资源
  - 未能知悉正在制定的标准
- 因此，ISO 标准可能具有自身的局限性。
- 在不作任何修改的情况下，国家或地区在将自愿性的 ISO 标准更改为强制性标准时，务必谨慎行事。此举可能导致一些现有的安全、有效产品无法继续在国内销售，而这并不是 ISO 标准的目的。

1. https://www.iso.org/about-us.html

1: https://www.iso.org/about-us.html

Important Code of Conduct重要行为准则

- Working group members are volunteers and not paid by ISO. They have to follow the code of conduct:
  - Work for the net benefit of the international community[3]
    - Over and above the interests of any individual or organization[3]
  - Uphold consensus and governance[3]
    - Transparency, openness, impartiality[3]
  - Behave ethically[3]
    - Act in good faith, avoid collusive and anticompetitive behavior, and promote a culture of fair and ethical behavior[3]:
      - For example: One must not develop ISO standard as a means to block competitors.
  - Respect others in meetings[3]
    - Conducting in a professional manner, respect other and their opinion, accept group decision, and ensuring the views of all are heard and understood[3].

- 工作组成员为志愿者，不从国际标准化组织处获取报酬。志愿者们必须遵守以下行为准则：
  - 为国际社会的净利益而工作
    - 高于任何个人或组织的利益
  - 坚持共识和治理
    - 透明、公开、公正
  - 行为符合道德规范
    - 诚信行事，杜绝串通和反竞争行为，提倡公平、道德的行为文化；
      - 例如：不得将制定 ISO 标准作为阻止竞争对手的手段。
  - 在会议中尊重他人
    - 以专业的方式开展事务，尊重他人及其意见，接受小组决定，确保听取和理解所有人的观点。

3. https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100397.pdf

Basic steps (typically 3 years)基本步骤（通常为期 3 年）

	Main activity	Deliverable
Preliminary[4]	Receive and review new project proposal	TC decision on if new project should proceed
Proposal[4]	New project proposal is voted by national bodies	National body voting on if new standard should be developed
Preparatory[4]	Develop working draft (WD) of the new standard	Initial committee draft (CD)
Committee[4]	Gather comments on and revise CD to reach consensus	draft International Standard (DIS)
Enquiry[4]	DIS is voted by national bodies and comments addressed	final draft international standard (FDIS)
Approval[4]	FDIS is voted by national bodies and editorial errors addressed	FDIS will proceed to publication
Publication[4]	Publish the new International Standard	

	主要活动	交付成果
初步	接收并审查新项目提案	技术委员会就是否应进行新项目的决定
提案	由国家机构对新项目提案进行投票表决	国家机构就是否应制定新标准的投票决定
准备	制定新标准的工作草案	委员会初稿（CD）
委员会	收集意见并修订委员会初稿以达成共识	国际标准草案（DIS）
调查	由国家机构对国际标准草案投票并发表意见	国际标准终稿（FDIS）
批准	由国家机构对国际标准终稿投票并修正编写错误	之后将对国际标准终稿进行发布
发布	发布新的国际标准	

4. https://www.iso.org/stage-codes.html

revisions修订

- International standards are to be reviewed every 5 years[5].
  - National bodies will vote to confirm, revise, or withdrawal
  - If revision is needed, similar process discussed will follow
- Amendment can be made to published standard before the 5-year review.

- 国际标准每 5 年审查一次。
  - 国家机构将通过投票进行确认、修订或撤销
  - 如需进行修订，则将遵循上述的类似流程开展修订
- 在 5 年评审前，可对已发布标准进行修正。

5. https://www.iso.org/files/live/sites/isoorg/files/store/en/Guidance_systematic_review.pdf

Implementation 实施

- In US, when a new standard is released, there are several ways the standard become recognized by FDA.
  - Any interested party may submit a request for recognition[6].
    - FDA has 60 days to respond[6]
  - In general, the FDA actively assesses the impact of new consensus standards and revisions of existing standards on the premarket review process and recognizes these standards, as appropriate. [6]
    - In the case of ISO/TC 84/WG9, there are two members representing FDA.
  - FDA may recognize all, part, or none of a standard[6].

- 在美国，新的标准发布之时，获得 FDA 认可存在几种方式。
  - 任一利害关系方可提出公认申请[6]。
    - FDA拥有六十（60）天的时间给予答复[6]。
  - 一般而言，对于新的共识标准和现有标准的修订，FDA会积极评估其对上市前审评过程的影响，并酌情认可这些标准。[6]
    - 相对于ISO/TC 84/WG9，有两名成员代表FDA。
  - FDA可公认所有或部分标准，甚至不公认任一标准[6]。

6. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm#intro

Enforcement 执行

- In US, when a new standard is adopted as recognized standard, FDA often gives manufacturers 3 yrs (grace period) to comply but may be shorter.
  - Conformance is voluntary, unless a standard is incorporated by reference into regulation[6].
  - Change to standards are not retroactive[7]. Therefore, no action is needed for existing products to continue legally marketed in US unless design update requires new filing.
- Demonstrating conformance to the recognized standard facilitates the premarket review process[6].
  - Manufacturers are encouraged to use FDA-recognized consensus standards in their premarket submissions[6].
  - If a product does not meet a standard, manufacturers must provide alternative data or information along with a scientific rationale for why the alternative addresses the applicable regulations, as part of the filings.
  - FDA makes the final decision on acceptability for commercial release.

- 在美国，当新标准被采纳作公认标准时，食品药品监督管理局通常会给予制造商三（3）年或更短的时间（宽限期）用于遵守新标准。
  - 应主动遵守标准，除非该标准被涵盖在法规内[6]。
  - 标准变更不具备追溯效力[7]。因此，除非设计更新需重新备案，否则现有产品可继续在美国进行合法销售而无需采取任何措施。
- 证明符合公认标准有利于进行上市前审评[6]。
  - 对于上市前的提交资料，鼓励制造商采纳FDA认可的共识标准[6]。
  - 若产品不符合一个标准，制造商则必须提供替代资料或信息以及科学合理的理由，用以解释其可替代适用法规作为文件的一部分。
  - FDA最终决定其商用发行的可接受性。

6. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm#intro
7. Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, FDA, Sept. 14, 2018

Q & A
问答

1: https://www.iso.org/about-us.html

机器人领域国际标准研究的最新进展

Recent progress of international standard development for robotics

杨书评 Shuping YANG
北京 2019年3月15号

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Self Introduction自我介绍

Key Roles:

- Professor of Beijing Research Institute of automation for machinery industry 北京机械工业自动化研究所研究员
- Secretary general of ISO/TC299 mirror committee (SAC/TC159/SC2) in China 机器人分技术委员会SAC/TC159/SC2秘书长（对口ISO/TC299）
- ISO/TC299/WG6 co-convener of modularity for service robot（2016-2019）ISO/TC299/WG6
  服务机器人模块化联合组长（2016-2019）
- Member of ISO/TC299/SG1,WG3,WG4,JWG5,JWG35
  ISO/TC299/SG1,WG3,WG4,JWG5,JWG35成员

Self Introduction自我介绍

Key Activities:

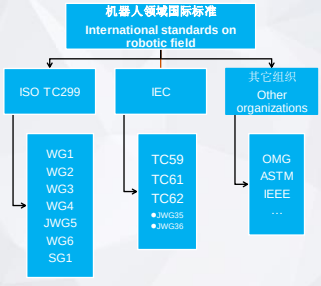
I have been working on robotics standardization research for more than 10 years, mainly responsible for domestic SAC/TC159/SC2 standardization work management and international standard coordination.

长期从事机器人标准化研究工作，负责国内SAC/TC159/SC2机器人标准化工作管理和国际标准协调。

Introduction of RIAMB北京机械工业自动化研究所介绍

- Beijing Research Institute Of Automation For Machinery Industry (RIAMB) was founded in 1954, is the former Ministry of Machinery Industry directly under the comprehensive scientific research institution, in 1999 was transformed into a large-scale science and technology enterprises directly under the central government.
- 北京机械工业自动化研究所有限公司(以下简称:北自所)创建于1954年，是原机械工业部直属的综合性科研机构，1999年转制为中央直属大型科技企业，现隶属于国资委监管的机械科学研究总院。
- Mirror committees of “Automation System and Integration ISO/TC184 ”, “ Robotics ISO/TC299 ” “Bionics ISO/TC266” “Fluid power systems ISO/TC131 ”
- 北自所也是“自动化系统与集成标委会（ISO/TC184）”、”机器人ISO/TC299 “、“仿生学（ISO/TC266）”、“体系结构通信和集成框架分技术委员会（ISO/TC184/SC5）”、“液压与气动标委会（ISO/TC131）”的国内对口单位。

总体介绍 General introduction



总体介绍 General introduction

与机器人相关的国际标准化组织 International Standardization Organization related to robotics:

