中美医疗器械标准体系技术研讨会

US-China Medical Device Standardization Workshop

指导单位：
美国贸易发展署

Sponsored by:
US Trade and Development Agency (USTDA)

主办单位：
美国先进医疗技术协会
美国国家标准化机构

Organized by:
Advanced Medical Technology Association(AdvaMed)
American National Standard Institute(ANSI)

2018年3月26日 北京

Content / 目录

Part I **Agenda/会议议程 ……P3**

Part II **Sponsor and Organizer Overviews / 主办及承办单位介绍……..……..P9**

Part III **Speaker Biographies / 演讲人介绍……P19**

Part IV **Presentations / 演讲材料……P27**

Agenda

会议议程

AGENDA

US-China Medical Device Standardization Workshop

March 26th, 2018 | Beijing, China

8:30 Registration and Welcome Breakfast

Morning session moderated by Davey Han, BioHan Consulting

9:00 Welcome Remarks
Bill Sutton, US FDA
Li Jun, CFDA
Leslie McDermott, ANSI
Yu Xinhua, CMDSA
Zach Helzer, AdvaMed

9:15 China Medical Device Standardization Administration
Yu Xinhua, CMDSA

10:00 Complementary Functions of Regulations and Standards
Bill Sutton, US FDA

10:45 Coffee Break

11:00 Implementation of IEC60601 standards in the US
Liang Yening, Stryker Global

12:00 Lunch

Afternoon session moderated by Yu Xinhua, CMDSA

1:30 Adoption of International Medical Device Standards
Derek Liu, Johnson & Johnson

2:15 Progress of basic standards for medical electrical equipment in China
Jia Zheng, CMDSA

3:00 Coffee Break

3:15 Best Practice Standards Development Process
George Odero, Hologic

4:00 International Best Practice of Test Labs
Daniel Chen, Philips

4:30 Q&A Discussion
Davey Han, BioHan Consulting

4:55 Closing Remarks
Steven Winkates, USTDA

5:00 Adjourn

日程

医疗器械标准：加速国际协调发展

2018 年 3 月 26 日|中国，北京

8:30 会议签到

主持：百涵生物技术咨询公司总裁兼总经理韩德辉先生主持

9:00 欢迎致辞

Bill Sutton	*美国食品药品管理局(FDA)驻华办公室助理主任*
李军	*国家食品药品监督管理总局医疗器械注册管理司*
Leslie McDermott	*美国国家标准化机构国际发展高级主任*
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*
Zach Helzer	*美国先进医疗技术协会*

9:15 概述：中国医疗器械标准
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 法规和标准的互补功能
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

11:15 IEC 60601 标准在美国的贯彻实施
Yening Liang，史赛克公司，国际法规事务

12:00 午餐

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主持

1:30 国际医疗器械标准的采纳
刘恒达，强生 DePuySynthes 法规事务部副总监

2:15 中国医用电气设备基础标准制定进展
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

3:00 茶歇

3:15 标准制定过程的最佳实践
豪洛捷公司-George Odero

4:00 检测实验室的国际最佳实践
谌达宇，飞利浦全球法规与标准部门高级经理,

4:30 提问解答
百涵生物技术咨询总裁韩德辉

4:55 闭幕辞
温凯时，美国贸易发展署东亚区项目管理主任

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) helps to promote U.S. technologies and expertise for priority development projects in emerging economies. USTDA links U.S. businesses to export opportunities by funding project planning activities, pilot projects, and reverse trade missions while creating sustainable infrastructure and 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 that support large investments in infrastructure that contribute to host country development. Key sectors in China include the transportation, energy, 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 support increased protection of intellectual property rights, fair and transparent government procurement practices, science-based agricultural biotechnology regulations, and standards across a wide range of industry sectors.

International Business Partnership Program

Under the Agency's International Business Partnership Program, USTDA has increased its support for programs designed to bring procurement officials to the United States to witness U.S. technology and ingenuity firsthand and develop the relationships with U.S. companies necessary to spur increased commercial cooperation with emerging economies. These investments include reverse trade missions, technology demonstrations, training and specialized sector-specific workshops and conferences.

Cooperation Programs

The Agency's success in China is due in part to the public-private cooperative programs that USTDA supports in country. These programs provide a forum wherein government agencies and private companies from both the U.S. and China can share technical, policy, and commercial knowledge relevant to a specific field. USTDA has successfully established programs based on this model in the aviation, standards and conformity assessment, energy, and healthcare sectors.

By adapting to the evolving needs of China's market and closely coordinating with Chinese decision makers, these public-private partnerships have enjoyed long-term success, providing continued trade opportunities and enhancing the development of China's key industries.

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。

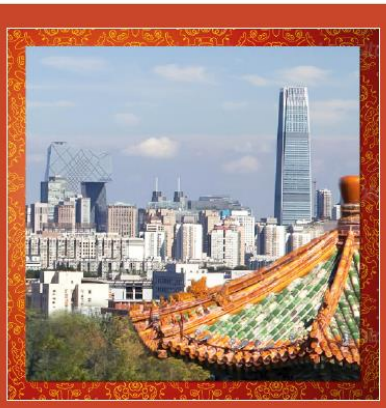
国际商业伙伴关系项目

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
Ms. Madeleine McDougall
Program Manager
American National Standards Institute (ANSI)
1899 L St. NW – Eleventh Floor
Washington, DC 20036

T: 202.331.3624
F: 202.293.9287
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

Ms. Madeleine McDougall

项目经 理

美国国家标准协会(ANSI)

1899 L St. NW – Eleventh Floor

Washington, DC 20036

T: 202.331.3624

F: 202.293.9287

E: us-chinasccp@ansi.org

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 more than 90 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 its nearly 1,000 companies, organization, government agency, institutional and international members through its office in New York City, and its headquarters in Washington, D.C.

美国国家标准协会（ANSI）

American National Standards Institute（ANSI——美国国家标准协会）是由公司、政府和其他成员组成的自愿组织，负责协商与标准有关的活动，审议美国国家标准，并努力提高美国在国际标准化组织中的地位。ANSI 是 IEC 和 ISO 的 5 个常任理事成员之一，也是 4 个理事局成员之一，参加 79%的 ISO/TC 的活动，参加 89%的 IEC/TC 活动。ANSI 是泛美技术标准委员会（COPANT）和太平洋地区标准会议（PASC）的成员。

美国国家标准学会（American National Standards Institute: ANSI）成立于 1918 年。当时，美国的许多企业和专业技术团体，已开始了标准化工作，但因彼此间没有协调，存在不少矛盾和问题。为了进一步提高效率，数百个科技学会、协会组织和团体，均认为有必要成立一个专门的标准化机构，并制订统一的通用标准。1918 年，美国材料试验协会（ASTM）、与美国机械工程师协会（ASME）、美国矿业与冶金工程师协会（ASMME）、美国土木工程师协会（ASCE）、美国电气工程师协会（AIEE）等组织，共同成立了美国工程标准委员会（AESC）。美国政府的三个部（商务部、陆军部、海军部）也参与了该委员会的筹备工作。1928 年，美国工程标准委员会改组为美国标准学会（ASA）。为致力于国际标准化事业和消费品方面的标准化，1966 年 8 月，又改组为美利坚合众国标准学会（USASI）。1969 年 10 月 6 日改成现名：美国国家标准学会（ANSI）。

美国国家标准学会是非赢利性质的民间标准化组织，是美国国家标准化活动的中心，许多美国标准化学协会的标准制修订都同它进行联合，ANSI 批准标准成为美国国家标准，但它本身不制定标准，标准是由相应的标准化团体和技术团体及行业协会和自愿将标准送交给 ANSI 批准的组织来制定，同时 ANSI 起到了联邦政府和民间的标准系统之间的协调作用，指导全国标准化活动，ANSI 遵循自愿性、公开性、透明性、协商一致性的原则，采用 3 种方式制定、审批 ANSI 标准。

ANSI 现有工业学、协会等团体会员约 200 个，公司（企业）会员约 1400 个。领导机构是由主席、副主席及 50 名高级业务代表组成的董事会，行使领导权。董事会闭会期间，由执行委员会行使职权，执行委员会下设标准评审委员会，由 15 人组成。总部设在纽约，卫星办公室设在华盛顿。

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

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

Dr. Han, Davey
President and CEO of BioHan Biotech Consulting (Beijing) Co. Ltd.

The company is dedicated to provide the services in medical device quality management & regulatory affairs, clinical study, registration submission, marketing research and policy/regulation analysis.

Dr. Han has broad experiences from government agency, academies to medical industry. He worked for Chinese Academy of Medical Sciences, and National Health Economics Institute of MOH. Then, Dr. Han entered into global high-tech medical industries (St. Jude Medical and Siemen), holding various positions from manager, Asian-regional senior manager, general manager of quality & regulatory affairs, and government & key customer relations director. From 2010 to 2013, Dr. Han joined the world-wide largest healthcare market research consulting company-IMS, leading the IMS China Institute.

Dr. Han involves with enthusiasm in the activities of medical industry cooperation and exchanges with government authorities. When employed by industry companies, he took many social roles respectively, including Chair, Medical Device Forum of American Chamber of Commerce in China; Chair, Health Equipment Working Group of European Chamber of Commerce; Vice-Chair of Asian Harmonization Working Party (AHWP) in medical device regulations and standards, and China Director of Medical Imaging & Technology Alliance.

Dr. Han graduated from Tongji Medical University in 1984. From 1993 -1997, he studied at the University of Minnesota and earned the Master of Science in Health Services Research and Policy, and also completed his post-doctorate program in Epidemiology and Clinical Research at the same university.

韩德辉
百涵生物技术咨询（北京）有限公司总裁兼总经理

公司致力于为国内外医疗器械与诊断产品企业提供质量管理、临床研究、产品注册、市场调研和政策法规分析服务。

韩先生在业界、学界和政府界有着广泛的经历。曾先后就职于中国医学科学院及卫生部卫生经济研究所（现卫生发展研究中心）。此后于 1997 年，韩先生加入了国际医疗高科技企业行业（圣犹达和西门子），历任经理、亚太区高级经理、质量法规事务总经理、政府与对外事务总监等职。2010 年至 2013 年，韩先生加入全球最大的医药市场研究与咨询公司-艾美仕（IMS）公司，担任 IMS 中国研究院院长。

韩先生热心推动医药行业同国家医药卫生监管部门交流与合作，在国际企业工作期间曾先后兼任中国美国商会（AmCham-China）医疗器械分会主席、中国欧盟(EUCCC)医疗设备分会主席、亚洲医疗器械标准与法规协调工作组（AHWP）副主席、美国医学影像技术联盟（MITA）中国总监。韩先生于 1984 年毕业于同济医科大学，于 1993-1997 年求学于美国明尼苏达大学，获得卫生经济与政策研究硕士学位、完成流行病与临床研究博士后研究。

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喝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。

Xinhua Yu
National Institutes For Food and Drug Controls, Institute for medical device standard administration, Deputy director, in charge of medical device standard management and research.

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，负责医疗器械标准管理和研究工作。

Yening Liang, RAC, MS

International Regulatory Affairs, Stryker Corporation, San Jose California.
Focus: Global Medical Device registrations and standards management.
MS in Regulatory Sciences from University of Southern California;
Regulatory Affairs Certification (RAC) certified USA and International

美国和国际法规事务专业认证
国际法规事务，史赛克公司，加州圣荷西
专注领域：医疗器械全球注册和标准管理
南加州大学药学院法规科学硕士

Derek Liu

Senior Principal Scientist, Associate Director of Regulatory Affairs, DePuy Synthes Products, LLC; Companies of Johnson & Johnson.

Derek has thirty years of experience in materials research, characterization, and process development to manufacture new products. A recent example is as a leading scientist, he developed highly porous titanium foams and their implants have been launched successfully to global market including US and European countries since early 2012. These products were also obtained CFDA approval in 2016. Derek is familiar with the materials used for joint replacement such as titanium, CoCrMo alloys, and UHMWPE as well as process quality control and validation. His areas of expertise include studying materials microstructures, phase transitions and mechanical properties. Since 2011 he has been providing technical support to J&J China RA. Derek received his Ph.D. in Materials Science & Engineering at University of Surrey in England.

刘恒达
高级首席科学家，强生 DePuy Synthes 法规事务部副总监

刘恒达，英国萨里大学材料科学与工程博士。从事材料研究及新产品制造工艺的研发三十年。近期的一例是作为项目的主要技术负责人，领导研发了高孔隙度的多孔钛材料，其产品自 2012 年初起已在全球包括美国和欧洲的多个国家成功上市，并于 2016 年获中国药监局的批准。他熟悉各种人工骨关节置换材料，如钛，钴铬钼合金和超高分子量聚乙稀的特性及其生产工艺的质量控制和认证。他的专长包括研究材料的显微结构，相变及力学性能的测试。自 2011 年起开始为强生中国公司的法规事务部提供技术方面的支持。

Jia Zheng

National Institutes For Food and Drug Controls, Institute for medical device standard administration, Associate researcher, management and research of standards for medical electrical equipment.

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，从事医用电气设备相关标准管理工作。

George Odero

Corporate Regulatory Affairs, Systems & Standards, Hologic Inc.

George Odero (Odero) is the Director, Corporate Regulatory Affairs, Systems & Standards for Hologic Inc. based in Marlborough, MA where he is accountable to design, develop and establish global Corporate RA strategic planning and tactical execution ensuring a superior-level and proactive approach with global consistency. Odero is also responsible for leading global Systems and Standards methodologies to improve compliant fast-to-market strategies that enable International revenue growth.

Born in Nairobi, Kenya, Odero is a RAC(Global) credentialed, Regulatory, Quality, Systems & Standards, and Clinical professional, with over 20+ years International 'hands-on' experience spanning governmental, private healthcare, and biotechnology industries with a focus on medical devices (including combination devices) and IVD industries. Odero studied Biochemistry, Medical Science (with emphasis on Microbiology & Immunology), and Industrial Property Law (emphasis on Patent, Designs and Trade Mark) and recently completed the RAPS (Regulatory Affairs Professional Society) Executive Development Program at Northwestern Kellogg School of Management in Evanston, IL, USA.

Daniel Chen

Member of SAC/TC10/SC1 and SAC/TC10/SC2, Sr. manager Global Regulations & Standards of Philips. Participated in the research of medical devices technologies, provided technical consultancy to the pre-marketing activities, and widely joined regulatory and standardization relevant activities.

谌达宇

SAC/TC10/SC1 与 SAC/TC10/SC2 委员，飞利浦全球法规与标准部门高级经理。曾参与医疗器械技术的研发，为上市前提供技术咨询，广泛参与法规与标准相关工作。

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

温凯时的职务是美国贸易发展署东亚区项目主任，就任于美国驻华使馆。他负责美国贸易发展署在中国和蒙古的项目，指导业务拓展，协调项目所在国相关方与美方的关系，并推动美国贸易发展署与两国潜在合作伙伴的合作。

在就任之前，温凯时在北京一家从事交通基础设施项目的美国咨询公司工作。在此之前，他担任过美国贸易发展署负责中国，东南亚项目的项目经理。还有过在美国商务部从事政策分析的经历。温凯时拥有罗德大学文学学士和乔治城大学公共政策硕士学位。

Presentations

演讲材料

中国医疗器械标准管理
China Medical Device Standardization Administration

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）
余新华
2018.3.26

医疗器械标准管理中心主要职能 Responsibilities of Center for Medical Device Standardization Administration

01 组织开展医疗器械标准体系的研究，拟定医疗器械标准规划草案和标准制修订年度工作计划建议

02 依法承担医疗器械标准制修订的管理工作，承担医疗器械标准信息化工作，组织医疗器械行业标准出版

03 依法承担医疗器械标准化技术委员会的管理工作

04 承担医疗器械标准宣传、培训的组织工作

05 组织对标准实施情况进行调研，协调解决标准实施中的重大技术问题

06 承担医疗器械国际标准化活动和对外合作交流的相关工作

CONTENTS

1 中国标准化改革 China standardization reform

2 医疗器械标准管理 Medical device standardization administration

1.1 中国标准化改革进程Process of China's standardization reform

2015.3 国务院《深化标准化工作改革方案》 'Deepening the reform program for standardization work'

2016.1 国务院办公厅《强制性标准整合精简工作方案》 Program for the consolidation and reduction of mandatory standards

2016.3 国家标准委印发《关于培育和发展团体标准的指导意见》 'Guidance on the development of group standards'

2017.11 《中华人民共和国标准化法》发布 'People's Republic of China Standardization Law' released

1.2 标准化改革措施Measures of China's standardization reform

01 建立标准化统筹协调机制 Establishment of the standardization and coordinating mechanism

02 整合精简强制性标准 consolidation and reduction of mandatory standards

03 优化完善推荐性标准 Optimization of voluntary standards

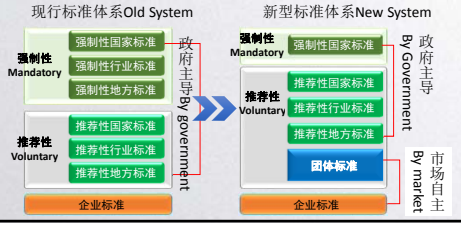
04 培育发展团体标准 Development of association standards

05 放开搞活企业标准 Invigoration of enterprise standards

06 提高标准国际化水平 Improvement of standard internationalization level

1.3 标准化改革总体目标 Target of standardization reform

➢建立政府主导制定的标准与市场自主制定的标准协同发展、协调配套的新型标准体系 To establish a new standard system for coordination of the standards developed by government and by the market



1.4 政府标准的种类 Government standard

强制性国家标准 Mandatory national standards

必须执行 Must be implemented

•对保障人身健康和生命财产安全、国家安全、生态环境安全以及满足经济社会管理基本需要的技术要求。
To address technical requirements for ensuring people's health and the security of their lives and property, safeguarding national and eco-environmental security, and meeting the basic need of economic and social management.
•国务院有关行政主管部门依据职责负责强制性国家标准的项目提出、组织起草、征求意见和技术审查。国务院批准发布或者授权批准发布。
Relevant administrative departments under the State Council shall, according to their duties and responsibilities, propose mandatory national standards and organize drafts, solicit opinions and conduct technical reviews thereof. Mandatory national standards shall be approved and published, or authorized for approval and publication, by the State Council.