ISO/TC199 Safety of Machinery机械安全
WG12: Human-machine interactions 人机交互
ISO/TC204 Intelligent transport systems 智能交通运输系统/WG 17
ISO/TC 20/SC16 Aircraft and space vehicles /Unmanned aircraft systems 无人机系统
ISO/TC 110 Industrial trucks 工业车辆
ISO/TC 23 Tractors and machinery for agriculture and forestry拖拉机和农林机械
ISO/TC 67 Materials, equipment and offshore structures for petroleum, petrochemical and natural gas industries石油与天然气工业用材料、设备和海上结构 水下机器人）
ISO/TC 85 Nuclear energy, nuclear technologies, and radiological protection （核能、核技术和辐射防护 Nuclear robot ）

IEC/TC59：Performance of Household and Similar Electrical Appliances 家用和类似用途电器性能
IEC/TC61：Safety of Household and Similar Electrical Appliances 家用和类似用途电器安全
IEC/TC62: Electrical equipment in medical practice 医用电器设备

ISO/TC299

1984
ISO/TC184/SC2 Industrial automation systems - Industrial robots
一工业机器人分技术委员会

2006
ISO/TC184/SC2 Automation system and integration- Robots and robotic devices
—机器人与机器人装备分技术委员会

2015
ISO TC299 Robotics
—机器人技术委员会


Traditional robot workcell setup

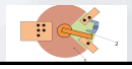

Servant

Service robots （close human-robot collaboration）


Surgeon

）

Even industrial robots moving towards collaborative application



ISO/TC299

ISO/TC299 Robotics——机器人技术委员会

Scope工作范围：

Standardization in the field of robotics, excluding toys and military applications.

除玩具和军事应用以外的机器人领域标准化。

Aim 工作目标:

The ambition is to ensure that the resulting standards can effectively be implemented, tested and integrated.（追求的目标是保证发布的标准能够得以有效执行、测试和集成。）

The committee also sets as an ambition to promote the area of robotics throughout global markets.（本委员会追求的另一目标是提升全球机器人市场。）

ISO /TC299

ISO TC299 Robotics——机器人技术委员会

P成员国-27

- Australia (SA)
- Canada (SCC)
- Austria (ASI)
- China (SAC)
- Czech Republic (UNMZ)
- Denmark (DS)
- Finland (SFS)
- France (AFNOR)
- Germany (DIN)
- Hungary (MSZT)
- India (BIS)
- Ireland (NSAI)
- Italy (UNI)
- Japan (JISC)
- Korea, Republic of (KATS)
- Mexico (DGN)
- Netherlands (NEN)
- Norway (SN)
- Portugal (IPQ)
- Romania (ASRO)
- Russian Federation (GOST R)
- Singapore (ESG)
- Spain (UNE)
- Sweden (SIS)
- Switzerland (SNV)
- United Kingdom (BSI)
- United States (ANSI)

O成员国-10

- Belgium (NBN)
- Honduras (OHN)
- Iran, Islamic Republic of (ISIRI)
- Israel (SII)
- Luxembourg (ILNAS)
- Pakistan (PSQCA)
- Poland (PKN)
- Serbia (ISS)
- Slovakia (UNMS SR)
- Ukraine) （DSTU）

ISO /TC299 工作组 Working group

AG 1 Communications group通讯组
CAG Chairman's Advisory Group主席咨询组
SG 1 Study group on gaps and structure结构与缺失研究组
WG1 ： Vocabulary and characteristics词汇和特性
WG2 ： Personal care robot safety个人护理机器人安全
将改名为 Service robots safety服务机器人安全
WG3 ： Industrial safety工业机器人安全
WG4： Service robots服务机器人
将改名为Service robots服务机器人性能
JWG5：ISOTC184/SC2和IEC/SC62A 应用机器人技术的医疗设备的安全
WG6 : Modularity for service robots服务机器人的模块化

JWG35：ISOTC299和IEC/SC62D 手术机器人安全
JWG36： ISOTC299和IEC/SC62D 康复机器人安全

ISO 机器人领域 WG1

robot: programmed actuated mechanism with a degree of autonomy, moving within its environment, to perform intended tasks
机器人：具有两个或两个以上可编程的轴，以及一定程度的自主能力，可在其环境内运动以执行预期的任务的执行机构。
（ISO 8373:2012 Robots and robotic devices – Vocabulary ）

Robot：programmed actuated mechanism with a degree of autonomy (2.2) to perform locomotion, manipulation or positioning
具有一定程度的自主能力，可编程的执行机构，用以执行运动、操作和定位。
Note 1 to entry: A robot includes the control system (2.7) and interface of the control system.
Note 2 to entry: The classification of robot into industrial robot (2.9) or service robot (2.10) is done according to its intended application.
注1：机器人包括控制系统和控制系统的接口。
注2：按照所期望的应用区分工业机器人和服务机器人。
（ISO/CD 8373 Robotics -- Vocabulary ）

ISO 机器人领域 WG1

service robot: robot that performs useful tasks for humans or equipment excluding industrial automation applications
服务机器人：除工业自动化应用外，能为人类或设备完成有用任务的机器人。

industrial robot: automatically controlled, reprogrammable multipurpose manipulator, programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications
自动控制的、可重复编程（2.4）、多用途(2.5)的操作机(2.1)，可对三个或三个以上轴（4.3）进行编程。它可以是固定式或移动式。在工业自动化中使用。

ISO 机器人领域 WG1

autonomy: ability to perform the intended tasks based on current state and sensing, without human intervention
自治（自主）：基于当前状态和感知信息，无人为干预地执行预期任务的能力。
personal care robot (WG2): service robot that performs actions contributing directly towards improvement in the quality of life of humans, excluding medical applications

medical robot (JWG9): a robot or a robotic device intended to be used as medical electrical equipment (MEE) or as medical electrical systems (MES)
用于医用电子设备（MEE）或医用电子系统(MES)的机器人或机器人设备。

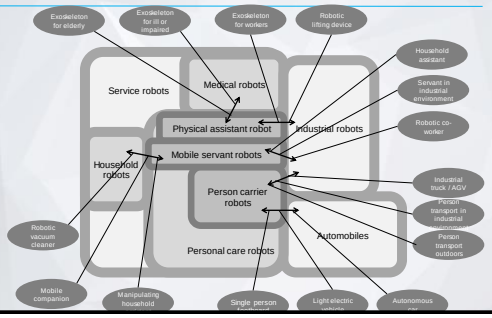
ISO TC299工作组 WG2

Convenor: MO Tokhi, CLAWAR, UK;
Scope: Safety requirements for personal care robots allowing close human-robot interactions. Three types of robots defined: mobile servant, physical assistant and person carrier robots
工作范围： 个人助理机器人的安全要求
定义三种类型的机器人：
Key standards: EN ISO 13482:2014, Safety requirements for personal care robots

Current work正在制定的标准:
ISO/DTR 23482-1 Robotics -- Application of ISO 13482 -- Part 1: Safety-related test methods 机器人 ISO 13482 应用 第1部分：与安全相关的测试方法

ISO/DTR 23482-2
Robotics -- Application of ISO 13482 -- Part 2: Application guide
机器人ISO 13482 应用第2部分：应用指南

ISO /TC299工作组 SG1



ISO TC299工作组 WG3

Convenor: Roberta Nelson, Universal Robots, USA;

Key standard关键标准:
ISO 10218-1: 2011 Robots and robotic devices -- Safety requirements for industrial robots –Part 1: Robots
工业环境用机器人 安全要求 第1部分：机器人
ISO 10218-2:2011 Robots and robotic devices -- Safety requirements for industrial robots –Part 2: Robot systems and integration
机器人与机器人装备 工业机器人的安全要求 第2部分：机器人系统与集成
ISO TS 15066, Robots and robotic devices -- Collaborative robots机器人与机器人装备 协作机器人
ISO 20218-2:2018 Robotics -- Safety requirements for industrial robots -- Part 1: Industrial robot system end of arm tooling (end-effector)机器人 工业机器人安全要求 第1部分：末端执行器

Current work正在制修订的标准:
ISO CD 10218-1, Safety Industrial robot safety requirements - Part 1: Robots
ISO CD 10218-2, Safety reqs for ind robots - Part 2: Robot systems & integration
ISO/DTR 20218-1 End of arm tooling

ISO TC299工作组 WG4

Convenor: Seungbin Moon, Sejong University, Korea
Scope: Performance of service robots

范围：服务机器人性能
Published standards发布的标准：
ISO 18646-1,2016 Performance criteria and related test methods for service robots - Part 1: Locomotion for wheeled robots

Current work正在制定的标准：
7. ISO/DIS 18646-2
Robotics -- Performance criteria and related test methods for service robots -- Part 2: Navigation 机器人 服务机器人性能规范及其相关试验方法 第2部分：导航
8. ISO/AWI 18646-3
Robotics -- Performance criteria and related test methods for service robots -- Part 3: Manipulation 机器人 服务机器人性能规范及其相关试验方法 第3部分：操作
9 . ISO/AWI 18646-4
Robotics -- Performance criteria and related test methods for service robots -- Part 4: Wearable robots 机器人 服务机器人性能规范及其相关试验方法 第4部分 可穿戴机器人