推荐性国家标准 Voluntary national standards

鼓励采用 Encourage adoption

•对满足基础通用、与强制性国家标准配套、对各有关行业起引领作用等需要的技术要求。To address technical requirements that are needed to serve basic and generic purposes, support mandatory national standards or play a leading role in relevant industries.

•由国务院标准化行政主管部门制定 。Voluntary national standards shall be developed by the administrative department in charge of standardization under the State Council.

推荐性标准 Voluntary standards

鼓励采用 Encourage adoption

•行业标准：对没有推荐性国家标准、需要在全国某个行业范围内统一的技术要求，可以制定行业标准行业标准。由国务院有关行政主管部门制定。Sector standards shall be developed by relevant administrative departments under the State Council and submitted to the administrative department in charge of standardization under the State Council for registration.
•地方标准：为满足地方自然条件、风俗习惯等特殊技术要求。由省、自治区、直辖市人民政府标准化行政主管部门制定。 Local standards may be developed to address local special technical requirements, such as natural conditions and customs. Local standards shall be developed by administrative departments in charge of standardization of people's governments of provinces, autonomous regions and municipalities directly under the central government.

1.5 市场标准的种类 Market standard

团体标准 Association standards

团体成员约定采用或社会自愿采用 adopted by their members upon agreement or maybe made publicly available for voluntary adoption by others

•制定主体： 依法成立的社会团体
•Who: Association established according to law
•制定范围：无限制
Range :No limit
•制定原则：不得低于强制性标准的相关技术要求，鼓励高于推荐性标准相关技术要求
Principles :must not be less strict than relevant technical requirements of mandatory national standards， encourage stricter than relevant technical requirements of voluntary standards.

企业标准 Enterprise standards

自用 Adoption by enterprise

•制定主体：企业或企业联合
Who: Enterprise or work with other enterprises
•制定范围：无限制
Range: No limit
•制定原则：不得低于强制性标准的相关技术要求，鼓励高于推荐性标准相关技术要求
Principles :must not be less strict than relevant technical requirements of mandatory national standards， encourage stricter than relevant technical requirements of voluntary standards.

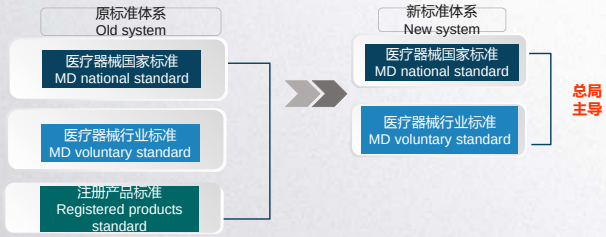
CONTENTS

1 中国标准化改革 China standardization Reform
2 医疗器械标准管理 Medical device standardization administration

医疗器械标准化改革
MD standardization reform

- 《标准化法》：“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”。
  Standardization Law: Where laws, administrative regulations and decisions of the State Council otherwise provide concerning developing mandatory national standards, those provisions shall prevail
- 《医疗器械监督管理条例》：“生产医疗器械，应当符合医疗器械国家标准；没有国家标准的，应当符合医疗器械行业标准。”
  Regulations on the supervision and administration of medical device: Medical devices shall meet the mandatory national standards, or mandatory professional standards when there are no relevant mandatory national standards available.

2.1 医疗器械标准体系变化
Changes of MD standard system

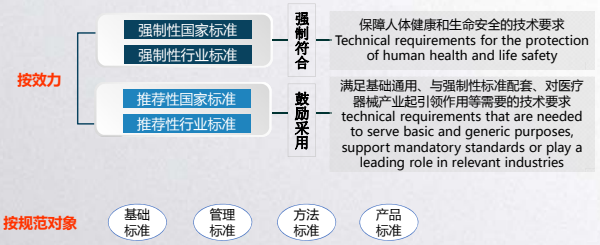


2.2 器械标准管理法规修订
Revision of MD standardization regulations

《医疗器械标准制修订工作管理规范》发布
CFDA published ‘Specification for medical device development administration ’
2017.12

2017.2
《医疗器械标准管理办法》发布（局令第33号），17年7月1日实施
CFDA released ‘Regulation for medical device standard administration’

- 明确了医疗器械标准的分类及依据The classification of medical device standards



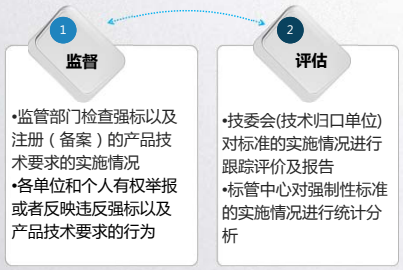
- 明确各相关方承担的标准化职责和工作内容Clarify responsibilities of the relevant parties

- 明确标准制修订每个环节的实施主体Clarify implementation department for each step of the standard development progress

➢增加重点环节工作要求，提高制修订过程的广泛参与度和公开透明度Increasing requirement of key steps to improve the extensive participation and transparency of the process

立项	增加立项提案向社会公开征集以及标准计划项目公示等程序。
起草	任何医疗器械生产经营企业、使用单位、监管部门、检测机构以及有关教育科研机构、社会团体等，均可以提出起草单位的申请。
征求意见	在技委会及归口单位组织征求意见的基础上，增加医疗器械标准管理中心向社会公开征求意见，时间延长至2个月。
信息化	对医疗器械标准实行信息化管理要求，标准立项、发布、实施等信息及时向公众公开。
快速程序	对监管亟需标准，新增快速程序，在立项、征求意见、报批等环节缩短时间。

➢加强实施监督，实现对医疗器械标准的闭环管理
Increase the requirements for standard implementation tracking and evaluation



2.3 推进标准制修订Improving standard development

➢ 截止2018年2月，医疗器械标准总数已达到1580项。Until 2018.2, the number of MD standards is 1580（强制性454、推荐性1124）

2016-2017年医疗器械行业标准制修订情况统计表

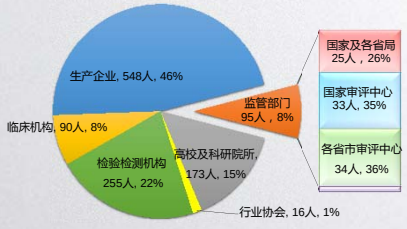
	制定	修订	小计
2016年发布行标	190	60	250
2017年发布行标	64	23	87
2017年完成项目	47	39	86
合计	301	122	423

2.4 提升标准管理工作 Improvement in standardization management

2.5 强化技委会管理工作 Improvement in TC management

➢ 加强24个技委会管理，优化技委会委员构成Strengthen the management of 24 TC and optimize the composition of the committee members

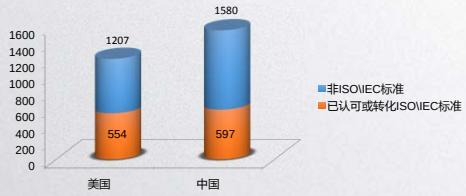
医疗器械标准化（分）技术委员会委员行业分布情况统计图



2.6 加快国际标准转化Accelerate the adoption of international standards

➢ 与国际标准一致性程度逐步提升，应转化国际标准转化率达94% Adoption rate is 94%

中美医疗器械标准ISO/IEC标准认可/转化情况统计图（需更新我国的情况）



2.7 深入开展国际标准交流合作 International Cooperation

一是大力扩展标准化国际“朋友圈“

•和ANSI、IEC、德国DKE、IEEE等组织在IEC60601-1第4版、外科器械、医用机器人、移动医疗等领域开展沟通合作

二是争取更多国际标准化活动“话语权“

•当选为IMDRF国际标准研究工作组副召集人，实质性参与国际医疗器械标准管理研究工作（优化为监管所用的标准指南）

三是培养中国医疗器械标准国际型人才

•承办IMDRF等国际标准研究工作会议，使我国更多年轻专家参加国际标准化活动

2.8 下一步工作思路 Next work plan

医疗器械监管新要求

国家标准改革新趋势

器械产业发展新需求

器械标准发展新任务

标准管理关键时期

持续提升医疗器械标准科学性和可实施性

充分发挥标管中心统筹协调、技术管理作用

以管理促进标准提升

以需求引领标准提升

以科技支撑标准提升

2.8.1 “十三五“医疗器械标准发展任务 The task of medical device standards in 13th Five-Year

2015.8 国务院《关于改革药品医疗器械审评审批制度的意见》

- •及时修订医疗器械标准
- •提高医疗器械国际标准的采标率

2016.3 国务院办公厅《关于促进医药产业健康发展的指导意见》

- •实施医疗器械标准提高行动计划
- •推动高风险医疗器械的质量标准升级
- •提高标准的科学性、合理性及可操作性、

2016.8 国务院常务会议《装备制造业标准化和质量提升规划》

- •高性能器械等重点领域标准化实现新突破
- •2020年重点领域国际标准转化率提高到90%

2.8.2 重点领域标准化战略规划 Standard strategic planning in key areas

➢ 加强完善医疗器械标准体系，重点研究与高性能医疗器械技术创新、产业发展趋势和需求相适应的标准工作规划Improve standard system of medical device, and focus on the standard strategic plan of high performance medical devices.

医用机器人

移动医疗

组织工程

高性能医疗器械

先进医学影像

新型生物材料

先进治疗设备

1 国内外产业发展和监管政策调研

2 国内外标准对比研究

3 3-5年标准体系规划

2.8.3 标准科研 Standard research

01 医用机器人 Medical Robotics

2项医疗器械行业标准

1项IEEE标准

02 设备能耗 Energy use

国家指导性文件《医用电气设备能源消耗评价导则》

03 移动医疗

2.8.4 国际合作

➢进一步深化国际合作，实质性参与国际标准制修订工作To further improve international cooperation and substantively participate in international standard development :

➢争取继续承办2018年IMDRF国际标准研究工作组会议

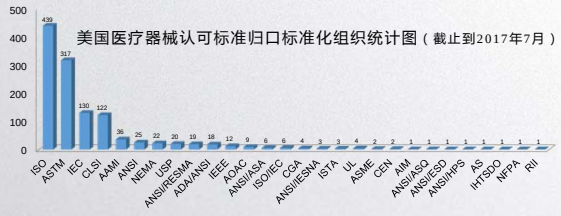
Meeting of IMDRF standard Working Group Meeting

➢选派更多中国专家参加IMDRF、IEC、IEEE标准工作组

To recommend more Chinese experts to participate IMDRF, IEC, IEEE

2.8.5 新型标准工作机制研究 Research of new mechanism for MD standards

➢研究政府标准和团体标准协调工作机制Research on the coordination mechanism of government standards and associate standards ：



U.S. FDA Complementary Functions of Regulations and Standards

Bill Sutton
萨盾
International Program and Policy Analyst (Medical Devices)
U.S. FDA China Office
U.S. Embassy, Beijing

March 26, 2018
Beijing, China

Presentation Outline

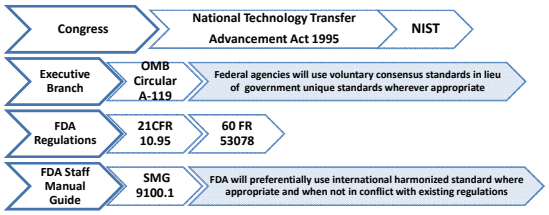
- U.S. National Standards Strategy
- Definition & types of standards
- Introduction to CDRH Standards Program
- Recognition
- Emerging Technologies "Digital Health"
- Resources for You

Why Are Standards Important?

Consistency + Predictability + Credibility

= Science Based Decisions

Legislative Authority, Executive Branch Policy and FDA Participation



Regulations vs Standards

Regulations

- Authority to issue from laws (statues) enacted by Congress.
- Agency issues proposed rule in *Federal Register*.
- Public comments received by the Agency.
- Final Rule published in *Federal Register*.
- Final Rule is ***enforceable!***

Standards

- Authority to recognize/use from (statues) enacted by Congress.
- Agency follows a process to recognize standards.
- FDA publishes in the *Federal Register* once per year a list of recognized standards.
- Use of any consensus standards is ***voluntary***.

Definitions

- The term "standard," or "technical standard" as cited in the National Technology Transfer and Advancement Act of 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."

"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."

Voluntary Consensus Standard

- Voluntary consensus standards are standards developed or adopted by voluntary consensus standards bodies, both domestic and international using agreed-upon procedures.
- A voluntary consensus standards body is defined by the following attributes:
  - Due Process
  - Openness
  - Balance
  - Consensus

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

7

Types of Standards

- Basic standard (broad ranging effects)
- Terminology standards
- Test and measurement standards
- Product specific (or related group of products) standards
- Process management standards
- Interface and data communication standards
- Performance standards
- Design standards

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

8

Other Types of Standards

- International standards such as:
  - International Organization for Standardization (ISO)
  - International Electrotechnical Commission (IEC)
- Harmonized standards, e.g., CEN/CENELEC (Annex Za Essential Principles)
- Country-specific standards
- Country-specific mirror adoptions of international standards
- Industry standards
- Government-unique standards

9

Center for Devices and Radiological Health (CDRH)Mission

- Protect and promote the public health
- Patients and providers have timely & continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products.
- 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.

10

CDRH Standards Involvement

- 660+ Committees and Working Groups
- 350+ Employees
- 1255 Recognized Standards
- 758 International Standards
- 19 Specialties
- 47 Federal Register Notices

Priorities:

- How effective is the scope of the standard in addressing/mitigating a potential health hazard?
- How useful is it in managing CDRH's workload?
- What would be the consequences of non-participation?

11

Horizontal Device Standards

- Quality Management (e.g., ISO 13485)
- Risk Management (e.g., ISO 14971)
- General Safety & Design (e.g., AAMI HE75, IEC 62366, etc.)
- Industrial Sterilization (e.g., ISO 11135, ISO 11137, etc.)
- Aseptic Processing (e.g., ISO 13408 series)
- Biological Evaluation (e.g., ISO 10993 series)
- Electrical Safety (e.g., AAMI ES60601-1, etc.)
- Medical Device Software (e.g., IEC 62034, IEC 80001, etc.)
- Medical Device Connectors (e.g., ISO 80369, etc.)

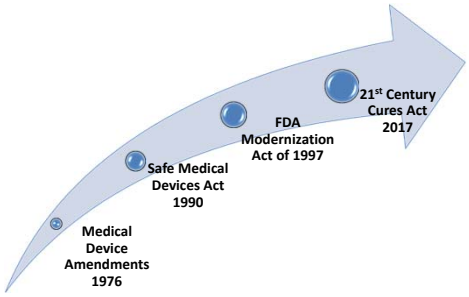
12

Vertical Device Standards

- Medical devices for therapy & surgery (e.g., ESUs, etc.)
- Patient monitoring (e.g., ECG, blood pressure, oximetry, etc.)
- Protective barriers (e.g., gloves, gowns, drapes, masks, etc.)
- Dialysis equipment (e.g., dialyzers, water for dialysis, etc.)
- Cardiovascular implants (e.g., heart valves, pacemakers, etc.)
- Transfusion, infusion and injection devices
- Hip, knee, joint implants
- Cochlear implants
- Intraocular implants

13

CDRH-Specific Laws & Amendments to FD&C Act Sec. 514(c)



14

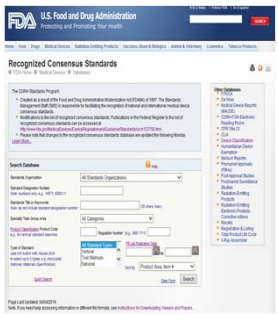
Recognition Notices

- Federal Register, February 25, 1998 (FR 9561)
  - Guidance document, 2007
  - Modifications (Table 1)
    - Withdrawals and replacements
    - Corrections of errors
    - Certain changes to supplementary information
  - New Standards (Table 2)

15

Supplementary Information

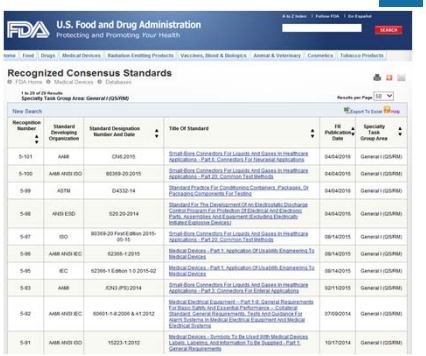
- One sheet per standard
- Updated on the Monday after FR publication
- Agency's position on recognition: complete or in part
- Soon to come: Non-Recognition



16

Typical Search Return

This is a screen shot of a search using the medical specialty: General I



17

Supplementary Information

A supplementary information sheet after selecting one of the standards.

18

Requests for FDA Recognition of Standards

- Any interested party may request recognition of a standard by Email at CDRHStandardsStaff@fda.hhs.gov
- Your Request should including the following:
  - Name & email (or mailing) address of the requestor
  - Title of the standard
  - Any reference number and date
  - Proposed list of device types for which a declaration of conformity would apply
  - Basis for recognition, e.g., including the scientific, technical, regulatory, or other basis for such request,
  - A brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.
- Once submitted, the process for recognition is essentially the same, and a recognized standard will appear in the Federal Register.

19

CDRH Philosophy

Standards:

- Developed when there is a clear need
- Based on current technology
- Developed with consensus
- Incorporated into guidance documents where possible
- Include requirements that are performance-based
- Avoid design standards where possible
- Avoid barriers to technical progress
- Promote inclusion of US technology, existing and emerging

Best Practise Philosophy: *"One product, one standard, one test world-wide."*

20

Emerging Technologies at CDRH

21

Digital Health

- Includes the following categories:
  - Software as a Medical Device (SaMD)
  - Mobile Medical Applications
  - Wireless Medical Devices
  - Digital Health Software Precertification (Pre-Cert) Programs
- Patients and consumers can use digital health to better manage and track their health and wellness related activities.

22

Why is U.S. FDA focusing on Digital Health?

- Many medical devices now have the ability to connect to and communicate with other devices or systems.
- CDRH has established the Digital Health Program
  - Fostering collaboration and outreach to digital health customers
  - Developing and implementing regulatory strategies and polices for digital health technology.

23

Digital Health Innovation Action Plan

- Internet at: https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf
- Questions or Comments by Email at:
  - digitalhealth@fda.hhs.gov

24

Internet Resources

- National Institute of Standards and Technology:
- https://www.nist.gov/standardsgov

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

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

- Device Advice: Comprehensive Regulatory Assistance:
- www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

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

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

25

Contact Information

William (Bill) Sutton

萨盾

美国食品药品管理局

驻华办公室助理主任

William.Sutton@fda.hhs.gov

+86 10-8531-3660 Desk Phone

26

美国食品药品监督管理局

美国食品药品监督管理局
法规与标准的互补功能

Bill Sutton
萨盾
国际项目和政策分析师（医疗器械）
美国食品药品监督管理局驻华办公室
美国驻北京大使馆

2018年3月26日
中国北京

大纲

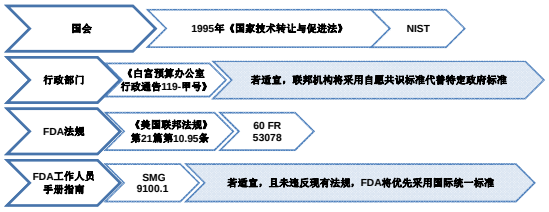
- 美国国家标准战略
- 标准的定义和类型
- CDRH标准计划简介
- 认可
- 新兴技术“数字医疗”
- 可用资源

标准的重要意义?

一致性 + 可预测性 + 可信性

= 基于科学的决策

立法当局、行政部门政策和FDA参与



法规对比标准

法规	标准
• 当局依据国会制定的法律（法令）颁发法规。	• 当局依据国会制定的（法令）认可/使用标准。
• FDA在《联邦公报》上发布拟定法规。	• FDA依照流程认可标准。
• FDA征求公众意见。	• FDA每年在《联邦公报》上发布经认可标准清单。
• 在《联邦公报》上发布最终法规。	• 共识标准应***自愿使用***。
• 最终法规应***强制执行！***	

定义

- 1995年《国家技术转让与促进法》（NTTAA）所引用的术语“标准”或“技术标准”：

“通用的和重复使用的产品或相关工艺和生产方法的规则、条件、指南或特性以及相关管理体系实践。”

“术语定义：零部件分类；程序描述；有关尺寸、物料、性能、设计或操作的说明；描述物料、工艺、产品、系统、服务或实践的质量和数量测量结果；检测方法和取样程序；或尺寸描述和大小或浓度测量。”

自愿共识标准

- 自愿共识标准是指国内外自愿共识标准机构采用约定程序制定或通过的标准。
- 自愿共识标准机构基于如下属性予以界定：
  - 正当程序
  - 公开
  - 公平
  - 共识

**共识是指普遍同意，不一定是全体一致同意，且包括相关方用于解决异议的流程。*

7

标准类型

- 基本标准（广泛影响）
- 术语标准
- 检测和测量标准
- 特定产品（或相关产品系列）标准
- 流程管理标准
- 接口和数据通信标准
- 性能标准
- 设计标准

→**备注**：若可能，NTTAA鼓励行政部门采用自愿共识标准，而无需编制特定政府标准。

8

其他标准类型

- 国际标准，如：
  - 国际标准化组织（ISO）
  - 国际电工技术委员会（IEC）
- 协调标准，如CEN/CENELEC（附录Za——基本原则）
- 特定国家标准
- 特定国家基于国际标准借鉴通过的标准
- 行业标准
- 特定政府标准

9

器械和辐射健康中心（CDRH）使命

- 保护并促进公众健康
- 患者和服务提供商及时并持续使用安全、有效且高质量的医疗器械和安全的辐射产品。
- 通过推进监管科学，向行业提供可预测的、一致的、透明的且高效的监管途径，确保消费者对在美国上市的器械保有信心，促进医疗器械创新。

10

CDRH标准的参与方

- 660多个委员会和工作组
- 350多位员工
- 1255个经认可标准
- 758个国际标准
- 19个专业
- 47个《联邦公报》通知

优先事项：

- 标准在解决/缓解潜在健康危害方面如何发挥作用？
- 标准在管理CDRH工作量方面起到哪些作用？
- 未参与标准相关工作会带来哪些后果？

11

横向器械标准

- 质量管理（如ISO 13485）
- 风险管理（如ISO 14971）
- 一般性安全与设计（如AAMI HE75、IEC 62366等）
- 工业杀菌（如ISO 11135、ISO 11137等）
- 无菌操作（如ISO 13408系列）
- 生物评价（如ISO 10993系列）
- 电气安全性（如AAMI ES60601-1等）
- 医疗器械软件（如IEC 62034、IEC 80001等）
- 医疗器械连接器（如ISO 80369等）

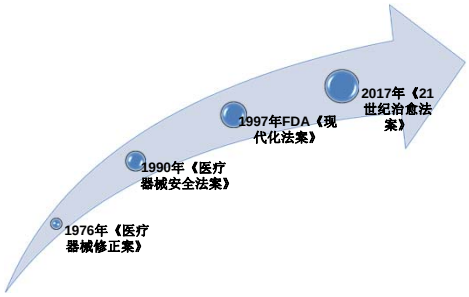
12

纵向器械标准

- 治疗和外科用医疗器械（如ESU等）
- 患者监测（如ECG、血压、血氧测定法等）
- 保护屏障（如手套、工作服、窗帘、面具等）
- 透析设备（如透析器、透析用水等）
- 心血管植入物（如心脏瓣膜、心脏起搏器等）
- 输血、输液和注射装置
- 髋关节、膝关节、关节植入物
- 人工耳蜗
- 眼内植入物

13

CDRH特定法律以及《食品、药品和化妆品法案》第514（c）条修正案



14

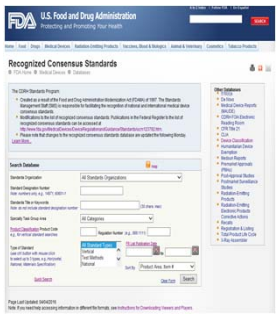
认可通知

- 1998年2月25日《联邦公报》（FR 9561）
  - 2007年指南文件
  - 修改内容（表1）
    - 撤销和取代
    - 错误更正
    - 对补充信息作出若干变更
  - 新标准（表2）

15

补充信息

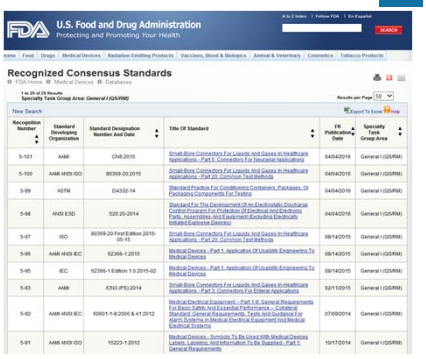
- 每个标准占一页
- 在《联邦公报》发布后的星期一进行更新
- FDA的认可意见：全部或部分认可
- 敬请期待：不认可



16

常见的搜索结果

这是采用医学专业—通用I类—得到的搜索结果截图



17

补充信息

在选择其中一个标准之后出现的补充信息页面

18

向FDA提交标准认可申请

- 任一相关方均可电邮至CDRHStandardsStaff@fda.hhs.gov申请认可某标准。
- 申请应载明如下各项：
  - 申请人姓名和电子邮箱（或邮寄）地址
  - 标准名称
  - 参考编号和日期
  - 符合性声明适用的拟定器械类型清单
  - 认可基准，如就该申请载明科学、技术、监管或其他基准
  - 符合性声明涵盖的有关器械检测或性能或其他特性的扼要说明。
- 针对所提交的申请，认可流程基本相同，经认可的标准将在《联邦公报》上公示。

19

CDRH理念

标准：

- 在有明确需求时予以制定
- 基于当前技术
- 应就标准制定达成共识
- 若可能，纳入指南文件
- 包含性能相关要求
- 若可能，规避设计标准
- 避免技术进步相关障碍
- 促成使用美国现有和新兴技术

最佳实践理念：“在全世界范围内，一个产品对应一个标准、一次检测。”

20

CDRH新兴技术

21

数字医疗

- 包括如下范畴：
  - 医疗器械软件（SaMD）
  - 移动医疗应用程序
  - 无线医疗器械
  - 数字医疗软件预认证（Pre-Cert）计划
- 患者和消费者可使用数字医疗以便更好地管理并跟踪他们的健康状况以及相关活动。

22

美国食品药品监督管理局为何重点关注数字医疗？

- 目前，许多医疗器械能够连接至其他器械或系统或与其他器械或系统进行通信。
- CDRH已经制定数字医疗项目
  - 促进协作和拓展数字医疗客户
  - 就数字医疗技术制定并实施监管战略和政策。

23

数字医疗创新行动计划

- 请登录 https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf
- 如有任何问题或意见，可电邮至：
  - digitalhealth@fda.hhs.gov

24

互联网资源

- 国家标准和技术协会：
- https://www.nist.gov/standardsgov

- CDRH标准计划：
  https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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

- 器械意见：综合性监管援助：
- www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

- CDRH相关信息：
- https://www.fda.gov/Training/CDRHLearn/default.htm

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

25

联系方式

William (Bill) Sutton

萨盾

美国食品药品监督管理局

驻华办公室助理主任

William.Sutton@fda.hhs.gov

+86 10-8531-3660（固定电话）

26

IEC 60601 standards

Implementation Progress in US

IEC 606601标准

在美国的实施与进展

Yening Liang

Yening.Liang@stryker.com

March 26th, 2018 Beijing

Yening Liang, *RAC, MS*

- International Regulatory Affairs, Stryker Corporation, San Jose California.
- 国际法规事务，史赛克公司，加州圣荷西
- Focus: Global Medical Device registrations and standards management.
- 专注领域：医疗器械全球注册和标准管理
- MS in Regulatory Sciences from University of Southern California;
- 南加州大学药学院法规科学硕士
- Regulatory Affairs Certification (RAC) certified USA and International
- 美国和国际法规事务专业认证

Agenda

- Role of Standards 标准的作用
- Global Adoption Status 全球采用状态
- Structure of 60601 Series 60601 系列标准的结构
- Implementation of 3rd ed. 第三版的实施
- 60601 Related Standards1 60601相关标准
- Documentation/TR Form 文件/测试报告表
- Current and future Changes 当前及未来的变化
- Challenges and Opportunities 挑战与机遇

Role of Standard 标准的作用

Role of *Standards*

- Consensus documents for Global Compliance 用于全球范围合规的共识性文件
- Defines Acceptable Level of Risk for Medical Devices 确定医疗器械可接受的风险水平
- Construction and performance requirements 制造和性能要求
- Fulfillment of Regulatory Requirements for Market Access 实现市场准入监管要求

Role of *Standards (in US)* 标准的作用

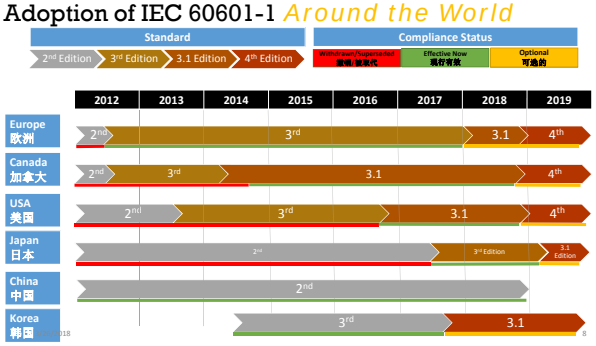
- FDA publishes a list of recognized consensus standards, and states, “conformance with recognized consensus standards can provide a reasonable assurance of safety and/or effectiveness for many applicable aspects of medical devices” .
- FDA公布了一份其认可的共识标准清单，并声明：“符合认可的共识标准可以为医疗器械的安全性和/或有效性在适用的情况下提供合理保证”。
- IEC 60601-1 + national differences is a recognized consensus standard
- IEC 60601-1 +国家差异就是一项FDA认可的共识标准

stryker

IEC 60601 Global Adoption Status 全球采用状态

3/26/2018 7

Adoption of IEC 60601-1 *Around the World*



3/26/2018 8

IEC 60601 in *United States*

stryker

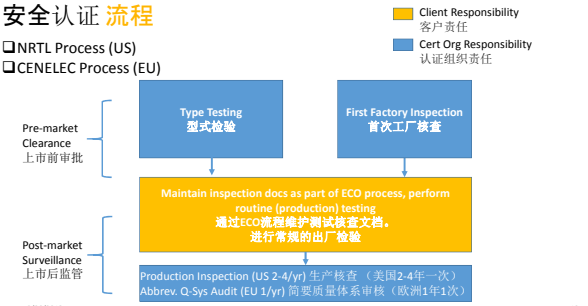
- US FDA Compliance required for entry into US market
- 进入美国市场需要通过美国FDA合规
- Enables supporting claims of safety and effectiveness
- 支持安全性和有效性的声明
- AAMI publishes ANSI/AAMI ES 60601:1:2005/(R)2012
- AAMI发布标准ANSI / AAMI ES 60601：1：2005 /（R）2012

3/26/2018 9

Safety Certification *Process* 安全认证 流程

stryker

❑NRTL Process (US)
❑CENELEC Process (EU)



3/26/2018 10

IECEE *CB Scheme*

stryker

- An international system for mutual acceptance of test reports and certificates
- 一个相互认可检测报告和认证的国际体系
- Accredited lab referred to as CBTL
- 认证实验室称为CBTL
- Accepted by more than 50 member countries
- 被全球50多个成员国所接收
- Intertek, TUV provide CB certificates
- Intertek, TUV等均提供CB认证

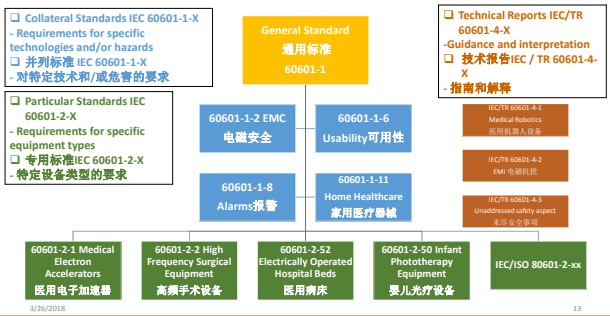
3/26/2018 11

stryker

Structure of IEC 60601 Series 标准体系架构

3/26/2018 12

60601 Series *Collaterals, Particulars*



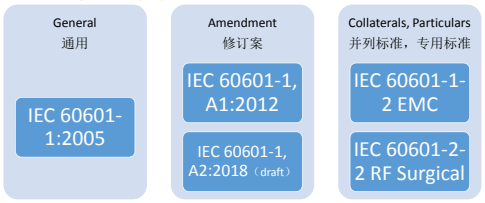
Those dashes *Matter*

- 60601-1 General Standard
  - Applies to all electrical medical devices
- 60601-1-X Collateral standards
  - Potentially applies to all medical devices
- 60601-2-X particular standards
  - May be available for particular device types
- ~~60601-3-X Essential performance standard~~
  - Officially withdrawn in 2012 based on the establishment of IEC 60601-1, 3rd ed
- 60601-4-X Technical Reports
  - Guidance & Interpretation

- 60601-1通用标准
  - 适用于于所有有源医疗器械
- 60601-1-X 并列标准
  - 可能适用于所有有源医疗器械
- 60601-2-X专用标准
  - 适用于标准范围中规定的有源医疗器械
- ~~60601-3-X 基本性能标准~~
  - 由于3版IEC 60601-1 的实施，已于2012正式废止。
- 60601-4-X 技术报告
  - 指导 & 解释

Particular Equipment *Example*
专用标准举例

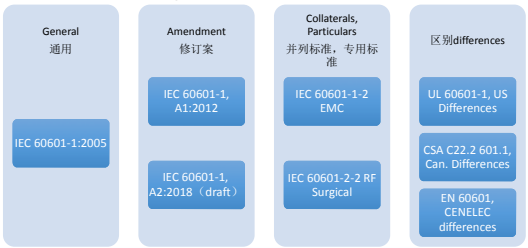
❑RF Surgical Equipment高频手术设备



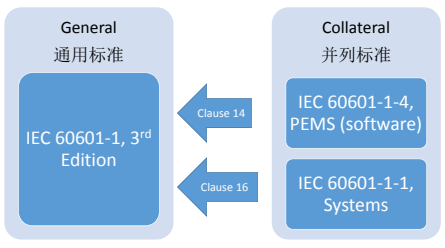
Note: Collaterals and Particulars also have Amendments
并列标准和专用标志也可能有修订案

National/Regional *Differences*
国家/地区 差异

❑Address National/Regional concerns 解决国家和地区的差异



Collaterals Inserted into General Standard, *3rd Edition*
并列标准包含在通用标准中, 第3版



Major sections of *IEC60601-1*
*IEC60601-1*主要组成部分

- Electrical safety – i.e. leakage, dielectric strength
- 电气安全 – i.e. 漏电流, 电介质强度
- Mechanical safety – i.e. stability, pinch
- 机械安全 – i.e. 稳定性, 挤压风险
- Temperature hazards, enclosure flammability – burns
- 超温危害, 外科可燃性 – 烧伤
- Medical systems – additive leakage current
- 医用电气系统 – 附加的漏电流
- Markings and documentations
- 标识和随机文件

Safety Certification *Policy*
安全认证 政策

	NRTL (US) and Canada	CENELEC (EU)
Collaterals **并列标准**	Optional 非强制的	Required 强制的
Particulars **专用标准**	Required 强制的	Required 强制的
Differences **区别**	Required 强制的	Required 强制的

Notes:
- Efficacy requirements left to FDA and Health Canada
- FDA and Health Canada需要提供功效要求
- ETL may require collaterals, CSA only requires a particular when published as CSA Standard, in all cases, check with particular cert org to be sure of policy
- ETL可能需要并列标准，只有专用标准转化为CSA标准时，CSA才要求。具体项目需咨询相应的组织以便确保符合政策。

3rd Edition *Impact*
第三版的影响

- Requires ***during*** the design process
  - Risk Management and Usability Engineering (human factors) processes;
  - Essential performance must be defined and pose acceptable risk during normal use, reasonably foreseeable misuse, and single fault conditions.
- 从设计阶段就开始*要求*
  - 风险管理和可用性工程（考虑人的因素）流程；
  - 必须定义基本性能并提出在正常使用时、合理可预见的误用时以及单一故障时可接受的风险.
- Consistent with regulatory design control requirements
- 与产品设计法规要求保持一致