ISO TC299工作组 WG6

Convenor: Gurvinder S Virk, CLAWAR, UK; gsvirk@clawar.org
Co-convenor 1: Shuping Yang, RIAMB, China;
Co-convenor 2: Prof Hongseong Park, Kangwon National Univ, S. Korea;

Scope: Formulate robot modularity guidelines from hardware and software perspectives
范围：从硬件和软件角度制定机器人模块化指南

Current work: ISO CD 22166-1 Modularity for service robots – Part 1 – General requirements
正在制定的标准 ：服务机器人模块化 第1部分：总则

- Wearable robotics is a use case example scenario in Annex A.
- **在附录A有一个可穿戴机器人的用例。**

ISO机器人领域 JWG5

JWG 5—— Medical robot safety (joint with IEC/SC 62A and 62D)

医用机器人安全（与IEC/SC62A和62D联合）

包含三个联合工作组：
ISO TC299-IEC TC62/SC62A JWG9: Medical electrical equipment and systems using robotic technology**应用机器人技术的医用设备的安全.**
ISO TC299-IEC TC62/SC62D JWG35: Medical robots for surgery.手术机器人
ISO TC299-IEC TC62/SC62D JWG36: Medical robots for rehabilitation. 康复机器人

JWG9： ISO /IEC TR 60601-4-1, Medical electrical equipment - Part 4-1: Guidance and interpretation – Medical electrical equipment and medical electrical systems employing a degree of autonomy 已于2017年2月出版.
医用电子设备 第4-1部分 具有自治程度的医用电子设备和医用电子系统

JWG35：ISO/IEC/DIS 80601-2-77
Medical electrical equipment – Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment
医用电气设备 第2-77 机器人辅助手术设备的基本安全和基本性能的专用要求

JWG36： ISO/ IEC/DIS 80601-2-78 Medical electrical equipment : Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation
医用电气设备 第2-78 康复、评估、补偿或缓解医用机器人的基本安全和基本性能的专用要求

ISO/TC299发布的国际标准 published ISO standards

截至2019年3月ISO/299已发布有关机器人的国际标准及技术报告有18项，其中工业机器人13项，服务机器人5项：

1. ISO 8373:2012 Robots and robotic devices – Vocabulary 机器人与机器人装备 词汇
2. ISO 9283:1998 Manipulating industrial robots -- Performance criteria and related test methods
工业机器人 性能规范及其试验方法
3 .ISO 9409-1:2004Manipulating industrial robots -- Mechanical interfaces -- Part 1: Plates
工业机器人 机械接口 第1部分：板类
4 .ISO 9409-2:2002Manipulating industrial robots -- Mechanical interfaces -- Part 2: Shafts
工业机器人 坐标系和运动命名原则（旧版，新版已上报）
6. ISO 9946:1999Manipulating industrial robots -- Presentation of characteristics
工业机器人 特性表示

ISO/TC299发布的国际标准 published ISO standards

7. ISO 10218-1: 2011 Robots and robotic devices -- Safety requirements for industrial robots – Part 1: Robots
工业环境用机器人 安全要求 第1部分：机器人
8. ISO 10218-2:2011 Robots and robotic devices -- Safety requirements for industrial robots – Part 2: Robot systems and integration
机器人与机器人装备 工业机器人的安全要求 第2部分：机器人系统与集成
9. ISO 11593:1996 Manipulating industrial robots -- Automatic end effector exchange systems Vocabulary and presentation of characteristics
工业机器人 末端执行器自动更换系统 词汇和特性表示
10. ISO/TR 13309:1995
Manipulating industrial robots -- Informative guide on test equipment and metrology methods of operation for robot performance evaluation in accordance with ISO 9283
工业机器人 基于SO 9283对机器人性能评估的试验设备和操作计量方法的指南
11. ISO 14539:2000
Manipulating industrial robots -- Object handling with grasp-type grippers – Vocabulary and presentation of characteristics
工业机器人 抓握型支持器物体搬运 词汇和特性表示

ISO/TC299发布的国际标准 published ISO standards

12. ISO 13482: 2014
Robots and robotic devices -- Safety requirements for personal care robots
机器人与机器人装备 个人助理机器人安全要求
13. ISO/TS15066 :2016Robots and robotic devices -- Collaborative robots
机器人与机器人装备 协作机器人
14 . IEC/TR 60601-4-1:2017
Medical electrical equipment -- Part 4-1: Guidance and interpretation -- Medical electrical equipment and medical electrical systems employing a degree of autonomy
医用电子设备 第4-1部分 具有自治程度的医用电子设备和医用电子系统
15. ISO 19649:2017
Mobile robots -- Vocabulary
移动机器人 词汇

ISO/TC299发布的国际标准 published ISO standards

16. ISO 18646-1:2016
Robotics -- Performance criteria and related test methods for service robots -- Part 1: Locomotion for wheeled robots
机器人 服务机器人性能规范及其试验方法 第1部分：轮式机器人运动
17. ISO/TR 20218-1:2018
Robotics -- Safety requirements for industrial robots -- Part 1: Industrial robot system end of arm tooling (end-effector)
机器人与机器人装备 工业机器人安全要求 第1部分：末端执行器
18. ISO/TR 20218-2:2017
Robotics -- Safety design for industrial robot systems -- Part 2: Manual load/unload stations
机器人 工业机器人安全设计 第2部分：手动装卸站

ISO/TC299正在研发的标准 ISO standards under development

ISO/TC299正在研发的标准12项，4项与工业机器人相关

1. ISO/CD 8373
Robots and robotic devices -- Vocabulary
机器人与机器人装备 词汇
2. ISO/CD 10218-1
Robots and robotic devices -- Safety requirements for industrial robots -- Part 1: Robots
3. ISO/CD 10218-2
Robots and robotic devices -- Safety requirements for industrial robots -- Part 2: Robot systems and integration
4.ISO/NP 11593
Manipulating industrial robots -- Automatic end effector exchange systems -- Vocabulary and presentation of characteristics
(以上4项均为修订)
5. ISO/DTR 23482-1 Robotics -- Application of ISO 13482 -- Part 1: Safety-related test methods 机器人 ISO 13482 应用 第1部分：与安全相关的测试方法

ISO/TC299正在研发的标准 ISO standards under development

6. ISO/DTR 23482-2
Robotics -- Application of ISO 13482 -- Part 2: Application guide
机器人 ISO 13482 应用 第2部分：应用指导
7. ISO/DIS 18646-2
Robotics -- Performance criteria and related test methods for service robots -- Part 2: Navigation 机器人 服务机器人性能规范及其相关试验方法 第2部分：导航
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ISO/TC299正在研发的标准 ISO standards under development

10.ISO/CD 22166-1
Robotics – Modularity for service robots -- Part 1: General requirements
机器人 机器人模块化 第1部分：总体要求
11.ISO/IEC/DIS 80601-2-77
Medical electrical equipment -- Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment
医用电气设备 第2-77 机器人辅助手术设备的基本安全和基本性能的专用要求
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Medical electrical equipment : Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation
医用电气设备 第2-78 康复、评估、补偿或缓解医用机器人的基本安全和基本性能的专用要求

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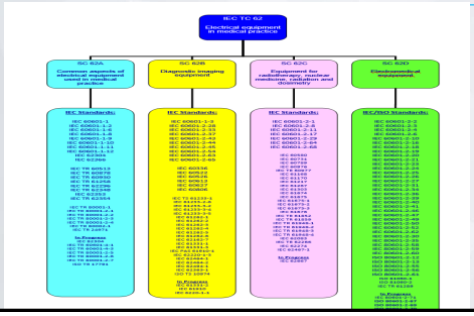
IEC /TC62

序号	编号	中文名称	英文名称	国际秘书处	对口国内秘书处
1	TC 62	医用电器	Electrical equipment in medical practice	德国	上海国家医疗器械质量监督检验中心
2	SC 62A	医疗电器的共同特性	Common aspects of electrical equipment used in medical practice	美国	上海国家医疗器械质量监督检验中心
3	SC 62B	诊断成像设备	Diagnostic imaging equipment	德国	辽宁医疗器械检测中心
4	SC 62C	高能放射设备和核医疗设备及辐射剂量	Equipment for radiotherapy, nuclear medicine and radiation dosimetry	德国	北京医疗器械检测中心
5	SC 62D	医用电子设备	Electromedical equipment	美国	上海国家医疗器械质量监督检验中心

IEC TC62标准族



Machine/ Medical Device safety 机器/医用设备的安全

ISO 12100:2010, Safety of machinery – General principles for design – Risk assessment and risk reduction, defines a standardised (3 step) approach for designing machines to achieve safety requirements:

ISO 12100:2010，机械安全-设计的一般原则-风险评估和风险降低，定义了设计机械以达到安全要求的标准化（3步）方法：

ROBOT AS A MACHINA

ISO 14971:2007, Medical devices –Application of risk management to medical devices, deals with the processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment and the environment. The risk management comprises systematic application of management procedures and practices to the tasks of:

ISO 14971:2007，医疗器械-医疗器械风险管理的应用，涉及管理风险的过程，主要针对患者，也包括操作员、其他人员、其他设备和环境。风险管理包括将管理程序和实践系统地应用于以下任务：

ROBOT AS A MEDICAL DEVICES

Machine/ Medical Device safety 机器/医用设备的安全

ISO:

1. Try to achieve the safety requirements by means of inherently safe design
2. If inherently safe designs are not possible, then try to achieve the requirements by means of safeguarding or protective measures
3. If neither of these solutions are possible, then provide information for use to the operator (warnings, instructions) to assist the operator in achieving acceptable safety

通过固有的安全设计来达到安全要求

如果无法进行本质安全的设计，则应设法通过保护或保护措施达到要求。

如果这两种解决方案都不可行，则向操作员提供信息（警告、说明），以帮助操作员实现可接受的安全。

ROBOT AS A MACHINA

IEC:

1. Risk analysis + Risk evaluation + Risk control
2. Evaluation of overall residual risk acceptability (risk-benefit balance)
3. Risk management report
4. Production and Post production information (Monitoring)

风险分析+风险评估+风险控制

总体剩余风险可接受性评价（风险-效益平衡）

风险管理报告

生产和生产后信息（监控）

ROBOT AS A MEDICAL DEVICES

其它组织 Other Organizations

1. **Institute of Electrical and Electronics Engineers Standards Association (IEEE) 电气和电子工程师协会**
2. **Object Management Group (OMG) 对象管理组织**
3. **American Society of Mechanical Engineers (ASME)美国机械工程师协会**
4. **National Institute of Standards and Technology (NIST) 国家标准和技术协会**
5. **Comité Européen de Normalisation (CEN)欧洲标准化委员会**
6. **Association for Computing Machinery (ACM) 美国计算机协会**

其它组织 Other Organizations

1. **美国电气电子工程师学会（Institute of Electrical and Electronics Engineers，IEEE）的标准联盟（Standards Association）目前在开展机器人相关标准项目的研究工作。**

- **Robot Map Data Representation WG 移动机器人环境地图数据表达标准**
- **Ontologies for Robotics and Automation WG主要负责机器人本体论标准工作**
- **ETHICALLY ALIGNED DESIGN《以伦理为基准的设计》**

其它组织 Other Organizations

2016 英国发布了世界上第一个机器人伦理标准：

BS 8611: 2016
Robots and robotic devices. Guide to the ethical design and application of robots and robotic systems.

机器人与机器人装备 机器人和机器人系统伦理设计和应用指导。

其它组织 Other Organizations

2. 对象管理组织（Object Management Group，OMG）中与机器人相关的标准化工作组包括

- Robotics Functional Services 机器人功能服务 WG、
- Infrastructure 结构 WG、
- Modeling for Robotics 机器人建模 WG、
- Robotics Localization Service 机器人定位 WG、
- Robotics Interaction Service Framework 机器人交互服务框架 WG

已发布机器人交互服务规范（Robotic Interaction Service），机器人本地化服务规范（Robotic Localization Service）和机器人技术组件规范（Robotic Technology Component）。

3. 美国试验与材料协会（American **Society for Testing and Materials，ASTM**）**已发布机器人标准40余项，涉及城市搜救机器人、应急响应机器人、无人机、潜水器术语、接口、性能、测试方法等方面。**
interfaces, performance, testing methods of urban search and rescue robots, emergency response robots, UAVs, submersible terminology,

Thank you for your kind attention

Efforts on standardization of artificial intelligence medical device(AIMD) in China

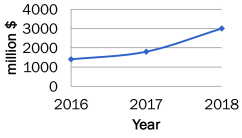
Haiping Ren, Ph.D.
National Institutes for Food and Drug Control

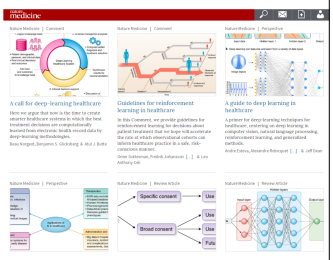
Outline

- **Background**
- Progress on AIMD standardization in China
- Research on evaluation of AIMD
- Summary

Current status of AIMD

- Academia
  - high quality papers ↑
- Industry trends
  -Number of companies↑
  -Investment↑
  -Premarket applications↑





Nature Medicine Jan., 2019

Intended use of AIMD

Common purposes

- Disease screening
  - diabetic retinopathy, etc.
- Lesion detection
  - pulmonary nodule, etc.
- Assisted diagnosis
  - X-ray, etc.
  - 心血管疾病
- In-vitro Diagnostics
  - digital pathology, etc.

Application scenario

- In hospital
  - AI+ diagnosis
  - AI+ therapeutics
  - AI+CDSS
  - AI integrated device
- Out patient
  - Risk alert
  - Guidance on drug use
  - Physiologic monitor
  - AI+ implants

Regulation in China

- Medical device classification catalog(2018) contains computer aided diagnosis
  - CAD products were approved before

Number	Primary class	Secondary class	Intended use	Administrative class
04	Decision support software	01 drug delivery software	To calculate drug dose	III
		02 Computer aided diagnosis/analysis software	To provide clue or suggestion for diagnosis and treatment	III
			To analyze medical data and provide reference value	II
		03 traditional Chinese medicine software	To facilitate traditional medical diagnosis or treatment	II

- AI medical device that are not listed in the catalog should apply for classification.
- Current classification rule: not fixed yet
  - novel products\products with uncertain risk are classified as III
  - may be reclassified as II with more clue gathered
- No evaluation standard is established yet

Standardization of AI worldwide

- Standardization Organizations
  - ISO/IEC JTC1: Information technology
    - SC42: Artificial intelligence
      - Published three standards in big data
      - AI standards are in an early stage
  - IEEE: Global Initiative on Ethics of Autonomous and Intelligent Systems
  - BSI: ethical design of robots
- Government agencies
  - the European Commission's High-Level Expert Group on Artificial Intelligence (AI HLEG): Draft AI Ethics Guidelines For Trustworthy AI
  - FDA: guidance on CADe, SaMD, etc.
- Research institute
  - Xavier: whitepapers on good machine learning practice, etc.
  - **AAPM CADSC:** evaluation of computer aided diagnostic products

Standardization related to AI in China

Organization in China	Counterpart in ISO	Topics
SAC/TC 28	ISO/IEC JTC1	Information technology
General Working Group on AI	ISO/IEC JTC1/SC 41	**Artificial intelligence in general**
SAC/TC 28/SC37	ISO/IEC JTC1/SC 37	Biometrics
SAC/TC 28/SC29	ISO/IEC JTC 1/SC 29	Coding of audio, picture, multimedia and hypermedia information
SAC/TC 28/SC24	ISO/IEC JTC 1/SC 24	Computer graphics, image processing and environmental data representation
SAC/TC 28/SC35	ISO/IEC JTC 1/SC 35	User interfaces

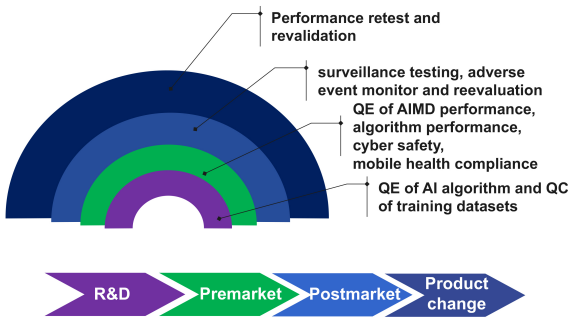
Outline

- Background
- **Progress on AIMD standardization in China**
- Research on evaluation of AIMD
- Summary

National standardization committee on AIMD

- Approved by NMPA in 2018
  - NIFDC serves as the secretariat.
- Responsibility
  - Develop and revise industry standards of AIMD in China
  - Public service
  - Participate in international standardization
    - ISO
    - IEEE

Scope: improve the quality in the lifecycle



Participation in international standards

- IEEE Artificial Intelligence Medical Device Working Group(AIMDWG)
  - Approved in Dec, 2018
  - Two standards are under development
    - P2802: Standard for the Performance and Safety Evaluation of Artificial Intelligence Based Medical Device: Terminology
    - P2801: Recommended Practice for the Quality Management of Datasets for Medical Artificial Intelligence
  - First kick-off meeting: Mar.14, 2019

IEEE P2802: terminology in the evaluation of AIMD

- Aim: to harmonize technical terms in R&D, quality evaluation and regulation work
- AI: branch of computer science devoted to developing data processing systems that perform functions normally associated with human intelligence, such as reasoning, learning, and self-improvement
  - from ISO 2382:2015 Information technology — Vocabulary
- AIMD: no definition has been given yet
  - Proposed concept: medical device that use artificial intelligence to implement intended clinical function

Scope

- The standard establishes terminology used in artificial intelligence medical device, including definitions of fundamental concepts and methodology that describe the safety, effectiveness, risks and quality management of artificial intelligence medical device.
- The standard provides definitions using the following forms, such as but not limited to literal description, equations, tables, figures and legends.
- The standard also establishes a vocabulary for the development of future standards for artificial intelligence medical device.