Implementation of 60601 3rd Risk Management 实施-风险管理

Safety *Philosophy（1）*
安全理念

- Clause 4.1 "…requirements shall apply in Normal USE and reasonably foreseeable misuse"
- 4.1条 "…要求应适用于正常使用和合理可预见的误用"
- Clause 4.2 "A RISK MANAGEMERNT PROCESS complying with ISO 14971 shall be performed"
  - Residual RISK must be acceptable
- 4.2条, 应执行符合ISO 14971 (YY/T 0316)的风险管理过程"
  - 剩余风险必须可接受
- Clause 4.7 "ME Equipment shall be SIGLE FAULT SAFE (free of unacceptable RISK under SIGLE FAULT CONDITION)
- 4.7条,"ME设备应被设计和制造成保持单一故障安全（在单一故障状态下无不可接受的风险）

Safety *Philosophy（2）*
安全理念

- **Clause 4.3** "During RISK ANALYSIS, the MANUFACTURER shall identify the performance of the clinical function(s) of the ME EQUIPMENT or ME SYSTEM, other than that related to BASIC SAFETY, that is necessary to achieve its INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM."
- **4.3条，**在风险分析中，除了与基本安全相关的性能外，制造商还应识别ME设备或系统临床功能的性能，这对于实现预期用途是必须的，或者能够影响ME设备或ME系统的安全性。
- **Clause 12.2** "Address in a USABILITY ENGINEERING PROCESS the RISK of poor USABILITY."
- **12.2条，** 制造商应通过符合IEC 60601-1-6的可用性工程过程来考虑可用性不足的风险

Equivalent *Safety*
同等安全

- "Equivalent Safety" clause
  - 2nd edition, Clause 3.4; 3rd edition, Clause 4.5
- "同等 安全" 条款
  - 2nd edition, Clause 3.4; 3rd edition, Clause 4.5
- Alternative means of addressing risks are acceptable provided that residual risk from applying the alternative means and the verifiable requirements in the standard are equivalent or the alternative means is better (less risk).
- 风险控制替代的措施或试验方法是可接受的。如果应用替代的风险控制措施及试验方法所得到的剩余风险仍然是可接受的或更低

Safety Philosophy *2nd vs 3rd Edition*
安全理念 *2*版 对比 *3*版

When desired, in many cases, 3rd Edition still a test standard with pass/fail criteria
如果需要,在很多情况下3版仍然是一个通过试验判定是否通过的标准

- Can presume acceptable risk with compliance with Clauses containing verifiable requirements
  - Annex A, Guidance and Rationale, Clause 4.2
- 在包括考核要求的条款中也可以保留可接受的风险
  - Annex A, 通用指南和原理说明, Clause 4.2

2nd Edition was foremost a test standard with pass/fail criteria
2版首先是个通过试验判定是否通过的标准

- When desired, allowed risk analysis to evaluate alternative constructions offering "equivalent degree of safety", Clause 3.4
- 如果需要，也可以做风险分析以便评估是否有可替代的方式做同等安全 "同等安全", Clause 3.4

3/26/2018 25

Risk Management *Process*

ISO 14971 Figure 1

3/26/2018 26

Risk Management *Standard*

- ISO 14971, 2nd ed. (2007) – Application of Risk Management to Medical Devices - Current
  - FDA either ISO 14971:2007 Rec#5-40 or AAMI/ANSI/ISO 14971:2007/*2010 Rec#5-70
- ISO 14971, 2nd ed. (2007) –医疗器械风险管理对医疗器械的应用（中国为YY 0316-2016)
  - FDA 对 ISO 14971:2007 Rec#5-40 或 AAMI/ANSI/ISO 14971:2007/*2010 Rec#5-70都认可
- ISO 14971, 3rd ed. – Draft
  - Estimated pub. June 2019
  - 预计于June 2019发布
  - Clarify Normative requirements/ Additional guidance
  - 阐明规范性要求/额外的指导
  - Intent not to change Normative requirements
  - 预期不改变规范性要求
  - ISO TR 24971, 2nd. (Guidance)
  - ISO TR 24971, 2nd. (指导文件)

3/26/2018 27

ISO 14971 Gap Analysis *Checklist*
ISO 14971 差异分析清单

3.1 Risk Management process
3.1风险管理过程
3.2 Management Responsibilities
3.2管理职责
3.3 Qualification of personnel
3.3人员资格
3.4 Risk Management Plan
3.4风险管理计划
3.5 Risk Management File
3.5风险管理文档

4.1 Risk Analysis Procedure
4.1风险分析过程
4.2 Intended use/intended purpose, etc.
4.2医疗器械预期用途和与安全有关特征的识别
4.3 Hazard Identification
4.3危险(源)的识别
4.4 Risk Estimation
4.4估计每个危险情况的风险
5.0 Risk Evaluation
5.0风险评价

3/26/2018 28

ISO 14971 Gap Analysis *Checklist* (cont'd)

6.1 Risk reduction
6.1 降低风险
6.2 Option analysis
6.2风险控制方案分析
6.3 Implementation of risk control measures
6.3风险控制措施的实施
6.4 Residual risk evaluation
6.4剩余风险评价
6.5 Risk-Benefit Analysis
6.5风险/受益分析
6.6 Other generated hazards
6.7 Completeness
6.7风险控制的完整性

7 Overall risk evaluation
7 综合剩余风险的可接受性评价
8 Risk management report
8 风险管理报告
9 Post-production information
- Public data bases
- Manufacturing
- CAPA
- Servicing
- Purchasing

9 生产和生产后信息
- 公共数据库
- 制造
- CAPA
- 服务
- 采购

3/26/2018 29

Implementation of 60601 3rd Usability
实施-可用性

3/26/2018 30

Usability Engineering *Requirements*

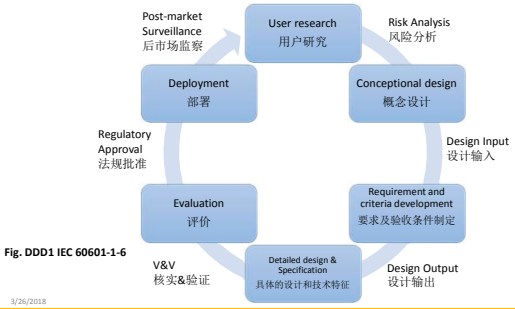


Fig. DDD1 IEC 60601-1-6

Usability *Standards*

- IEC 60601-1-6:2010 + A1 :2013 CSV (ed. 3.1) – MEE…Usability
  - Reference to IEC 62366:2007
  - Acts as a bridge between 60601-1-6 and 62366 reduce duplication of 62366 requirements
  - Current FDA Recognized Consensus standard Rec#5-89
- IEC 62366:2007 + A1 : 2014 CSV (ed. 1.1) – Medical Devices… usability
  - Withdrawn for IEC
  - FDA accepts currently but transition to IEC 62366-1:2015 as of Feb-1-2018 Rec#5-87
- IEC TR 62366-2:2016 (ed. 1.0)
  - Provide guidance
  - Not intended to be used for regulatory purposes

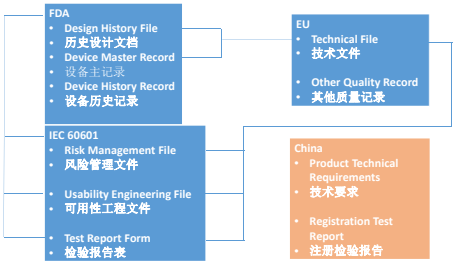
- IEC 60601-1-6:2010 + A1 :2013 CSV (ed. 3.1) – MEE…Usability
  - 参考 IEC 62366:2007
  - 起到 60601-1-6 和 62366间桥梁的作用，减少62366中的重复要求。
  - 是FDA 认可的一致性标准 Rec#5-89
- IEC 62366:2007 + A1 : 2014 CSV (ed. 1.1) – Medical Devices… usability
  - IEC 已废止
  - 2018年2月1日FDA开始只接受IEC 62366-1:2015 Rec#5-87
- IEC TR 62366-2:2016 (ed. 1.0)
  - 提供指南
  - 不用于法规目的

Related Standards 相关标准

60601 Related *Important Standards* 60601相关标准

Records/ Documentation/ Test Report 记录/文档/检测报告

Documentation / *Records* 文档 / 记录



IEC 60601-1 *Test Report Form*
IEC 60601-1 检验报告表

- De-facto world expectation for a Test Report Form is the CB Test Report Form
- 实际上全球通用的检验报告表为CB 检验报告

- IECEE CB Scheme
  - IECEE CB Scheme members agree to exchange IEC 60601-1 Test Report Forms (CB reports) with aim to simply certification through mutual acceptance of test data
- IECEE CB 计划
  - IECEE CB体系成员同意交换IEC 60601-1检验报告表（CB报告），旨在通过相互接受测试数据简化认证过程

- Desirable to use **common report** for global regulatory acceptance
- 希望使用**通用报告**进行不同国家/地区监管验收

Current and Future Changes
现状及未来变化

EMC *3rd vs 4th Edition*

IEC 60601-1-2:2007 + ISH1:10 (3rd ed.) EMC 电磁兼容	IEC 60601-1-2:2014 (4th ed) Electromagnetic disturbances 电磁干扰
• Withdrawn by IEC • IEC已废止此版本	•FDA requires 4th ed. 1/1/19 if not Home Use med device •FDA 要求非家用有源医疗器械需于2019年1月1日满足第4版要求 •FDA Final Guidance "Info to Support a Claim of EMC of Electrically Powered Med Devices" (Jul-11-16) •FDA 指导文件最终版本 "支持有源医疗器械EMC声明的信息" (16年7月11日) •Health Canada, EU under MDD & FDA transition end date of Dec-31-18 •加拿大，欧洲，美国FDA 过度日期截止到2018年12月31日

4th Edition – *Significant Changes*
第四版 – 重大变化

4th Edition and 3rd Edition overview

	3rd Edition	4th Edition
CISPR 11 Emissions	Class A*** or B	Class A*** or B
IEC 61000-3-2 Harmonics	Class A	Class A
IEC 61000-3-3 Voltage Fluctuation	PASS	PASS
IEC 61000-4-2 ESD	8kV contact discharge 8kV air discharge	8kV contact discharge 15kV air discharge
IEC61000-4-3 Radiated disturbance	30MHz – 2.5GHz 3* or 10** V/m	30MHz – 2.7GHz 3* or 10V/m**
IEC61000-4-3 Rearfield disturbance of wireless communication	No requirements	385MHz – 5.7GHz 9-28V/m
IEC61000-4-4 Burst	+/-2kV Repetition frequency 5kHz 1kV Line to Line 2kV Line to GND	+/-2kV Repetition frequency 100kHz 1kV Line to Line 2kV Line to GND
IEC61000-4-5 Surges	3A	30A
IEC61000-4-6 Magnetic Field	150kHz – 80MHz 3* or 10** V	150kHz – 80MHz 3 or 6V ISM* and amateur radio frequency**
IEC 61000-4-6 Conducted disturbance	<5% UT 0.5/1 Cycle 40% UT 5 Cycle 70% UT 25/30 Cycle <5% >UT 5s	0% UT 0.5 different angles 0% 1 Cycle 70% UT 25/30 Cycle 0% >UT 5s
IEC 61000-4-11 Voltage Dips	"life supporting **non-life supporting *** Hospital	* Professional Healthcare Facility Environment ** Home Healthcare Environment *** Hospital

Courtesy Friwo Blog Post Oct 14, 2016

IEC 60601-1, ed. 3.2 (3rd ed. + A2) and Collaterals *Draft*
IEC 60601-1, ed. 3.2 (3rd ed. + A2) 以及并列标准草案

- **Amendments Project**
- **修订案项目**
  - Target publication date Dec 2019
  - 预期于 2019年12月发布
  - 132 issues accepted between 60601-1 & Collaterals
  - 接受问题132个，包含通标与并列标准
  - 78 issues accepted for 60601-1, A2 project
  - 接受78 个其他问题

- **5 collateral standards are Included in project plan**
- **5个并列标准已在列入修订计划**
  - IEC 60601-1-2 Ed. 4.0 → Ed. 4.1
  - IEC 60601-1-6 Ed. 3.1 → Ed. 3.2
  - IEC 60601-1-8 Ed. 2.1 → Ed. 2.2
  - IEC 60601-1-10 Ed. 1.1 → Ed. 1.2
  - IEC 60601-1-11 Ed. 2.0 → Ed. 2.1

- **Amendments Project**
- **修订案项目**
  - Target publication date Dec 2019
  - 预期于 2019年12月发布
  - 132 issues accepted between 60601-1 & Collaterals
  - 接受问题132个，包含通标与并列标准
  - 78 issues accepted for 60601-1, A2 project
  - 接受78 个其他问题

- **5 collateral standards are Included in project plan**
- **5个并列标准已在列入修订计划**
  - IEC 60601-1-2 Ed. 4.0 → Ed. 4.1
  - IEC 60601-1-6 Ed. 3.1 → Ed. 3.2
  - IEC 60601-1-8 Ed. 2.1 → Ed. 2.2
  - IEC 60601-1-10 Ed. 1.1 → Ed. 1.2
  - IEC 60601-1-11 Ed. 2.0 → Ed. 2.1

IEC 60601-1, ed. 3.2 (3rd ed. + A2) and Collaterals *Draft*
IEC 60601-1, ed. 3.2 (3rd ed. + A2) 以及并列标准草案

- ❑ 3 supporting standards to IEC 60601 series updating to align with IEC 60601-1, ed. 3.2 (Critical Issue) to be added into 60601-1, ed. 3.2
- ❑60601系列标准的3个支持性标准进行了版本更新以便与新版IEC 60601-1相匹配。其中的重要内容将被直接包含在60601-1的3.2版中。

Supporting standards 支持性标准	Forecast Publication Date 预计发布日期	Corresponding China Standards 对应的中国标准	
IEC 62366-1:2015 + A1	2019-06-28	IEC 62366-1:2007, IDT	YY/T 1474-2016
IEC 62304, 2nd ed. (draft)	2019-03-29	IEC 62304:2006, IDT	YY/T 0664-2008
ISO 14971, 3rd ed.(draft)	2019-6-28	ISO 14971:2007, IDT	YY/T 0316-20

stryker

Benefits, Challenges and Opportunities
益处，挑战和机会

3/26/2018

43

Worldwide Benefits of Compliance with *IEC 60601-1*
符合 *IEC 60601-1* 带来的全球性益处

stryker

- **Facilitate legal market access**
  - Support declaration of conformity to regulatory safety requirements
- **Facilitate market acceptance**
  - Support obtaining third party marks
  - May give competitive advantage
  - May help resolve legal disputes
- **Facilitate government supervision and international trade**
  - Adoption of internationally advanced safety standards to supervise the quality of products is conducive to ensuring the safety of using medical devices
  - Support technological innovation and stimulate market vitality
  - Promote international trade of Chinese companies

- **促进合法市场准入**
  - 支持符合法规安全要求的声明
- **促进市场接受度**
  - 支持获得第三方认证标识
  - 可能会带来竞争优势
  - 可能有助于解决法律纠纷

- 促进政府监督和国际贸易
  - 以国际先进的安全标准对产品的质量监管，有利于保障人民群众的用械安全
  - 支持技术创新、激发市场活力
  - 促进中国企业国际贸易

3/26/2018

44

Challenges and *opportunities*
挑战和**机遇**

stryker

- Harmonize standards, technical regulations, and conformity procedures globally;
- Implement mutual recognition on conformity assessment globally;
- Enhance technical infrastructure and competency in laboratory testing, calibration, inspection, certification, and accreditation based on regionally/internationally accepted procedures and guides;
- Promote transparency in the development and application of standards, technical regulations, and conformity assessment procedures in line with WTO requirements;
- Strengthen post market surveillance systems to ensure the successful implementation of the harmonized technical regulations.