Evaluation of performance and safety

Attributes
- Robustness
- Reliability
- Cyber safety
- Transparency
- Autonomy
- Accountability
- Generalizability

Evaluation
- exploratory evaluation
- challenge evaluation
- advanced evaluation
- standalone testing
- adversarial testing

Metrics
- accuracy
- operating point
- reader performance
- figure of merit
- mark-labeling
- ROC\LROC
- consistency

Terms on datasets
- reference standard
- standardized data collection
- standard test dataset
- quality assurance dataset
- selection bias
- spectrum bias
- verification bias

IEEE P2801: quality management of datasets for AIMD

- Supervised learning requires high quality datasets
  - Public training sets are recognized
- Real world evidence and retrospective data are encouraged in product evaluation
  - FDA guidance：SaMD, RWE, CADe
- Third-party data sets are needed to understand AI performance.

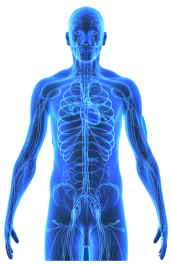
FDA's Comprehensive Effort to Advance New Innovations: Initiatives to Modernize for Innovation

Posted on August 29, 2018 by FDA Voice

Toward these goals, **the FDA is exploring the use of a neutral third party collect large annotated imaging data sets**, for example highly annotated radiology scans used in a variety of clinical trials for specific disease indications, for purposes of understanding the performance of a novel AI algorithm for a proposed indication. **Such a capability would enable a transparent benchmarking system for AI algorithm's performance, and help providers and payors compare AI systems with the best human standard of care.**

Datasets in medical AI

- Important resource for supervised learning
- Promote R&D and competitions



Radiology
- LIDC, Chest X, NCI, etc.
- Bone Age images(RSNA)

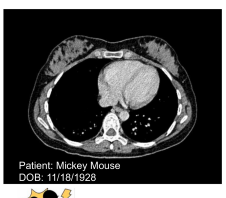
Ophthalmology
- EyePACS, Messidor, etc.
- Google

Electrophysiology
- MIT-BIH
- P300 interface dataset

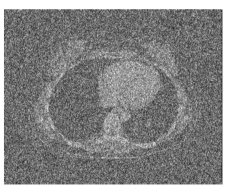
Risks associated with datasets

- Risks may happen without a good practice
  - privacy leakage, bias, pollution, etc.

Example: privacy leakage



Example: pollution

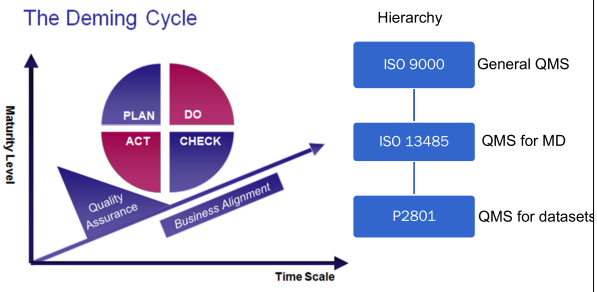


Scope

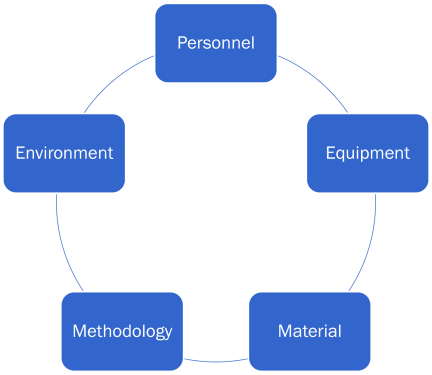
- The recommended practice identifies best practices for establishing a quality management system(QMS) for datasets used for artificial intelligence medical device.
- The recommended practice covers a full cycle of dataset management, including items such as but not limited to data collection, transfer, utilization, storage, maintenance and update.
- The recommended practice recommends a list of critical factors that impact the quality of datasets, such as but not limited to data sources, data quality, annotation, privacy protection, personnel qualification /training/evaluation, tools, equipment, environment, process control and documentation.

Concept of QMS for datasets

- A good QMS is the prerequisite for building good datasets.

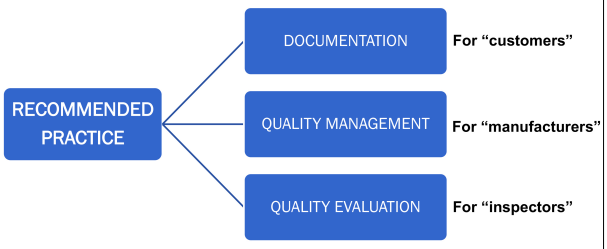


Key elements



Structure of P2801

- Basic idea: a dataset is a “product”



Documentation

- Requirement: to present the benefit and risk clearly

Value	• Expected scenario, user control, exchange, etc.
Labeling	• version, model number, UID, manufacturer info, etc.
Quality	• integrity, traceability, etc.

Quality management system

Quality evaluation

Inspection methods
- Sampling strategy

Inspection requirement
- Records and results

Overall evaluation
- Quality attributes

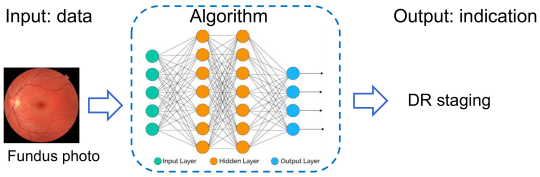
Evaluation of bias
- selection, spectrum, verification, etc.

Outline

- Background
- Progress on AIMD standardization in China
- **Research on evaluation of AIMD**
- Summary

Understanding of AI

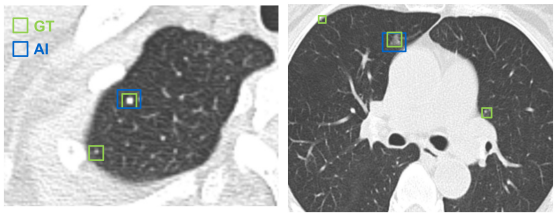
- Elusive mapping through a “black box”



- Special risk:
  - generalization ability in the real world
  - impact of input variation
  - fluctuation due to iteration

Robustness

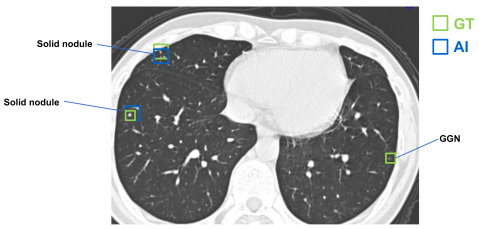
- Risk
  - How AI responds to real world data variability
- Example: pulmonary nodule



Recall changes with nodule size

Robustness

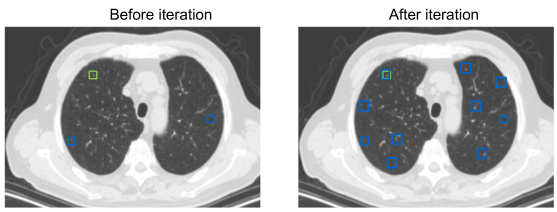
- Example: pulmonary nodule



Recall changes with nodule type

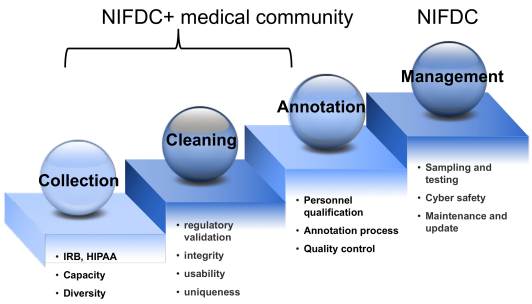
Repeatability

- Example: pulmonary nodule



After algorithm iteration, false positive results increased significantly

Pathway1: Construction of standard testsets



Brief introduction of NIFDC standard datasets

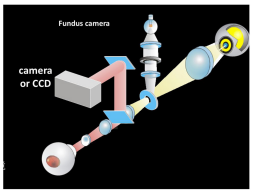
Items	Color fundus photograph dataset	Thoracic CT pulmonary nodule dataset
Patients	6000+	600+
Source	11 hospital from 10 provinces	22 hospitals from 9 provinces
Hardware	fundus camera models>13	CT model>16
Variability	Resolution, image/background ratio	Tube voltage, current, thickness, spacing
Disease	DR phase 0-4, other fundus disease, quality not acceptable	Pulmonary nodule, pleural nodule and plaque
Annotation	Disease classification	Detection/classification/
Grader	15 out of 47 candidates from 15 hospitals in 8 provinces	39 out of 185 candidates from 25 hospitals in 13 provinces
Grader Qualification	Attending physician at least	
	47% with senior title, 10 years experience on average	57% with senior title, 13 years experience on average
Annotation Rule	Based on consensus with expert groups from Chinese Society of Medicine	
Grader performance	SE/SP>80% ICC>85%, kappa>0.75	Precision/recall/IoU>80%
Process QC	3 graders+3 arbitration/QC experts	>3 graders+2arbitration/QC experts

Pathway2: challenging tests by simulated data

- Role: add supplementary information to regular tests
- Purpose:
  - expansion of test datasets
    - hardware variation
  - simulation of real world disturbance
- Method: transform clinical data mathematically and simulate variation in the real world

Example：color fundus photograph

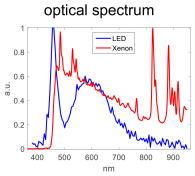
- Question：does AI have consist performance on data collected by different fundus cameras?
  - IDx-Dr relies on Topcon NW400, how about others?
  - is it necessary to compare cameras in clinical trials?
- Analysis：main differences between fundus cameras
  - detectors：CMOS is replacing CCD
  - light source：LEDs becoming popular, while Xenon lamp is widely used.



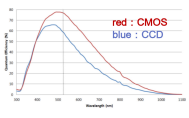
Experiment1：simulation of hardware change

- Targets
  - light source and detector changes
- Data
  - 1854 patients，DR1-4:24%，similar to prevalence in diabetic patients
  - original fundus cameras use CCD and Xenon lamp.
- Method
  - simulate the combination of CCD/CMOS and Xenon/LED numerically

optical spectrum

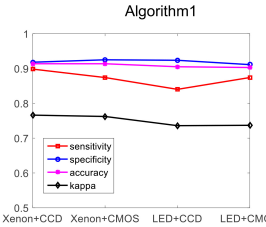


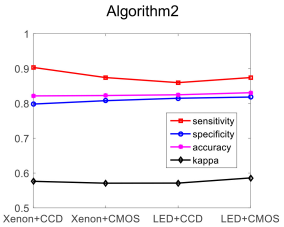
Quantum efficiency



Experiment1: result

- Classification: referable DR vs. nonreferable DR





Relative change	Algorithm1	Algorithm2
Se	-6.47%	-4.83%
Sp	0.76%	2.52%
Kappa	-3.95%	1.69%

The sensitivity of Algorithm1 fluctuates more, suggesting more attention should be paid to camera variation in clinical scenario.

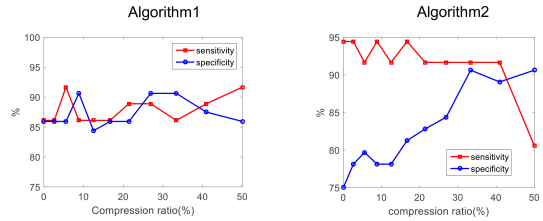
Specificity has less fluctuation.

Experiment2：impact of preprocessing

- Question：does preprocessing affect AI performance
  - examples of preprocessing methods
    - background cropping
    - smoothing
    - image compressing
- Simulation
  - background padding：add 0-100 background pixels to both sides
  - smoothing：moving average filter, size 1-21 pixels
  - compressing：use bicubic method, 0%-50%

Experiment2 results

- Impact of compression

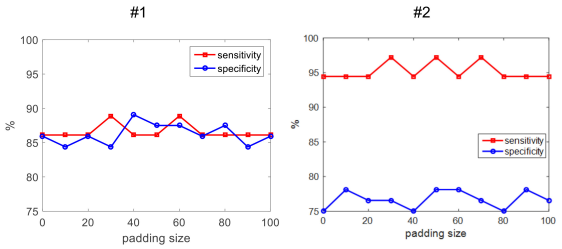


Relative change	Algorithm1	Algorithm2
Sensitivity	0% - 8.14%	-14.8% - 0%
Specificity	-2.35% - 5.81%	0% - 20.7%

- There is a balance between risk and benefit
- Accuracy of #1 is optimal at 35%
- Accuracy of #2 is optimal at 40%, with higher flucturation

Experiment2 results

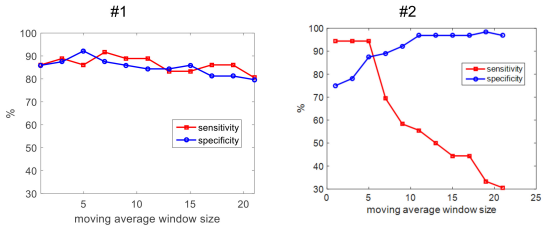
- Impact of background padding



Both fluctuates no more than ±5%

Experiment2 results

- Impact of smoothing



Relative change	#1	#2
Se	-6.98% - 5.81%	0%-68.42%
Sp	-6.98% - 7.27%	0% - 32%

- #1 is fluctuating and dropping slowly.
- #2 shows similar trend to results of compression, indicating that spatial resolution may impact AI performance.

Summary

- There is huge need for standardization of AIMD
  - data quality management
  - annotation
  - performance evaluation
  - product specific requirement
- Standardization efforts are driven by questions from life-cycle quality evaluation perspective.
- Collaboration and communication is precious

Acknowledgement

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人工智能医疗器械(AIMD)标准化工作介绍

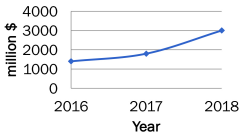
任海萍，博士
中国食品药品检定研究院

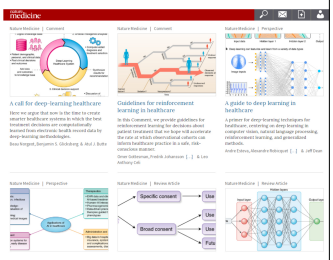
主要内容

- **背景与需求**
- 中国AIMD标准化研究进展
- AIMD评价研究
- 总结与展望

产业现状

- 学术界
  - 高质量文章层出不穷
- 行业前景
  - -企业剧增
  - -投资火热
  - -产品报检多





Nature Medicine Jan., 2019

AIMD预期使用情况

常见预期用途

- 疾病筛查
  - 糖尿病视网膜病变等 retinopathy, etc.
- 病灶标注
  - 肺结节等
- 辅助诊断
  - X射线等
  - 心血管疾病
- 临床检验
  - 数字化病理等

应用场景

- 院内
  - AI+诊断
  - AI+治疗
  - AI+临床决策支持
  - AI植入硬件
- 院外
  - 风险预警
  - 用药指导
  - 生理监测
  - AI+ 植入物

国内AI审批情况

- 医疗器械产品分类目录(2018) 包含计算机辅助诊断软件
  - CAD 有过批准先例

04	决策支持软件	01 药物计算软件	通常由软件安装光盘（或者从网络下载安装程序）组成，基于药代和动药物模型，患者生理参数与体征计算药物注射方案，为临床注射药物提供建议。	用于为临床注射药物提供建议。	胰岛素注射计算软件	II
		02 计算机辅助诊断分析软件	通常由软件安装光盘（或者从网络下载安装程序）组成，利用影像处理和或数据处理技术，由计算机软件对病灶进行自动识别，对病灶的性质等给出临床诊断治疗依据和或建议。	由计算机软件对病灶进行自动识别，对病灶的性质等给出临床诊断治疗依据和或建议。	乳腺X射线影像计算机辅助诊断软件，磁共计算机辅助诊断软件，肺部计算机辅助诊断软件，乳腺超声辅助诊断软件	II
			通常由软件安装光盘（或者从网络下载安装程序）组成，对影像或者数据进行分析，给出临床参考量。	对影像或者数据进行分析，给出临床参考量。	胃窥镜计算机辅助检测软件	I
		03 中医诊疗软件	通常由软件安装光盘（或者从网络下载安装程序）组成，利用中医证治的相关理论，使用数据统计等方法，实现各种证候的分析诊断和或提供治疗建议。	用于实现各种证候的分析诊断和或提供治疗建议。	脉象智能辅助诊疗软件，中医诊疗软件	I

- 未列入《分类目录》或分类界定通知等文件的AI器械需要分类界定
- 目前界定情况：没有明确结论。一般新产品、风险不明的一般为三类，随着认识深入可能二类。
- 没有检测标准

国外AI相关标准化工作

- 国际组织
  - ISO/IEC JTC1: 信息技术
    - SC42: 人工智能
      - 已发布3个大数据方面的标准
      - AI标准还在起草中
  - IEEE: 自治与智能系统伦理的全球倡议
  - BSI: 机器人伦理设计
- 政府机构
  - 欧盟：可信赖的人工智能伦理指南草稿
  - FDA: 计算机辅助检测、医用软件指导原则
- 研究机构
  - Xavier: 良好的机器学习白皮书、AI术语
  - AAPM CADSC:计算机辅助诊断产品评价