- 协调全球的标准，技术法规和合规程序;
- 全球实施符合性评定的互认;
- 根据区域/国际接受的流程和导则，强化实验室检测、计量、审核、认证、鉴定方面的技术基础设施和能力;
- 根据世贸组织的要求，提高标准，技术法规和合格评定程序在开发和应用方面的透明度;
- 加强后市场监管制度，确保协调一致的技术法规得到成功实施。

3/26/2018

45

stryker

Questions

3/26/2018

46

Adoption of International Medical Device Standards

Derek Liu

Ph.D., Senior Principal Scientist
Associate Director, Regulatory Affairs
DePuy Synthes Products, LLC.
Companies of Johnson & Johnson

March, 2018

Introduction

- Medical devices are highly regulated by CFDA in China through its rigorous registration process
- The selected materials and testing methods must follow the corresponding China National (GB) or Medical Industry (YY) standards
- Imported products are made according to the internationally recognized standards (ISO/ASTM)
- Ideally if these standards are identical or all acceptable by CFDA, but currently this is not the case
- This raises some questions and causes confusion

Raw Materials

- (Highly Crosslinked) UHMWPE
- Ti-6Al-4V & Ti-6Al-4V ELI Alloy
- CoCrMo Alloy
- Stainless Steel
- CP Ti & Ti-6Al-4V Powder





ASTM F2565-06 Translated into YY 0811-2010

— A good example to adopt international standard

Designation: F 2565 – 06

Standard Guide for
Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications[1]

ICS 11.040.40
C 35

YY

中华人民共和国医药行业标准

YY/T 0811—2010

外科植入物用大剂量辐射交联超高分子量聚乙烯制品标准要求

Standard guide for extensively irradiation—Crosslinked ultra-high molecular weight polyethylene fabricated forms for surgical implant applications

ASTM F2565 / YY 0811

— A standard for highly crosslinked UHMWPE

- This guide pertains only to UHMWPE irradiated by gamma or electron beam with a dose > 40 kGy
- Table 1 lists some tests & methods found useful for characterizing the highly crosslinked UHMWPE
- The manufacturer is responsible to develop their own minimum dataset for their process validation and identify which test methods will be performed routinely for quality control purpose

TABLE 1 Requirements for UHMWPE Fabricated Forms

Test Parameter	Test Method	Test Conditions
Tensile Strength, 23°C, MPa	ASTM D 638	Type IV, 5.08 cm/min
Ultimate		
Yield		
Elongation, %	ASTM D 638	Type IV, 5.08 cm/min
Izod Impact Strength, kJ/m²	ASTM F 648, Annex A1	
Ultimate Load, MPa	ASTM F 2183	
Fatigue Crack Propagation	ASTM E 647	
Compressive Modulus, MPa	ASTM D 1621	
Thermal Properties	ASTM D 3418	
Percent Crystallinity		
Melting Temperature, max		
Residual Free Radicals, spins/g	ESR	
Swell Ratio	ASTM D 2765 or F 2214	
Oxidation Index, SOI and OI max	ASTM F 2102	
t-Vinylene Content, TVI	ASTM F 2381	

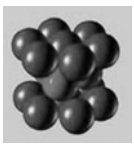
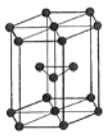
表1 高交联UHMWPE制品的要求

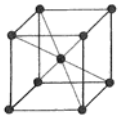
试验参数	试验方法	试验条件
拉拉强度，23°C/MPa 断裂 屈服	ASTM D 638	IV 型，5.08 cm/min
断裂伸长率（%）	ASTM D 638	IV 型，5.08 cm/min
悬臂梁冲击强度（kJ/m2）	ASTM D 648，附录A1	—
极限载荷（MPa）	ASTM F 2183	—
疲劳裂纹扩展	ASTM E 647	—
压缩模量（MPa）	ASTM D 1621	—
热性能 结晶度 熔点，最大值	ASTM D 3418	—
剩余自由基（spins/g）	电子自旋共振	—
溶胀度	ASTM D 2765或 ASTM F2214	—
氧化指数，SOI和OI最大值	YY/T 0722.4	—
反式亚乙烯指数（TVI）	ASTM F2381	—

Ti-6Al-4V & Ti-6Al-4V ELI

- Containing 6% Al (α-stabilizer), 4%V (β-stabilizer)
- ELI: extra-low-interstitial = higher purity
- Good corrosion resistance, strength and toughness
- Crystallographic structure: α + β phases

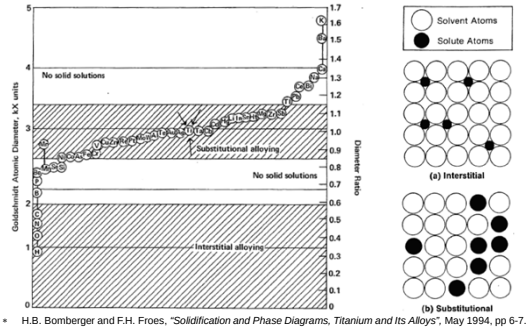
  α: hexagonal close-packed (hcp); β: body-centered cubic (bcc)



Ti-6Al-4V & Ti-6Al-4V ELI

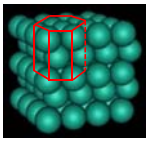
- Atomic diameters of elements
  - Only C. N. O and H can be interstitials for Ti due to their atom size and solubility*

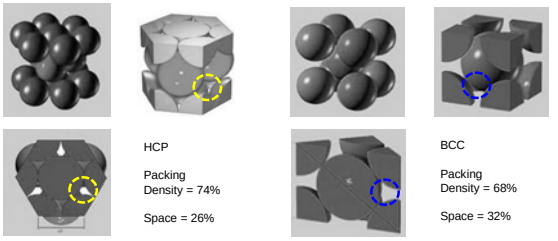


* H.B. Bomberger and F.H. Froes, *"Solidification and Phase Diagrams, Titanium and Its Alloys"*, May 1994, pp 6-7.

Ti-6Al-4V & Ti-6Al-4V ELI

- C, N, O & H take the interstices
- Locations of interstitials in HCP & BCC structures
- Interstitials make Ti alloy brittle and reduce toughness





HCP

Packing Density = 74%

Space = 26%

BCC

Packing Density = 68%

Space = 32%

Ti-6Al-4V & Ti-6Al-4V ELI

- Chemical composition & mechanical properties

	Ti-6Al-4V					Ti-6Al-4V ELI			
Chemical Composition	ISO 5832-3:1996 Wrought Ti-6Al-4V		YY0117.1-2005 Forging Ti-6Al-4V	GB/T 13810-2007 Wrought TC4		GB/T 13810-2007 Wrought TC4 ELI		ASTM F136 Wrought Ti-6Al-4V ELI	
Nitrogen, max	0.05		0.05	0.05		0.03		0.05	
Carbon, max	0.08		0.08	0.08		0.08		0.08	
Hydrogen, max	0.015		0.010	0.010		0.010		0.012	
Iron, max	0.30		0.30	0.30		0.25		0.25	
Oxygen, max	0.20		0.20	0.20		0.13		0.13	
Aluminum	5.5-6.75		5.5-6.75	5.5-6.75		5.5-6.5		5.5-6.5	
Vanadium	3.5-4.5		3.5-4.5	3.5-4.5		3.5-4.5		3.5-4.5	
Titanium	balance		balance	balance		balance		balance	
Mechanical Properties				GB/T 13810-2007 Wrought TC4		GB/T 13810-2007 Wrought TC4 ELI			
Tensile Strength: Rm (MPa) , min	sheet & strip	860	860	0.8~4.57(mm)	926	0.8~25(mm)	860	< 4.75(mm)	860
				>4.57~25(mm)	895			4.75~44.45(mm)	
	Bar	860		>7~50 (mm)	930	>7~45(mm)	860	44.45~63.50(mm)	825
				>50~90(mm)	895	45~90(mm)	825	63.50~101.60(mm)	
0.2% Yield Strength: $Rp_{0.2}$ (MPa) , min	sheet & strip	780	780	0.8~4.57(mm)	870	0.8~25(mm)	795	< 4.75(mm)	795
				>4.57~25(mm)	830			4.75~44.45(mm)	
	Bar	780		>7~50 (mm)	860	>7~45(mm)	795	44.45~63.50(mm)	760
				>50~90(mm)	830	45~90(mm)	760	63.50~101.60(mm)	
Elongation (%) , min	sheet & strip	8	10	0.8~4.57(mm)	10	0.8~25(mm)	10	< 4.75(mm)	10
				>4.57~25(mm)				4.75~44.45(mm)	
	Bar	10		>7~50 (mm)	10	>7~45(mm)	10	44.45~63.50(mm)	8
				>50~90(mm)		45~90(mm)	8	63.50~101.60(mm)	

Ti-6Al-4V & Ti-6Al-4V ELI

ISO 5832-3:2016(E)

Table 1 — Chemical composition

Element	Compositional limits % (m/m)
Aluminium	5.5 to 6.75
Vanadium	3.5 to 4.5
Iron	0.3 max.
Oxygen	0.2 max.
Carbon	0.08 max.
Nitrogen	0.05 max.
Hydrogen	0.015 max.[a]
Titanium	Balance

[a] Except for billets, for which the maximum hydrogen content shall be 0.010 % (m/m).

NOTE 2 A grade with more restrictive limits of oxygen and iron is known under the term "extra low interstitials" (ELI). Commercially available ELI material can also be ordered using this part of ISO 5832. For exact compositional limits of the ELI grade refer to ASTM F136 (UNS R54601) (www.astm.org).

5 Microstructure

The microstructure, when examined as indicated in Table 3, shall be alpha + beta globular and shall correspond to photomicrographs A1 to A9 in ISO 20160 for round bars or 3T1 to 3T13 in EN 3114-003 for sheet and plates (annealed condition each).

Staple - Ti3Al2.5V Alloy

Chemical Composition	GB/T 3620.1-2007	ASTM F3046-13
Nitrogen	≤ 0.05	≤ 0.03
Carbon	≤ 0.08	≤ 0.08
Hydrogen	≤ 0.015	≤ 0.015
Iron	≤ 0.25	≤ 0.25
Oxygen	≤ 0.12	≤ 0.15
Aluminium	2.0 ~ 3.5	2.5 ~ 3.5
Vanadium	1.5 ~ 3.0	2.0 ~ 3.0
Residual: Each	≤ 0.10	–
Residual: Total	≤ 0.30	–
Titanium	Rest	Balance

Ti3Al2.5V as per GB/T 3620 has different composition with compare to ASTM F3046-13

CoCrMo: Casting & Wrought

- Chemical composition & mechanical properties

	CoCrMo: Casting		CoCrMo: Wrought (warm worked)		
Chemical Composition (%)	ASTM F75-2012	YY 0117.3-2005	ASTM F1537-2011 (Alloy 2)	YY 0605.12-2007	ISO 5832-12:2007 (Alloy 2)
Chromium	27.0 ~ 30.0	26.5 ~ 30.0	26.0 ~ 30.0	26.0 ~ 30.0	26.0 ~ 30.0
Molybdenum	5.0 ~ 7.0	4.5 ~ 7.0	5.0 ~ 7.0	5.0 ~ 7.0	5.0 ~ 7.0
Nickel	≤ 0.5	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0
Iron	≤ 0.75	≤ 1.0	≤ 0.75	≤ 0.75	≤ 0.75
Carbon	≤ 0.35	≤ 0.35	0.15 ~ 0.35	≤ 0.35	0.15 ~ 0.35
Silicon	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0
Manganese	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0
Tungsten	≤ 0.2				
Phosphorous	≤ 0.02				
Sulfur	≤ 0.01				
Nitrogen	≤ 0.25		≤ 0.25	≤ 0.25	≤ 0.25
Aluminum	≤ 0.1				
Titanium	≤ 0.1				
Boron	≤ 0.01				
Cobalt	balance	balance	balance	balance	balance
Mechanical Properties	ASTM F75-2012	(= ISO 5832-4:2014)	ASTM F1537-2011 (Alloy 2)	(= ISO 5832-12:1996)	ISO 5832-12:2007 (Alloy 2)
0.2% Yield Strength ($Rp_{0.2}$)	≥ 65 ksi (450 MPa)	≥ 450 MPa	≥ 120 ksi (827 MPa)	≥ 827 MPa	≥ 827 MPa
Tensile Strength (Rm)	≥ 95 ksi (655 MPa)	≥ 665 MPa	≥ 170 ksi (1172 MPa)	≥ 1172 MPa	≥ 1192 MPa
Elongation	≥ 8%	≥ 8%	≥ 12%	≥ 12%	≥ 12%

CoCrMo: Wrought (warm worked)

- ISO made a correction in 2008

INTERNATIONAL STANDARD ISO 5832-12:2007
TECHNICAL CORRIGENDUM 1

Published 2008-09-15

Implants for surgery — Metallic materials —
Part 12:
Wrought cobalt-chromium-molybdenum alloy

TECHNICAL CORRIGENDUM 1

Implants chirurgicaux — Matériaux métalliques —
Partie 12: Alliage corroyé à base de cobalt, de chrome et de molybdène
RECTIFICATIF TECHNIQUE 1

Technical Corrigendum 1 to ISO 5832-12:2007 was prepared by Technical Committee ISO/TC 150, Implants for surgery, Subcommittee SC 1, Materials.

Page 2, Table 2, column 2, row 4

The tensile strength for warm worked material should read 1 172 MPa.

CoCrMo: Casting & Wrought

- Chemical composition & mechanical properties

	CoCrMo: Casting		CoCrMo: Wrought (annealed)		
Chemical Composition (%)	ASTM F75-2012	YY 0117.3-2005	ASTM F1537-2011 (Alloy 2)	YY 0605.12-2007	ISO 5832-12:2007 (Alloy 2)
Chromium	27.0 ~ 30.0	**26.5 ~ 30.0**	26.0 ~ 30.0	26.0 ~ 30.0	26.0 ~ 30.0
Molybdenum	5.0 ~ 7.0	**4.5 ~ 7.0**	5.0 ~ 7.0	5.0 ~ 7.0	5.0 ~ 7.0
Nickel	≤ 0.5	**≤ 1.0**	≤ 1.0	≤ 1.0	≤ 1.0
Iron	≤ 0.75	**≤ 1.0**	≤ 0.75	≤ 0.75	≤ 0.75
Carbon	≤ 0.35	≤ 0.35	0.15 ~ 0.35	**≤ 0.35**	0.15 ~ 0.35
Silicon	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0
Manganese	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0
Tungsten	≤ 0.2				
Phosphorous	≤ 0.02				
Sulfur	≤ 0.01				
Nitrogen	≤ 0.25		≤ 0.25	≤ 0.25	≤ 0.25
Aluminum	≤ 0.1				
Titanium	≤ 0.1				
Boron	≤ 0.01				
Cobalt	balance	balance	balance	balance	balance
Mechanical Properties	**ASTM F75-2012**	**(= ISO 5832-4:2014)**	**ASTM F1537-2011 (Alloy 2)**	**(= ISO 5832-12:1996)**	**ISO 5832-12:2007 (Alloy 2)**
0.2% Yield Strength ($Rp_{0.2}$)	≥ 65 ksi (450 MPa)	≥ 450 MPa	≥ 75 ksi (517 MPa)	**≥ 550 MPa**	≥ 517 Mpa
Tensile Strength (Rm)	≥ 95 ksi (655 MPa)	**≥ 665 MPa**	≥ 130 ksi (897 MPa)	**≥ 750 MPa**	≥ 897 Mpa
Elongation	≥ 8%	≥ 8%	≥ 20%	**≥ 16%**	≥ 20%

Wrought High Nitrogen Stainless Steel

- Chemical composition & mechanical properties

Chemical Composition (%)	ASTM 1586-2013		YY 0605.9-2007	ISO 5832-9:2007
Carbon	≤ 0.08		≤ 0.08	≤ 0.08
Manganese	2.00 ~ 4.25		2.00 ~ 4.25	2.00 ~ 4.25
Phosphorous	≤ 0.025		≤ 0.025	≤ 0.025
Sulfur	≤ 0.01		≤ 0.01	≤ 0.01
Silicon	≤ 0.75		≤ 0.75	≤ 0.75
Chromiun	19.5 ~ 22.0		19.5 ~ 22.0	19.5 ~ 22.0
Nickel	9.0 ~ 11.0		9.0 ~ 11.0	9.0 ~ 11.0
Molybednum	2.0 ~ 3.0		2.0 ~ 3.0	2.0 ~ 3.0
Nitrogen	0.25 ~ 0.50		0.25 ~ 0.50	0.25 ~ 0.50
Niobium	0.25 ~ 0.80		0.25 ~ 0.80	0.25 ~ 0.80
Copper	≤ 0.25		≤ 0.25	≤ 0.25
Iron	balance		balance	balance
Residual: Each	/		≤ 0.1	≤ 0.1
Total	/		≤ 0.4	≤ 0.4
Mechanical Properties (Annealed)	**ASTM 1586-2013**		**(= ISO 5832-9:1992)**	**ISO 5832-9:2007**
Tensile Strength: Rm (MPa), min	Bar	740	740 (d ≤ 80 mm)	740 (d ≤ 80 mm)
	Sheet & strip	740	**770**	**770**
0.2% Yield Strength: $Rp_{0.2}$ (MPa), min	Bar	430	430 (d ≤ 80 mm)	430 (d ≤ 80 mm)
	Sheet & strip	430	**465**	**465**
Elongation (%), min	Bar	35	35 (d ≤ 80 mm)	35 (d ≤ 80 mm)
	Sheet & strip	35	35	35

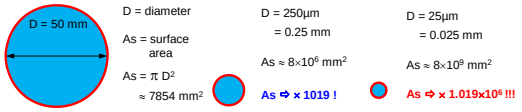
CP Ti & Ti-6Al-4V Powder

- YY & ISO do not have a standard for CP Ti or Ti-6Al-4V pre-alloyed powder
- ASTM F1580 is for CP Ti & Ti-6Al-4V alloy powder for coatings of surgical implants
- Chemical compositions of these powders were examined using corresponding bulk material standards in China

	Ti-6Al-4V		CP Ti	
Chemical Composition (%)	ISO 5832-3:1996 Wrought Ti-6Al-4V	ASTM F1580-2012 Ti-6Al-4V Powder	ISO 5832-2:1999 CP Ti grade 4	ASTM F1580-2012 CP Ti Powder
Nitrogen, max	0.05	0.05	0.05	0.05
Carbon, max	0.08	0.08	0.10	0.08
Hydrogen, max	0.015	0.015	**0.0125**	0.05
Iron, max	0.30	0.30	0.50	0.50
Oxygen, max	0.20	**0.20**	0.40	**0.40**
Copper, max	/	**0.10**		
Tin, max	/	**0.10**		
Aluminum	5.5-6.75	5.5-6.75		
Vanadium	3.5-4.5	3.5-4.5		
Titanium	balance	balance	balance	balance

CP Ti & Ti-6Al-4V Powder

- Small particles have larger surface area when occupy the same volume
- Ti and Ti alloys form a layer of titanium oxide film spontaneously in air on their surface
- Ti and Ti-6Al-4V alloy powders after sintering / 3D print processing usually show higher oxygen content, so they cannot meet the corresponding bulk material standards
- YY0118-2016 accepts ASTM F1580 for Ti & Ti-6Al-4V powder



About Raw Materials

- ISO 5832 (1 ~ 14) consists of metallic materials for surgical implants
- Note 1 in each **Scope** states:
  *"The mechanical properties of a sample obtained from a finished product made of this alloy **can differ from** those specified in this part of ISO 5832."*
- YY standards have the same statement
- It applies to metallic materials as well as other raw materials
- **Raw materials ≠ Finished products**
  - Sample dimension effects
  - Machining effects
  - Processing effects
- Properly designed product function tests play an important role to further examine the **safety** of the medical device

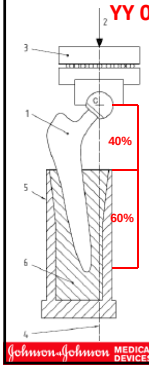
Testing Methods

- Hip stem distal fatigue test
- Suture needle test

ISO 7206-4: hip stem distal fatigue test

2002 vs. 2010: potting level change

YY 0118-2016 calls for ISO 2010 version



2002:
D = 0.4 CT

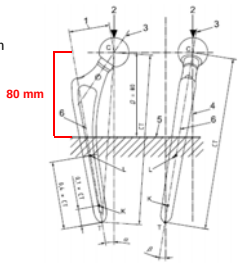
CT = 125 mm D_{125} = 50 mm

CT = 250 mm D_{250} = 100 mm

Key:

1. Test specimen
2. Load
3. Loading mechanism
4. Load line
5. Test specimen holder
6. Embedding medium

2010:
D = 80 mm



ISO 7206-4: 2010

Table 2 — Parameters for testing

Kind of stem	Short, monobloc, modular neck, modular femoral		
CT (mm)	⩽ 120	120 < CT ⩽ 250	> 250
F_D (N)	1 200[a]	2 300[b]	1 200[c]
Number of cycles	5×10^6		
Number of unbroken specimens	6		

NOTE 1 Alternative methods might be deemed to be acceptable if minimum run-out loads calculated by statistical means meet the requirements given by this part of ISO 7206 at 95 % confidence.