国内AI相关标准化工作

国内的标准化委员会	对应的ISO标技委	领域
SAC/TC 28	ISO/IEC JTC1	信息技术
General Working Group on AI	ISO/IEC JTC1/SC 41	人工智能
SAC/TC 28/SC37	ISO/IEC JTC1/SC 37	生物特征识别
SAC/TC 28/SC29	ISO/IEC JTC 1/SC 29	音频、图像编码、多媒体及超媒体信息
SAC/TC 28/SC24	ISO/IEC JTC 1/SC 24	计算机图形、图像处理和环境数据表示
SAC/TC 28/SC35	ISO/IEC JTC 1/SC 35	用户界面

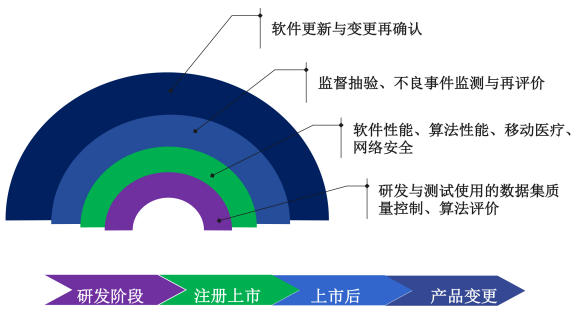
主要内容

- 背景与需求
- **中国AIMD标准化研究进展**
- AIMD评价研究
- 总结与展望

人工智能医疗器械标准化技术归口单位

- 2018年经NMPA批准成立
  - 中检院作为秘书处承担单位.
- 职责
  - 制修订中国AIMD行业标准
  - 其他公共事务
  - 参与国际标准化工作
    - ISO
    - IEEE

出发点：面向全生命周期的质量提升



参与国际标准化工作

- IEEE 人工智能医疗器械工作组(AIMDWG)
  - 2018年12月获批成立
  - 两个标准正在起草中
    - P2802: Standard for the Performance and Safety Evaluation of Artificial Intelligence Based Medical Device: Terminology性能与安全评价术语
    - P2801: Recommended Practice for the Quality Management of Datasets for Medical Artificial Intelligence数据集质量管理
  - 启动大会: 2019年3月14日

IEEE P2802: AIMD评价术语

- 目的: 统一在研发、质控和法规事务中出现的AIMD专有术语
- AI:计算机科学的一个分支，致力于开发数据处理系统，这些系统执行通常与人类智能有关的功能，如推理、学习和自我改进
  - from ISO 2382:2015 Information technology — Vocabulary
- AIMD: 目前还无定义
  - 建议定义为:使用人工智能实现预期临床功能的医疗设备

P2802适用范围

- 该标准建立了人工智能医疗器械性能与安全评价中使用的术语，包括描述人工智能医疗器械的安全性、有效性、风险和质量管理的基本概念和方法的定义。
- 该标准还为未来人工智能医疗器械标准的发展建立了词汇表。

性能和安全性评估

Attributes属性
- Robustness鲁棒性
- Reliability可靠性
- Cyber safety计算机安全
- Transparency透明度
- Autonomy自主性
- Accountability问责制
- Generalizability普适性

Evaluation评价
- exploratory evaluation探索性评价
- challenge evaluation挑战性评价
- advanced evaluation先进性评价
- standalone testing独立测试
- adversarial testing对抗测试

Metrics指标
- Accuracy准确性
- operating point作业点
- reader performance功能实现
- figure of merit灵敏度
- mark-labeling标注
- ROC\LROC
- Consistency一致性

Terms on datasets数据集术语
- reference standard参考标准
- standardized data collection标准化数据采集
- standard test dataset标准数据集
- quality assurance dataset高质量数据集
- selection bias选择性偏倚
- spectrum bias范围偏倚
- verification bias事实偏倚

IEEE P2801:数据集在AI研发和监管中的角色

- 目前AI产品大多采用监督学习，研发阶段需要高质量的数据集
  - 公开数据集对行业发展有积极作用（例如LIDC、MIT-BIH）
- 真实世界数据、回顾式临床数据允许用于AI产品评价
  - FDA指导原则：软件临床评价、真实世界数据使用、CADe
- 第三方数据集在AI监管中扮演重要角色，中美两国的认识相似

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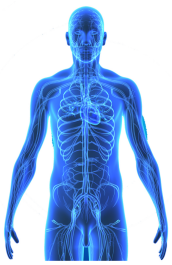
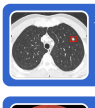
Toward these goals, **the FDA is exploring the use of a neutral third party collect large annotated imaging data sets**, for example highly annotated radiology scans used in a variety of clinical trials for specific disease indications, for purposes of understanding the performance of a novel AI algorithm for a proposed indication. **Such a capability would enable a transparent benchmarking system for AI algorithm's performance, and help providers and payors compare AI systems with the best human standard of care.**

医疗AI中的数据集建设

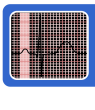
- 是监督式学习中的重要资源
- 促进了研发和竞赛





放射学
- LIDC, Chest X, NCI, Bone Age images(RSNA)

眼科
- EyePACS, Messidor, etc.
- Google

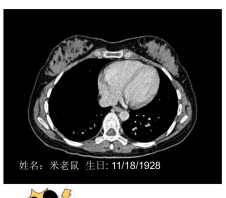


电生理学
- MIT-BIH
- P300 接口数据集

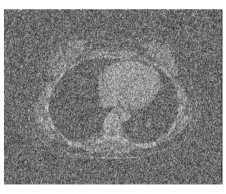
数据集面临的质量风险

- 在缺乏规范的情况下，数据集的开发面临各种风险
  - 隐私泄露、偏倚、数据污染等

例：隐私泄露



例：数据污染

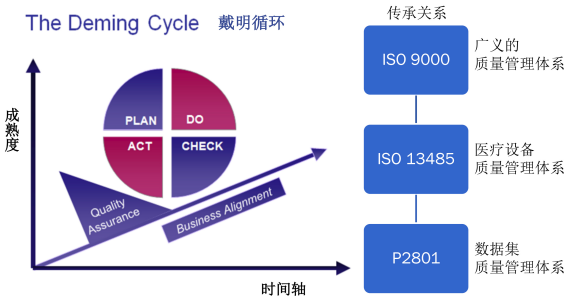


P2801适用范围

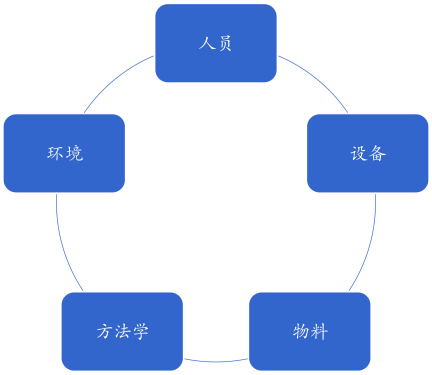
- 为人工智能医疗器械用的数据集建立质量管理系统(QMS)推荐操作指南。
- 包括数据集管理的整个周期，包括但不限于数据收集、传输、使用、存储、维护和更新等项。
- 给出了影响数据集质量的关键因素列表，例如但不限于数据源、数据质量、注释、隐私保护、人员资格/培训/评估、工具、设备、环境、过程控制和文档要求。

数据集质量管理体系的概念

- 优秀的质量管理体系是成功建立数据集的先决条件。

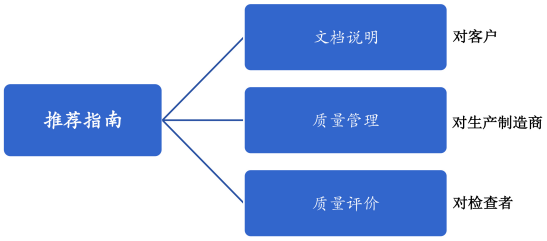


关键元素



P2801架构

- 基本概念：数据集是一个产品



文档说明

- 要求: 清楚列明收益与风险

价值	• 预期用途，用户管理，数据交互，等等.
标识	• 版本，产品型号，用户界面设计，制造商信息，等等.
质量	• 完整性，真实性，可审查性，可溯源性，等等.

质量管理

质量评价

检查方法
- 抽样策略

检查要求
- 原始记录和实验结果

综合评价
- 质量特征

偏倚评价
- 选择偏倚，范围偏倚，真实偏倚，等等.