NOTE 2 For modular femoral stems additional tests might be necessary.

[a] This value is not based on extensive clinical experience but given as a lower limit and may need to be adjusted upwards based on design and material considerations, and clinical experience with stems of similar design and material that have been implanted in significant numbers with a long-term (> 5 years) history with no significant numbers of fractures in the highly stressed regions evaluated by this test method.

[b] This value is based on the previous requirement in ISO 7206-6 for a stem for the average patient (in Europe). Some smaller stems in the size range (120 mm to 250 mm) and not intended for use in the average patient (in Europe) have been used clinically long-term without fracture and have not met the 2 300 N requirement. Smaller stems in this size range could have a performance requirement lower than 2 300 N when they can be shown to be as strong as stems of similar design and material, which have been implanted in significant numbers with a long-term (> 5 years) history with no significant numbers of fractures in the highly stressed regions evaluated by this test method.

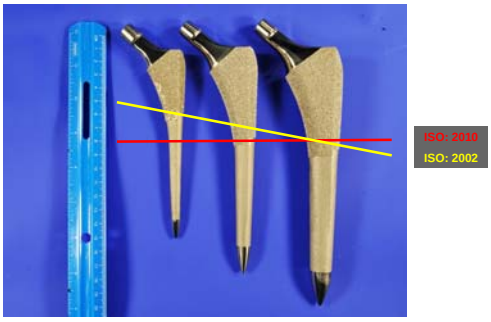
[c] This value is based on limited clinical experience but given as a lower limit and may need to be adjusted upwards based on design and material considerations, and clinical experience of similar devices.

Summit hip stem family: sizes 1 – 10

Stem Size: 1 2 3 4 5 6 7 8 9 10

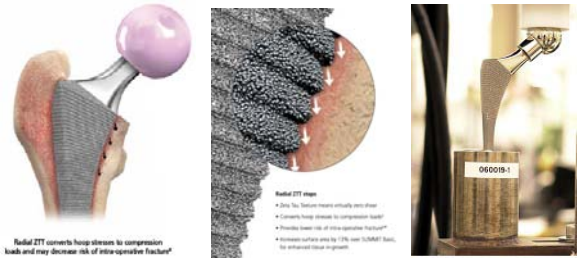
Load Force ≡ 2300 N (patients use sizes 1 and 10 respectively have different body weight)

Potting level change in small, medium & large Summit hip stems



Stem Size: 1 6 10

Summit hip stems: biologic fixation in proximal region



- Cortical contact proximal encourages proper load distribution
- Reduced proximal stress shielding

ISO 7206-4: 2010

Table 2 — Parameters for testing

Kind of stem	Short, monobloc, modular neck, modular femoral		
CT (mm)	⩽ 120	120 < CT ⩽ 250	> 250
F_D (N)	1 200[a]	2 300[b]	1 200[c]
Number of cycles	5×10^6		
Number of unbroken specimens	6		

NOTE 1 Alternative methods might be deemed to be acceptable if minimum run-out loads calculated by statistical means meet the requirements given by this part of ISO 7206 at 95 % confidence.

NOTE 2 For modular femoral stems additional tests might be necessary.

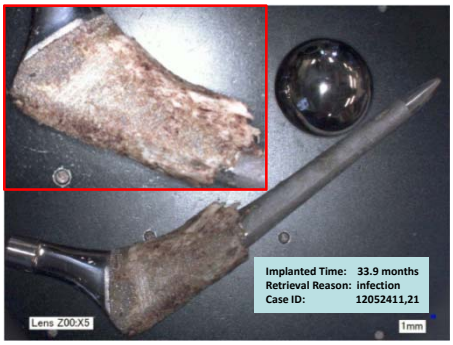
[a] This value is not based on extensive clinical experience but given as a lower limit and may need to be adjusted upwards based on design and material considerations, and clinical experience with stems of similar design and material that have been implanted in significant numbers with a long-term (> 5 years) history with no significant numbers of fractures in the highly stressed regions evaluated by this test method.

[b] This value is based on the previous requirement in ISO 7206-6 for a stem for the average patient (in Europe). Some smaller stems in the size range (120 mm to 250 mm) and not intended for use in the average patient (in Europe) have been used clinically long-term without fracture and have not met the 2 300 N requirement. Smaller stems in this size range could have a performance requirement lower than 2 300 N when they can be shown to be as strong as stems of similar design and material, which have been implanted in significant numbers with a long-term (> 5 years) history with no significant numbers of fractures in the highly stressed regions evaluated by this test method.

[c] This value is based on limited clinical experience but given as a lower limit and may need to be adjusted upwards based on design and material considerations, and clinical experience of similar devices.

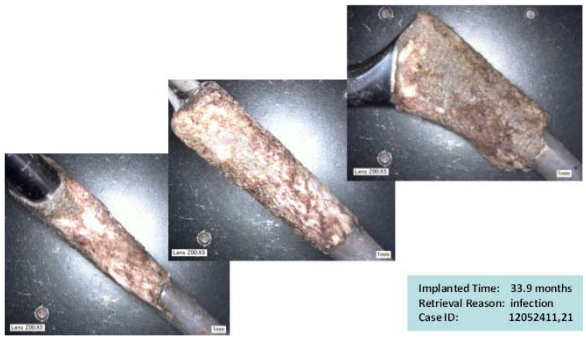
Retrieved Summit Stem

— Dartmouth Biomedical Engineering Center for Orhtopaedics



Retrieved Summit Stem

— Dartmouth Biomedical Engineering Center for Orhtopaedics

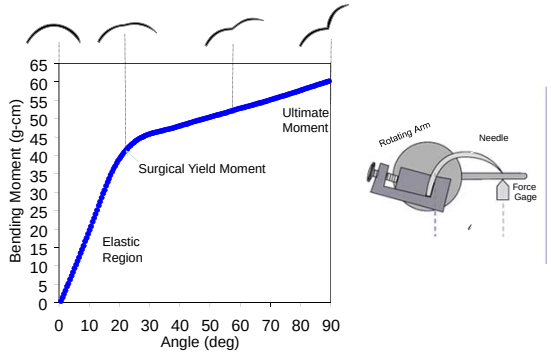


Surgical Needles and Standards

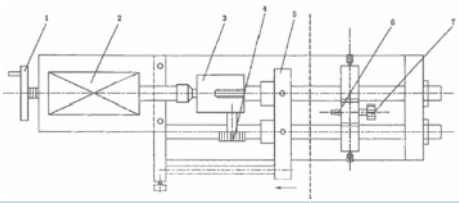
ASTM Standards vs. YY/T 0043-2016

- **Strength and Ductility Testing**
  - Follow ASTM F1874-98 standard
- **Penetration Performance**
  - Follow ASTM F3014-14 standard

Results generated using the standard test method for bend testing of needles ASTM F1874-98



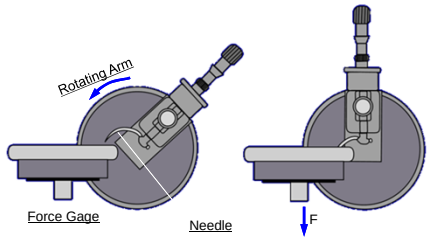
YY/T 0043-2016: Schematic diagram of testing device for elasticity and toughness of suture needle



Notes:

1 - Nut moved manually;
2 - Remove electronically (available);
3 - Suture needle fixture;
4 - Suture needle fixture nut;
5 - Press scale fixed plate of suture needle;
6 - Needle tail fixture;
7 - Fastening nut.

ASTM F3014-14: Needle Penetration Testing

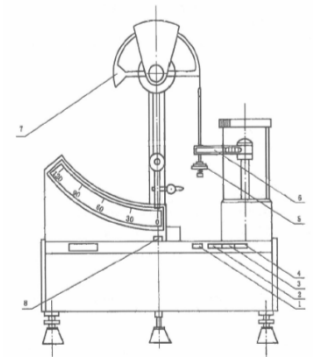


Penetration occurs in a very smooth controlled manner at a rate specified by ASTM F3014-14

The force gage is used to measure the maximum force required for needle penetration

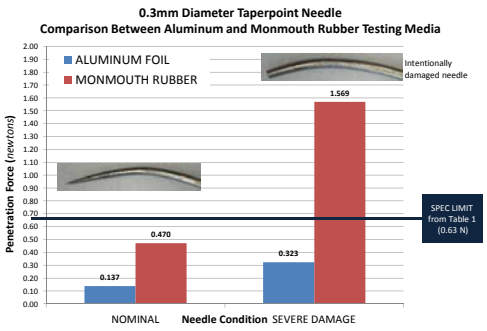
Synthetic rubber media is used to approximate soft tissue and approach some clinical relevance

YY/T 0043-2016: Tester for penetration force of suture needle tip



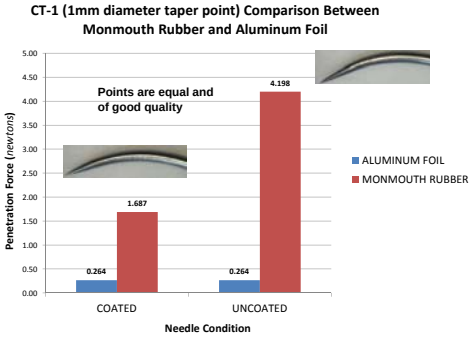
Notes:
1- power switch;
2~4 - operation control switch;
5 - aluminum foil fixture;
6 - suture needle fixture;
7- adjusting swinging rod;
8 - gradienter.

Puncture/Penetration Force Test



The aluminum foil puncture test may not detect damaged points. Rubber penetration media test does detect damaged points.

Puncture/Penetration force test



Aluminum foil cannot detect the significant improvement provided by the silicone coating

Summary

- Currently GB, YY, ISO and ASTM standards do show their differences in raw materials and test methods
- These differences do have the impact on product registration in China
- An ideal solution is to harmonize these standards, making them more compatible or acceptable, so as to eliminate ambiguity and confusion
- This will reduce the unnecessary cost, allowing more efforts being made on truly improving the product safety and efficacy

Thank You !

Questions?

采纳国际医疗器械标准

刘恒达

材料科学与工程博士，高级首席科学家
法规事务部副总监
德培依辛迪斯骨科产品分公司
美国强生公司

2018年3月

前言

- 在中国，医疗器械的注册受到CFDA的严格监管
- 所选的材料及其试验方法必须遵循相应的中国国家标准（GB）或医药行业标准（YY）
- 进口产品的制造则是依照国际公认的标准（ISO / ASTM）
- 理想的情况是，这些标准能够保持一致或全部被CFDA认可，但目前情况并非如此
- 这就产生了一些问题并引起了困惑

原材料

- （高交联）超高分子量聚乙烯
- 钛6铝4钒与钛6铝4钒ELI合金
- 钴铬钼合金
- 不锈钢
- 纯钛与钛6铝4钒合金粉末





ASTM F2565-06 转化为 YY 0811-2010标准

—— 采纳国际标准的一个好的例子

Designation: F 2565 – 06

Standard Guide for
Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications[1]

ICS 11.040.40
C 35

YY

中华人民共和国医药行业标准

YY/T 0811—2010

外科植入物用大剂量辐射交联超高分子量聚乙烯制品标准要求

Standard guide for extensively irradiation—Crosslinked ultra-high molecular weight polyethylene fabricated forms for surgical implant applications

ASTM F2565 / YY 0811

—— 高交联超高分子量聚乙烯材料的标准

- 本标准适用于接受总剂量超过 40 kGy的γ或电子束电离辐射形成交联的超高分子量聚乙烯材料
- 表1中列出了一些被发现是有用的来表征高交联超高分子量聚乙烯材料的试验和方法
- 材料生产商须负责制定其生产工艺验证最少的试验数据组并决定将哪些试验方法作为例行程序，在质量控制程序中加以实施

TABLE 1 Requirements for UHMWPE Fabricated Forms

Test Parameter	Test Method	Test Conditions
Tensile Strength, 23°C, MPa	ASTM D 638	Type IV, 5.08 cm/min
Ultimate		
Yield		
Elongation, %	ASTM D 638	Type IV, 5.08 cm/min
Izod Impact Strength, kJ/m²	ASTM F 648, Annex A1	
Ultimate Load, MPa	ASTM F 2183	
Fatigue Crack Propagation	ASTM E 647	
Compressive Modulus, MPa	ASTM D 1621	
Thermal Properties	ASTM D 3418	
Percent Crystallinity		
Melting Temperature, max		
Residual Free Radicals, spins/g ESR		
Swell Ratio	ASTM D 2765 or F 2214	
Oxidation Index, SOI and OI max	ASTM F 2102	
trans-Vinylene Content, TVI	ASTM F 2381	

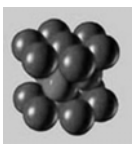
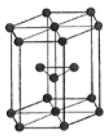
表1 高交联UHMWPE制品的要求

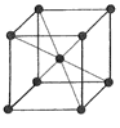
试验参数	试验方法	试验条件
抗拉强度，23°C/MPa 断裂 屈服	ASTM D 638	IV 型，5.08 cm/min
断裂伸长率（%）	ASTM D 638	IV 型，5.08 cm/min
悬臂梁冲击强度（kJ/m2）	ASTM D 648，附录A1	—
极限载荷（MPa）	ASTM F 2183	—
疲劳裂纹扩展	ASTM E 647	—
压缩模量（MPa）	ASTM D 1621	—
热性能 结晶度 熔点，最大值	ASTM D 3418	—
剩余自由基（spins/g）	电子自旋共振	—
溶胀度	ASTM D 2765或 ASTM F2214	—
氧化指数，SOI和OI最大值	YY/T 0722.4	—
反式亚乙烯指数（TVI）	ASTM F2381	—

钛6铝4钒与钛6铝4钒ELI合金

- 含6% 铝（α-稳定剂）和4% 钒（β-稳定剂）
- ELI：超低间隙原子 = 更高纯度
- 具有良好的耐腐蚀性、高强度和韧性
- 晶体结构：α+β混合相

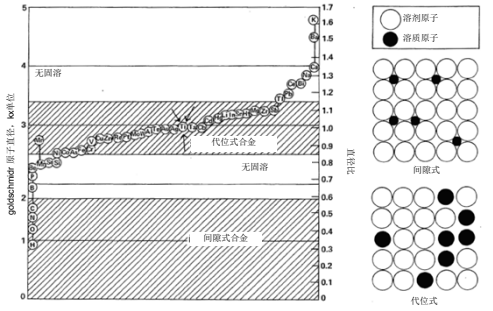
  α相：密排六方（hcp）；β相：体心立方（bcc）



钛6铝4钒与钛6铝4钒ELI合金

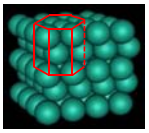
- 元素的原子直径
  - 受原子大小和溶解度的限制，只有碳、氮、氧、氢可作为钛的间隙原子*

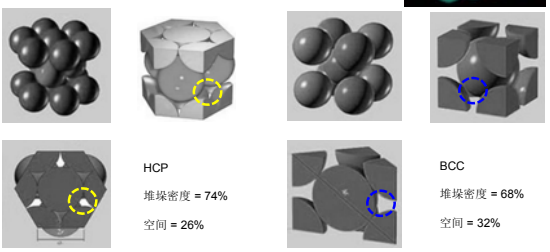


* H.B. Bomberger and F.H. Froes, *"Solidification and Phase Diagrams, Titanium and its Alloys"*, May 1984, pp 6-7.

钛6铝4钒与钛6铝4钒ELI合金

- 碳、氮、氧、氢原子占据间隙位置
- HCP与BCC结构中的间隙位置
- 间隙原子会使钛合金变脆而降低韧性





HCP

堆垛密度 = 74%

空间 = 26%

BCC

堆垛密度 = 68%

空间 = 32%

钛6铝4钒与钛6铝4钒ELI合金

- 化学成分和机械性能

	Ti-6Al-4V				Ti-6Al-4V ELI			
化学成分	ISO 5832-3:1996 Ti-6Al-4V钛合金锻件		YY0117.1-2005 Ti-6Al-4V 钛合金锻件	GB/T 3620.1-2007 TC4钛合金锻件	GB/T 3620.1-2007 TC4 ELI钛合金锻件		ASTMF136 Ti-6Al-4V ELI钛合金锻件	
氮，最大值	0.05		0.05	0.05	0.03		0.05	
碳，最大值	0.08		0.08	0.08	0.08		0.08	
氢，最大值	0.015		0.010	0.010	0.010		0.012	
铁，最大值	0.30		0.30	0.30	0.25		0.25	
氧，最大值	0.20		0.20	0.20	0.13		0.13	
铝	5.5-6.75		5.5-6.75	5.5-6.75	5.5-6.5		5.5-6.5	
钒	3.5-4.5		3.5-4.5	3.5-4.5	3.5-4.5		3.5-4.5	
钛	余量		余量	余量	余量		余量	
力学性能				GB/T 13810-2007 TC4钛合金锻件	GB/T 13810-2007 TC4 ELI钛合金锻件			
抗拉强度: Rm (MPa), 最小值	片材和带材	860	860	0.8~4.57(mm)	895	0.8~25(mm)	860	< 4.75(mm)	860
				>4.57~25(mm)	895			4.75~44.45(mm)	
	棒材	860		>7~50 (mm)	930	>7~45(mm)	860	44.45~63.50(mm)	825
				>50~90(mm)	895	45 ~90(mm)	825	63.50~101.60(mm)	
0.2% 屈服强度: $Rp_{0.2}$ (MPa), 最小值	片材和带材	780	780	0.8~4.57(mm)	870	0.8~25(mm)	795	< 4.75(mm)	795
				>4.57~25(mm)	830			4.75~44.45(mm)	
	棒材	780		>7~50 (mm)	860	>7~45(mm)	795	44.45~63.50(mm)	760
				>50~90(mm)	830	45 ~90(mm)	760	63.50~101.60(mm)	
伸长率 (%), 最小值	片材和带材	8	10	0.8~4.57(mm)	10	0.8~25(mm)	10	< 4.75(mm)	10
				>4.57~25(mm)				4.75~44.45(mm)	
	棒材	10		>7~50 (mm)	10	>7~45(mm)	10	44.45~63.50(mm)	8
				>50~90(mm)		45~90(mm)	8	63.50~101.60(mm)	

钛6铝4钒与钛6铝4钒ELI合金

ISO 5832-3:2016(E)

表1 - 化学成分

元素	化学成分 %（m/m）
铝	5.5 – 6.75
钒	3.5 – 4.5
铁	0.3（最大值）
氧	0.2（最大值）
碳	0.08（最大值）
氮	0.05（最大值）
氢	0.015（最大值）[a]
钛	基体

[a]除坯料外，最大氢含量应为0.010%（m/m）。

注2 根据术语“超低间隙”（ELI），对氧元素和铁元素有更严格的限制。使用ISO 5832的此部分，可用于采购商用ELI材料。关于ELI等级的确切化学成分，参见ASTM F136（UNS R54601）（www.astm.org）。

5 显微组织

当按表3所列方法检测时，显微结构应为α+β球状，还应与ISO 20160所列的显微照片A1到A9（对于圆棒料）或EN 3114-003所列的3T1到3T13（对于带材与板材）（均在退火状态下）保持一致。

吻合器钉 - 钛3铝2.5钒合金

化学成分	GB/T 3620.1-2007	ASTM F3046-13
氮	≤ 0.05	≤ 0.03
碳	≤ 0.08	≤ 0.08
氢	≤ 0.015	≤ 0.015
铁	≤ 0.25	≤ 0.25
氧	≤ 0.12	≤ 0.15
铝	2.0 ~ 3.5	2.5 ~ 3.5
钒	1.5 ~ 3.0	2.0 ~ 3.0
其他元素： 单个	≤ 0.10	—
其他元素： 总和	≤ 0.30	—
钛	基体	基体

相比ASTM F3046-13，GB/T 3620规定的Ti3Al2.5V具有不同的化学成分

钴铬钼合金：铸造和锻造

- 化学成分和机械性能

	钴铬钼合金：铸造		钴铬钼合金：锻造（温加工）		
化学成分(%)	ASTM F75-2012	YY 0117.3-2005	ASTM F1537 (Alloy 2)	YY 0605.12-2007	ISO 5832-12:2007 (Alloy 2)
铬	27.0 ~ 30.0	26.5 ~ 30.0	26.0 ~ 30.0	26.0 ~ 30.0	26.0 ~ 30.0
钼	5.0~ 7.0	4.5 ~ 7.0	5.0 ~ 7.0	5.0 ~ 7.0	5.0 ~ 7.0
镍	≤ 0.5	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0
铁	≤ 0.75	≤ 1.0	≤ 0.75	≤ 0.75	≤ 0.75
碳	≤ 0.35	≤ 0.35	0.15 ~ 0.35	≤ 0.35	0.15 ~ 0.35
硅	≤ 1.0	≤ 1.0	≤1.0	≤ 1.0	≤ 1.0
锰	≤ 1.0	≤ 1.0	≤1.0	≤ 1.0	≤ 1.0
钨	≤ 0.2				
磷	≤ 0.02				
硫	≤ 0.01				
氮	≤ 0.25		≤ 0.25	≤ 0.25	≤ 0.25
铝	≤ 0.1				
钛	≤ 0.1				
硼	≤ 0.01				
钴	余量	余量	余量	余量	余量
力学性能	ASTM F75-2012	(=ISO 5832-4:014)	ASTM F1537 (Alloy 2)	(=ISO 5832-12:1996)	ISO 5832-12:2007 (Alloy 2)
0.2% 屈服强度 ($Rp_{0.2}$)	≥ 65ksi (450 MPa)	≥ 450 MPa	≥ 120 ksi (827 MPa)	≥ 827 MPa	≥ 827 MPa
抗拉强度 (Rm)	≥ 95 ksi (655 MPa)	≥ 665 MPa	≥ 170 ksi (1172 MPa)	≥ 1172 MPa	≥ 1192 MPa
伸长率	≥ 8%	≥ 8%	≥ 12%	≥ 12%	≥ 12%

钴铬钼合金：锻造（温加工）

- 2008年ISO做出一次修正

国际标准ISO5832-12：2007
技术勘误表

2008年9月15日发布

外科植入物-金属材料-第12部分：钴铬钼合金锻件

技术勘误表1

ISO5832-12：2007的技术勘误表1由技术委员会ISO/TC 150：外科植入物，分委员会SC1，材料编制。

第2页，表2，第2列，第4行

退加工材料的抗拉强度应为1172MPa。

钴铬钼合金：铸造和锻造

- 化学成分和机械性能

	钴铬钼合金：铸造		钴铬钼合金：锻造（退火）		
化学成分(%)	ASTM F75-2012	YY 0117.3-2005	ASTM F1537-2011 (Alloy 2)	YY 0605.12-2007	ISO 5832-12:2007 (Alloy 2)
铬	27.0 ~ 30.0	26.5 ~ 30.0	26.0 ~ 30.0	26.0 ~ 30.0	26.0 ~ 30.0
钼	5.0 ~ 7.0	4.5 ~ 7.0	5.0 ~ 7.0	5.0 ~ 7.0	5.0~ 7.0
镍	≤ 0.5	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0
铁	≤ 0.75	≤ 1.0	≤ 0.75	≤ 0.75	≤ 0.75
碳	≤ 0.35	≤ 0.35	0.15 ~ 0.35	≤ 0.35	0.15 ~ 0.35
硅	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0
锰	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0
钨	≤ 0.2				
磷	≤ 0.02				
硫	≤ 0.01				
氮	≤ 0.25		≤ 0.25	≤ 0.25	≤ 0.25
铝	≤ 0.1				
钛	≤ 0.1				
硼	≤ 0.01				
钴	余量	余量	余量	余量	余量
力学性能	**ASTM F75-2012**	**(=ISO 5832-4:2014)**	**ASTM F1537-2011 (Alloy 2)**	**(=ISO 5832-12:1996)**	**ISO 5832-12:2007 (Alloy 2)**
0.2% 屈服强度 ($Rp_{0.2}$)	≥ 65ksi (450 MPa)	≥ 450 MPa	≥ 75 ksi (517 MPa)	≥ 550 MPa	≥ 517 MPa
抗拉强度 (Rm)	≥ 95 ksi (655 MPa)	≥ 665 MPa	≥ 130 ksi (897 MPa)	≥ 750 MPa	≥ 897 MPa
伸长率	≥ 8%	≥ 8%	≥ 20%	≥ 16%	≥ 20%

锻造高氮不锈钢

- 化学成分和机械性能

化学成分 (%)		ASTM 1586-2013	YY 0605.9-2007	ISO 5832-9:2007
碳		≤ 0.08	≤ 0.08	≤ 0.08
锰		2.00 ~ 4.25	2.00 ~ 4.25	2.00 ~ 4.25
磷		≤ 0.025	≤ 0.025	≤ 0.025
硫		≤ 0.01	≤ 0.01	≤ 0.01
硅		≤ 0.75	≤ 0.75	≤ 0.75
铬		19.5 ~ 22.0	19.5 ~ 22.0	19.5 ~ 22.0
镍		9.0 ~ 11.0	9.0 ~ 11.0	9.0 ~ 11.0
钼		2.0 ~ 3.0	2.0 ~ 3.0	2.0 ~ 3.0
氮		0.25 ~ 0.50	0.25 ~ 0.50	0.25 ~ 0.50
铌		0.25 ~ 0.80	0.25 ~ 0.80	0.25 ~0.80
铜		≤ 0.25	≤ 0.25	≤ 0.25
铁		余量	余量	余量
残留物：	每种	/	≤ 0.1	≤ 0.1
	总计	/	≤ 0.4	≤ 0.4
力学性能 (退火)		**ASTM 1586-2013**	**(=ISO 5832-9:1992)**	**ISO 5832-9:2007**
抗拉强度: Rm (MPa), 最小值	棒材	740	740 (d ≤ 80 mm)	740 (d ≤ 80 mm)
	片材和带材	740	770	770
0.2% 屈服强度: $Rp_{0.2}$ (MPa), 最小值	棒材	430	430 (d ≤ 80 mm)	430 (d ≤ 80 mm)
	片材和带材	430	465	465
伸长率 (%), 最小值	棒材	35	35 (d ≤ 80 mm)	35 (d ≤ 80 mm)
	片材和带材	35	35	35

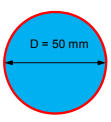
工业纯钛与钛6铝4钒合金粉末

- YY和ISO标准对工业纯钛或钛6铝4钒预合金粉末没有做任何规定
- ASTM F1580对用于外科植入物涂层的CP Ti和Ti-6Al-4V合金粉末做出了规定
- 在中国，曾将相应块状材料的标准用于检验这些粉末的化学成分

	Ti-6Al-4V		CP Ti	
化学成分 (%)	ISO 5832-3:1996 Ti-6Al-4V锻件	ASTM F1580-2012 Ti-6Al-4V 粉末	ISO 5832-2:1999 CP Ti，4级	ASTM F1580-2012 CP Ti 粉末
氢，最大值	0.05	0.05	0.05	0.05
碳，最大值	0.08	0.08	0.10	0.08
氢，最大值	0.015	0.015	0.0125	0.05
铁，最大值	0.30	0.30	0.50	0.50
氧，最大值	0.20	0.20	0.40	0.40
铜，最大值	/	0.10		
镍，最大值	/	0.10		
铝	5.5-6.75	5.5-6.75		
钒	3.5-4.5	3.5-4.5		
钛	余量	余量	余量	余量

工业纯钛与钛6铝4钒合金粉末

- 当占据相同体积时，小颗粒具有更大的表面积
- 在空气中，钛和钛合金表面会自发形成一层氧化钛膜
- 钛和钛6铝4钒合金粉末在烧结 / 经3D打印工艺处理后通常具有更高的氧含量，因而不再满足相应块状材料标准的要求
- 对于钛和钛6铝4钒合金粉末，YY0118 – 2016行标采纳了ASTM F1580规定的要求



D = 直径

As = 表面积

As = π D^2

≈ 7854 mm^2

D = 250μm
= 0.25 mm

As ≈ 8×10^6 mm^2

As ⇨ x 1019 !

D = 25μm
= 0.025 mm

As ≈ 8×10^9 mm^2

As ⇨ x 1.019×10^6 !!!

关于原材料

- ISO 5832（第1-14部分）涵盖了外科植入物用金属材料
- 各部分的“范围”注释1均做出以下说明：
  “从这种合金制成的成品中抽取的样品，其力学性能可不同于ISO 5832这一部分的规定。”
- YY标准也有相同的声明（“取自成品的试样，其力学性能可不必遵循本部分的规定”）
- 该声明既适用于金属材料也适用于其它原材料
- **原材料 ≠ 成品**
  - 样品尺寸效应
  - 机加工效应
  - 工艺处理效应
- 鉴于此，合理设计的植入物功能测试在深入评估医疗器械安全性方面发挥着重要作用

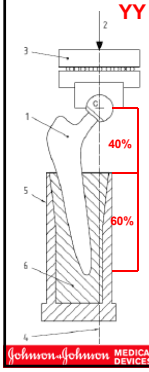
试验方法

- 股骨柄远端疲劳试验
- 缝合针试验

ISO 7206-4：股骨柄远端疲劳试验

2002与2010版本的对比：包埋深度的变化

YY 0118-2016 将采纳ISO 2010版本的规定



2002:
D = 0.4 CT

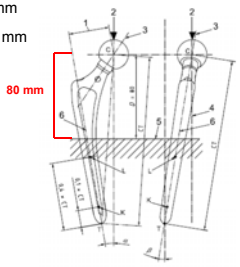
CT = 125 mm D_{125} = 50 mm

CT = 250 mm D_{250} = 100 mm

图解：

1. 试样
2. 载荷
3. 加载机制
4. 加载线
5. 试样夹持器
6. 包埋介质

2010:
D = 80 mm



ISO 7206-4: 2010

表2 –试验参数

股骨柄种类	短，单块式，组配式颈，组配式柄		
CT (mm)	≤ 120	120 < CT ≤ 250	>250
F_D (N)	1 200[a]	2 300[b]	1 200[c]
循环次数	5 x 10^6		
未断试样数量	6		

注1 如果采用统计方法计算出的最小终止载荷满足 ISO 7206这一部分在95%置信区间下的规定，则替代方法被视为可接受。
注2 对于组配式股骨柄，可能需要额外测试。

a 该值不是基于广泛的临床经验而是作为下限，可能需要根据设计和材料因素向上调整，同时考虑同类设计和材料的股骨柄临床经验；这些股骨柄应具有长期应用史[> 5年]、植入数量多、采用该方法评估时不得有大量样本在高应力区断裂）。

b 该值基于早期ISO 7206-8对用于普通患者（欧洲）的股骨柄做出的规定。一些尺寸范围在120mm-250mm且不用于普通患者（欧洲）的较小股骨柄已在临床应用很长时间，且无断裂报告，即使没有达到2300N的要求。只要这类股骨柄经证实与具有长期应用史[> 5年]、植入数量多、采用该方法评估时无大量样本在高应力区断裂的同类设计和材料股骨柄具有相同的强度，便可不要求达到2300N的性能要求。

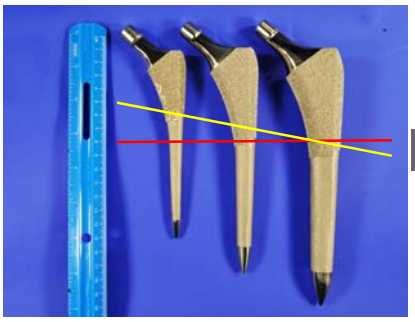
c 该值不是基于广泛的临床经验而是作为下限，可能需要根据设计和材料因素向上调整，同时考虑同类股骨柄的临床经验

Summit 股骨柄系列：规格1 - 10号

柄的规格： 1 2 3 4 5 6 7 8 9 10

载荷 ≡ 2300 N（分别使用1号和10号柄的患者具有不同的体重）

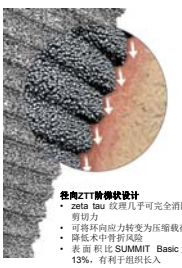
包埋深度变化：大、中 、小号 Summit 股骨柄



股骨柄规格： 1 6 10

Summit 股骨柄：近端区域生物固定

径向ZTT将环向应力转变为压缩载荷，有助于降低术中骨折风险



径向ZTT肋骨状设计
- zeta tau 纹理几乎可完全消除剪切力
- 可将环向应力转变为压缩载荷
- 降低术中骨折风险
- 表面积比 SUMMIT Basic 大13%，有利于组织长入

- 近端接触皮质骨可促进负荷均匀分布
- 减少近端应力遮挡

ISO 7206-4: 2010

表2 –试验参数

股骨柄种类	短，单块式，组配式颈，组配式柄		
CT (mm)	≤ 120	120 < CT ≤ 250	>250
F_D (N)	1 200[a]	2 300[b]	1 200[c]
循环次数	5×10^6		
未断试样数量	6		

注1 如果采用统计方法计算出的最小终止载荷满足 ISO 7206这一部分在95%置信区间下的规定，则替代方法被视为可接受。
注2 对于组配式股骨柄，可能需要额外测试。

a 该值不是基于广泛的临床经验而是作为下限，可能需要根据设计和材料因素向上调整，同时考虑同类设计和材料的股骨柄临床经验；这些股骨柄应具有长期应用史[> 5年]、植入数量多、采用该方法评估时不得有大量样本在高应力区断裂）。

b 该值基于早期ISO 7206-8对用于普通患者（欧洲）的股骨柄做出的规定。一些尺寸范围在120mm-250mm且不用于普通患者（欧洲）的较小股骨柄已在临床应用很长时间，且无断裂报告，即使没有达到2300N的要求。只要这类股骨柄经证实与具有长期应用史[> 5年]、植入数量多、采用该方法评估时无大量样本在高应力区断裂的同类设计和材料股骨柄具有相同的强度，便可不要求达到2300N的性能要求。

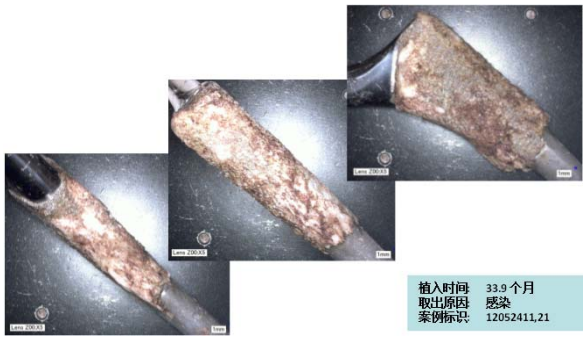
c 该值不是基于广泛的临床经验而是作为下限，可能需要根据设计和材料因素向上调整，同时考虑同类股骨柄的临床经验