主要内容

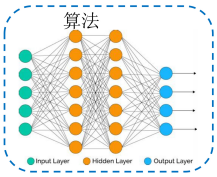
- 背景与需求
- 中国AIMD标准化研究进展
- **AIMD评价研究**
- 总结与展望

对AI的认识

- AI技术特点：黑盒式的映射关系

输入：数据

眼底图像



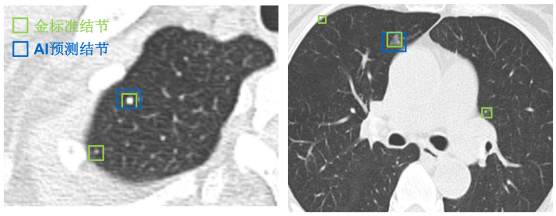
输出：算法分析结果

糖网分期

- 特殊风险：
  - 真实世界中的泛化能力
  - 输入的波动对输出造成的干扰:鲁棒性
  - 算法迭代带来的性能变化：重复性

鲁棒性

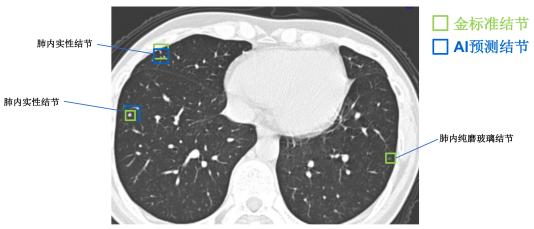
- 风险来源
  - 训练集是否充分体现真实世界的数据多样性
  - 应用场景及实际用途对性能的挑战
- 举例：肺结节



召回率随结节尺寸变化

鲁棒性

- 举例：肺结节

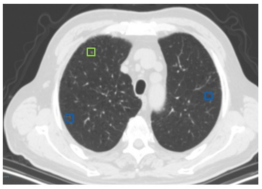


召回率随结节类型变化

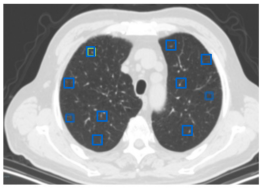
重复性

- 举例：肺结节

算法更新前



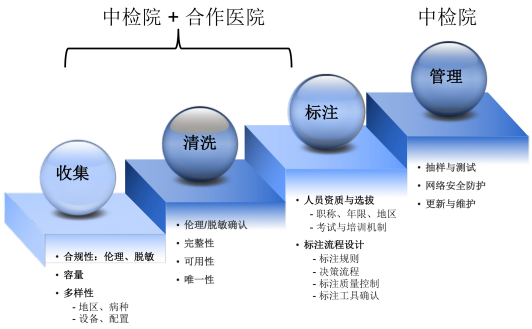
算法更新后



金标准结节
AI预测结节

对本例而言，算法更新后召回率有所提高，假阳性结果也显著增多，精确度下降

途径1：标准数据集建设要点



中检院标准数据集介绍

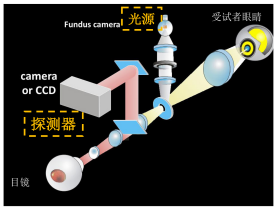
名称	彩色眼底图像标准数据集	肺部CT影像肺结节标准数据集
病例数	6000+	600+
数据来源	10省市11家医院	9省市22家医院
成像设备	>13种眼底相机	>16种CT机型
参数设置	分辨率、图像/背景比例	管电压、管电流、剂量、层厚、层间距
入选病种	DR（5种分期）+其他疾病（23种）+不可识别	肺内结节（4种）+胸膜结节（2种）+其他
标注内容	疾病分类（以DR为主线）	肺结节检出、分类、边界分割、尺寸测量
医生来源	47人参加考试，15人入选，来自8省市的15家医院	185人参加考试，39人入选，来自13省市的25家医院
医生资质	最低为主治，47%有高级职称，平均10年经验	最低为主治，57%有高级职称平均13年经验
标定规则	中华医学会眼底病学组、中山眼科中心等参与制订	中华医学会放射分会、上海长征医院等参与制订
医生表现	灵敏度、特异性、准确率>80% 稳定性>85%，kappa>0.75	精确度、灵敏度、平均交并比>80%
标注控制	3标片+3仲裁	至少3标片+2仲裁

途径2：模拟对抗方法研究

- 定位：对基于标准测试集的评价方法的补充
- 作用
  - 样本量的扩充（例如同一患者在不同机型下的数据）
  - 对真实世界数据波动的模拟
- 技术路线
  - 根据数学物理模型对现有数据进行变换，观测AI的变化

研究举例：彩色眼底图像

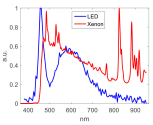
- 问题：不同机型采集的数据是否引起AI性能变化？
  - 美国IDx-Dr绑定Topcon NW400眼底相机，其他产品如何声称？
  - 是否需要在临床试验中对同一批患者用多机型成像进行比较？
- 分析：机型间硬件差异及趋势
  - 探测器：CMOS越来越多，而传统相机使用CCD居多
  - 光源：手持式眼底相机多采用LED，传统使用氙灯



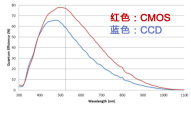
试验1：对硬件变化的模拟

- 模拟对象
  - 光源（照明光谱）和探测器（QE曲线）
- 原始样本
  - 1854张临床图像，DR1-4期总比例24%，接近全国统计
  - 采集原始样本的设备使用CCD和氙灯组合
- 变换方法
  - 模拟CCD/CMOS与氙灯/LED两两组合，计算图像校正系数

照明光谱

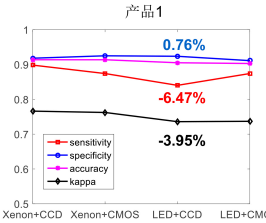


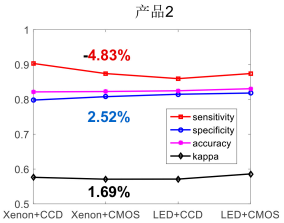
探测器QE



试验1结果

- 模拟不同光源与探测器组合下，糖网转诊的分类情况





相对变化	产品1	产品2
灵敏度	-6.47%	-4.83%
特异性	0.76%	2.52%
Kappa	-3.95%	1.69%

产品1灵敏度相对变化幅度更大，提示临床试验应更关注不同机型的影响

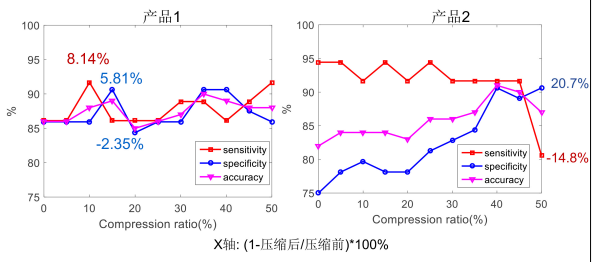
特异性的相对变化幅度均比灵敏度小

试验2：对AI产品预处理算法的模拟

- 问题：AI产品的预处理算法对性能有无影响？
  - 检验中发现的预处理算法举例
    - 黑色背景剪切：节约内存
    - 平滑预处理：降噪
    - 图像压缩：节约内存
- 模拟方法：
  - 黑色背景比例调整：左右两侧同时填充0-100像素
  - 平滑预处理：使用二维均值滤波算子，1-21像素
  - 图像压缩：使用双三次曲线进行压缩与插值，0%-50%

试验2结果

- 图像压缩对糖网转诊分类的影响



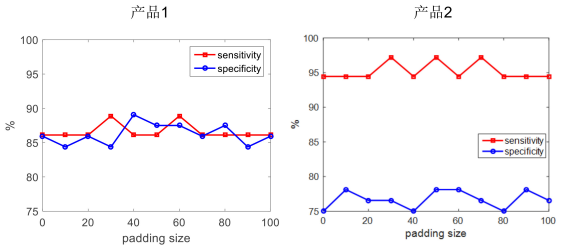
X轴: (1-压缩后/压缩前)*100%

相对变化	产品1	产品2
灵敏度	0% - 8.14%	-14.8% - 0%
特异性	-2.35% - 5.81%	0% - 20.7%

- 图像压缩算法体现了风险与收益的博弈
- 产品1相对平稳，准确率在35%达到最优
- 产品2波动较大，准确率在40%达到最优

试验2结果

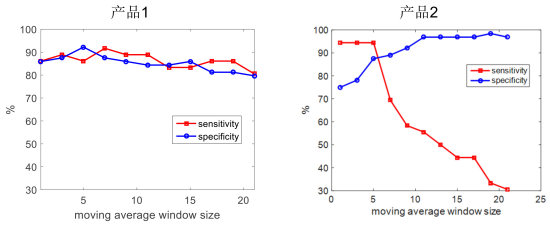
- 背景填充对糖网转诊分类的影响



两个产品指标变化幅度均在5%以内，无明显趋势

试验2结果

- 平滑预处理对糖网转诊分类的影响



相对变化	产品1	产品2
灵敏度	-6.98% - 5.81%	0%-68.42%
特异性	-6.98% - 7.27%	0% - 32%

- 产品1指标交替变化，缓慢下降
- 产品2灵敏度与特异性变化较大
  - 与图像压缩结果一致，提示空间频率对产品2性能可能有影响

总结与展望

- 人工智能医疗器械的质量评价工作任重道远
  - 数据质量管理
  - 标注
  - 评价
  - 产品具体要求
- 标准化工作是由全生命周期质量提升的需求驱动的
- 国际合作与沟通非常珍贵，需要群策群力

致谢

感谢医学、AI、学术、监管领域各位专家的支持

任海萍

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