取出的 Summit 股骨柄

— Dartmouth骨科生物医学工程中心

取出的 Summit 股骨柄

— Dartmouth骨科生物医学工程中心

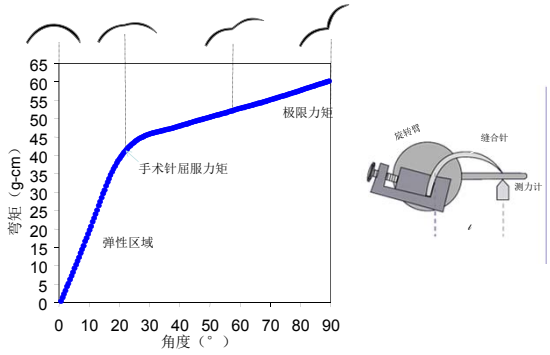


外科手术用针和标准

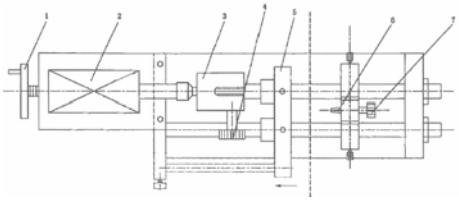
ASTM标准与 YY/T 0043-2016

- **强度与延性测试**
  - 遵循ASTM F1874-98标准
- **刺穿性能**
  - 遵循ASTM F3014-14标准

采用ASTM F1874-98缝合针弯曲试验的标准试验方法获得的结果



YY/T 0043-2016：缝合针弹性和韧性测试装置示意图

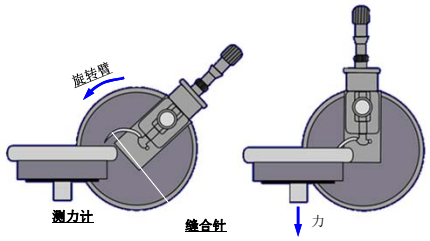


弹性测试区	韧性测试区

说明：

1 - 手动移动螺母；
2 – 电动移动（可用）；
3 – 缝针固定夹具；
4 – 缝针夹具螺母；
5 - 缝针顶压刻度固定板；
6 - 针尾固定夹具；
7 – 固定螺母。

ASTM F3014-14：针刺穿测试

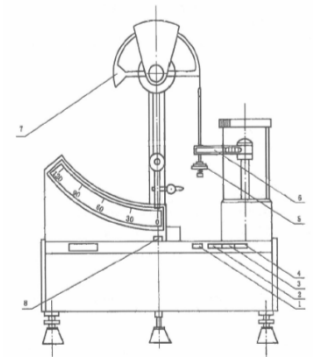


在极平稳的控制方式下以ASTM F3014-14指定速度刺穿。

测力计被用来测量缝合针刺穿所需的最大力

合成橡胶介质被用来模拟软组织且贴近临床应用情况

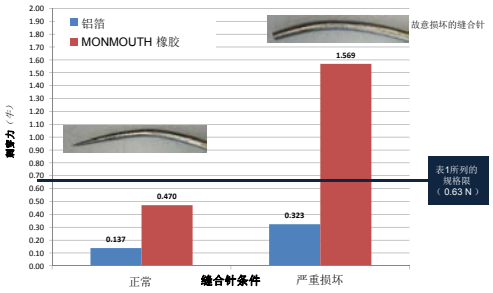
YY/T 0043-2016：缝合针针尖刺穿力测定仪



说明：
1 –电源开关；
2~4 –工作控制开关；
5 - 铝箔夹具；
6 – 缝针夹具；
7 –调节摆杆；
8 – 水平仪。

刺穿 / 刺穿力试验

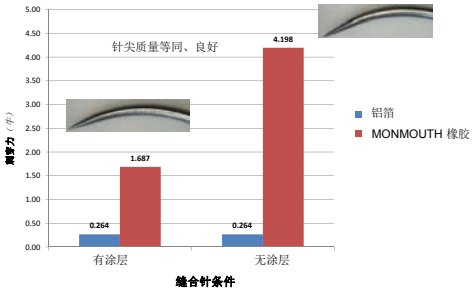
直径0.3mm的圆尖缝合针
铝箔和Monmouth橡胶测试介质对比图



铝箔刺穿试验可能未检测到损坏针尖。
橡胶刺穿介质试验检测到损坏针尖。

刺穿/刺穿力试验

CT-1（直径为1mm的圆针）
Monmouth橡胶和铝箔对比图



铝箔无法检测到由硅树脂涂层所带来的显著改善

要点归纳

- 现行的GB、YY、ISO和ASTM标准在原材料和试验方法上确实存在差异
- 这些差异对在中国进行的产品注册确实会有影响。
- 理想的解决方案是协调这些标准，以便提高这些标准的兼容性或可接受性，由此消除歧义和困惑
- 这会减少不必要的成本，从而可将更多的努力用于真正提高产品安全性和有效性的相关工作

谢谢大家！

有问题吗？

中国医用电气设备基础标准制定进展
Progress of basic standards for medical electrical equipment in China

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）
郑佳

2018年3月26

目录
CONTENTS

PART 1: IEC60601系列标准转化进展
Progress of IEC60601 series transformation

PART 2: 新兴医疗器械技术标准体系研究
Research of new-emerging medical device standard system

GB9706.1制定历程
Development of GB9706.1

Time	No.	Transformation in China	No.
1977	IEC601-1	1988	GB9706.1-1988
1988	IEC60610-1+A1：1991	1995	GB9706.1-1995
1995	IEC60610-1+A1：1991+1995（Ed. 2）	2007	GB9706.1-2007
2005	IEC60610-1：2005（Ed. 3）	/	/
2012	IEC60610-1：2012（Ed. 3.1）	Under transformation	

GB 9706系列的重要性
Importance of GB9706 series

- GB 9706（对应IEC60601）对中国医疗器械监管和产业具有十分重要的影响
  GB 9706（ IEC 60601）plays a very important role in China‘s medical device supervision and industry：

强制实施，涉及所有医用电气产品的基础安全
Mandatory to all medical electrical equipment

影响生产企业、监管、审评、检测等多个机构Manufacture, supervision, review, testing, etc.

组织实施Organization

- 国家总局高度重视第3.1版的转化工作
  CFDA attaches great importance to the transformation of Ed. 3.1
- 标管中心负责该标准转化实施研究工作，为总局实施该标准提供技术支持
  CMDSA is responsible for research on transformation and implementation of the 3.1st edition, and provide technical support to CFDA
- 标管中心成立专项工作组，监管、检测、技委会、企业等多部门总动员
  CMDSA established a professional working group, including experts from technical committees, testing centers, supervision authorities, evaluation centers, foreign and domestic manufactures
- 超过100名志愿者参与标准翻译、培训教材编写等工作
  More than 100 volunteers involved in standard translation, training material preparation etc.

GB 9706.1修订进展
Development progress of GB 9706.1

- 2013年3月，正式向国标委提交了GB9706.1标准修订的立项申请 NP to revise GB 9706.1 to SAC
- 2014年9月，正式批准GB 9706.1标准修订立项 Approved
- 2015年11月，第一次审定 First time vote
- 2017年11月，重新审定 Revote

影响GB 9706.1修订的主要因素
Main factor affecting development

- 2015年11月日本神户IEC TC62年会确定将对IEC 60601-1第3.1版修订
  2015.11, Japan's Kobe IEC TC62 determined to revise IEC 60601-1 ed3.1
- 经反复讨论，中国决定暂缓GB9706.1的报批进程，待IEC60601-1确定了修改内容后一并修改。
  After discussions, China decided to postpone the process of GB9706.1, and revise it according to IEC60601-1 amendment
- 2017年IEC TC62整体工作滞后，年会取消，第3.2版计划推迟至2019年发布。
  In 2017, the overall work of IEC TC62 was lagging behind, the annual meeting was cancelled, and the 3.2 edition was postponed to 2019.

第3.2版主要修改内容
Main content in A2

	Main changes	Number
1	新的或改进的技术要求 New technical requirement	30
2	不一致	26
3	安全空白点 Safety issue	19
4	技术错误 technical error	7
5	印刷错误 publish error	7
6	监管机构已知的问题 RA issues	6
7	关键标准更新reference update	4
8	编辑改进 Editing	4
9	其他:澄清 Clarify	3
10	技术发展最新水平 State of art	1
合计		107

GB 9706.1与IEC60601-1主要差异
Main difference of GB9706.1 and IEC60601-1

1. 规范性引用IEC或ISO标准改为引用国家标准 Change reference to national standards
2. 增加部分技术要求Add some technical requirements
3. 对原标准明显错误之处进行修正 Modification to obvious errors
4. 参考A2提出的问题进行修正 Modification according to proposed A2

GB 9706.1下一步修订计划
Plan for GB9706.1 revision

- 2018年，GB9706.1将报批
  2018，GB9706.1 will be submitted to be approved
- 标管中心将组织研究制定实施方案
  CMDSA will organize research to develop implementation plan
  - 设立合理的过渡期 To establish reasonable transition period
  - 过渡期内，新老版本可同时使用 During transition period，both new and old edition can be effective

GB 9706.1培训教材
Training Material for GB9706.1

IEC 60601系列标准转化情况
IEC60601 series standard transformation

- 强制性国家标准32项，23项已立项，9项即将立项
  The number of mandatory national standards is 32
- 强制性行业标准31项，推荐性行业标准2项
  The number of mandatory trade standards is 31，voluntary standards is 2
- 预计2019年将完成所有并列及专用标准的转化
  It is expected that all parallel and particular standards will be completed the transformation in 2019

目 录
CONTENTS

PART 1: IEC60601系列标准转化进展
Progress of IEC60601 series transformation

PART 2: 新兴医疗器械技术标准体系研究
Research of new-emerging medical device standard system

标准战略支撑作用
Support of standard to industrial development

- 《中国制造2025》"made in China 2025 " plan:

科技战略 Technology strategy

- **2016.7 国务院发布《"十三五"国家科技创新规划》 The "13th Five-Year" National Science and technology innovation plan ：**

健全技术标准体系
To improve technical standard system

加强基础通用和产业共性技术标准研制
Strengthen the development of basic general and industrial common technical standards

大力培育发展团体标准
Development of associate standards

科技计划加强技术标准研制

- 2016年9月20日，《关于在国家科技计划专项实施中加强技术标准研制工作的指导意见》：根据专项项目（课题）预期成果的应用范围和技术成熟度等特点，宜将研制标准作为研究内容。

In September 20, 2016, "guidance on the national science and technology plan to strengthen the implementation of technical standards in the research work " : It is encouraged that development of standards is one of the research target.

技术标准创新战略
Strategy for technical standard innovation

- 2017年6月13日，科技部 、质检总局、国家标准委印发《"十三五"技术标准科技创新规划》13th Five-Year scientific and technological innovation plan for technical standards

全面落实创新驱动发展战略，以实施技术标准战略为主线

1	2	3
着力	着力	着力
•构建新型技术标准体系 •进一步发挥技术标准在淘汰落后产能、助推产业转型升级和提高产品质量的引领作用	提升科技创新、技术标准研制与产业发展的互动支撑能力	健全技术标准创新服务体系、服务新形势下产业变革过程中的大众创业、万众创新

医疗器械技术标准创新思路
MD standard innovation plan

➢积极探索技术标准研制和科研同步的新型工作机制，为各利益相关方搭建协同合作的平台To actively explore new mechanisms for synchronization of technology standards and research, and establish platform for cooperation among all stakeholders

医疗器械标准体系研究和战略性新兴产业同步

研究制定产业和监管急需的关键技术标准

掌握战略性新兴产业国际标准制定主动权

产、学、研、检、医、标、审

充分发挥标准在支撑监管、产业发展、科技创新中的导向和保障作用

医疗器械产业重点研发方向
Key development areas of industry

01	《装备制造业标准化和质量提升规划》Equipment manufacturing industry standardization and quality improvement plan	•医用机器人medical Robots •医用影像设备 Imaging MD •移动医疗设备 Mobile MD
02	《医药工业发展规划指南》Guidelines for the development of pharmaceutical industry	•高端CT High-end CT •远程医疗、可穿戴 Remote, wearable MD
03	《“健康中国2030”规划纲要》The outline of "healthy China 2030"	•可穿戴设备wearable MD • 高性能医疗器械 High performance MD
04	《智慧健康养老产业发展行动规划（2017-2020）》Smart health pension industry development action plan	•可穿戴设备wearable MD •便携监测设备Portable •monitoring MD

医用机器人标准化工作组

2016年2月，标管中心牵头成立由跨部门技术专家组成的“医用机器人标准化专项工作组”：

➢8个研究小组

- 术语和定义
- 电气安全
- 电磁安全
- 机械安全
- 性能
- 软件
- 物理化学生物相容性
- 风险评估

➢工作内容

- 研究国际标准
- 研究医用机器人主要风险点、
- 研究检测方法
- 培训

15

深度结合科研需求Participation in research

➢ 参与医用机器人相关国家科研项目Participation in scientific research projects related to medical robotics

•积极跟踪参与胸腔微创手术机器人的研发工作

•了解科研机构、生产企业在技术创新过程中对标准的需求

•组织医疗器械检测、标准及审评技术专家及时给予科研人员指导和支持

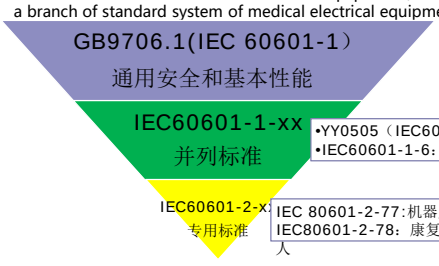
跟踪医用机器人国际标准
Follow international standards

➢ IEC/TC62和ISO/TC299已成立两个联合工作组JWG35（手术机器人）和JWG36（康复机器人），国内对口单位医用电器设备标准化技术委员会（SAC/TC10）

➢ 两项国际标准正在起草：

- IEC 80601-2-77《医用电气设备 第2-77部分：机器人辅助外科手术设备基本安全和基本性能的专用要求》
- IEC 80601-2-78《医用电气设备 第2-78部分：康复、评估、补偿或缓解医疗机器人基本安全和基本性能的专用要求》

➢ 医用机器人属于医用电气设备，其标准体系作为医用电气设备标准体系的一个分支As medical robot is one of medical electrical equipment , the standard system is a branch of standard system of medical electrical equipment.

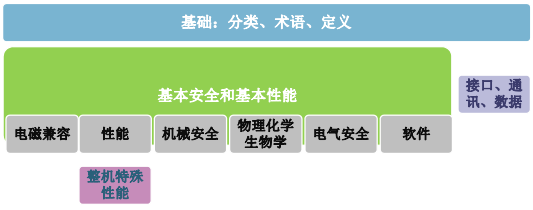


•YY0505（IEC60601-1-2）：电磁兼容
•IEC60601-1-6：可用性

IEC 80601-2-77:机器人辅助手术设备
IEC80601-2-78：康复、评估、代偿或缓解机器人

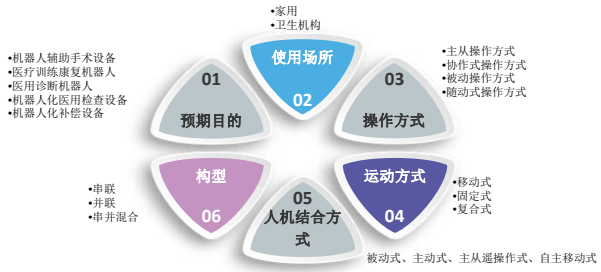
医用机器人标准体系
Standard system of medical robotics

➢ 中国医用机器人标准体系，包括三个层级 standard system of medical robotics in China includes three levels：



医用机器人分类
Classification of medical robotics

➢ 对医用机器人按6个维度进行分类classify medical robots in 6 dimensions ：



下一步工作计划 Next Plan

深化国际合作

•成立IEEE联合工作组
•提出医用机器人IEEE标准新项目

PART 1

完善组织架构

•成立康复机器人标准化专项工作组

PART 2

推动标准制定

- 加快推进《医用机器人分类、术语和定义》等2项标准作为2018年医疗器械行业标准立项项目

PART 3

医疗器械产业重点研发方向
Key development areas of industry

THANK

郑佳 zhegnjia@nifdc.org.cn

HOLOGIC®
The Science of Sure

U.S. - China Standards Workshop & Conformity Assessment Cooperation Program

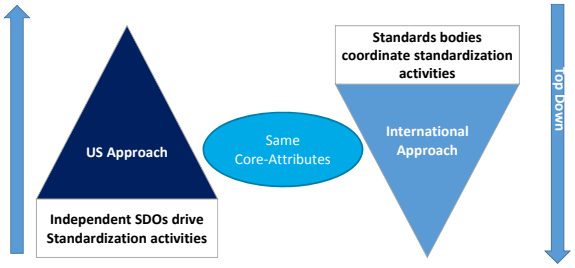
Standards Development Process: 'Best Practice' Approaches & Core-Attributes

Beijing, China. 26 March 2018

Agenda

- Two Primary Best Practice Approaches to Standards Development
- Overview of Best Practices (US/EN/ISO)
- Recommendations for Effective Standards Development Activities 'Best Practice'
- Conclusion
- Questions

Two Primary Approaches to Standardization 'Best Practice'



What is the Standards Development Process?
Standards development is a method of documenting processes, principles, or technical requirements and recommendations that are established by authority, custom, or consent

Overview of US Standards Development Process

- The US relies upon the US Standards 'Strategy'. ANSI (American National Standards Institute) is the main body that oversees standards development in the US
- The 'Strategy' outlines twelve globally accepted principles for standards development:
  - Transparency, Openness, Impartiality,
  - Effectiveness and Relevance, Consensus, Performance-Based, Coherence,
  - Due Process, Technical Assistance,
  - Flexibility, Timely, Balanced.
- OMB Circular A-119: Provides guidance to U.S. federal agencies from the Office of Management and Budget (OMB) in accordance to the National Technology Transfer and Advancement Act (NTTAA) – Public Law 104-113

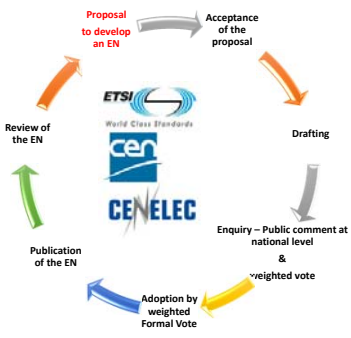
Ref: ANSI Essential Requirements: Annex B: Procedures for the Development of a Provisional American National Standard (ANS) or a Provisional Amendment to an ANS

US Participation in International Standards Development e.g. ISO, IEC via TAGs

- ANSI has oversight of US Secretariats at ISO/IEC
- US TAGs (Technical Advisory Groups) promote U.S.-based technology globally, through the establishment of Partnership Standards Developing Organization (PSDO) agreements.
- TAGs are composed of participants from companies, technical and trade organizations, government agencies, academia and individuals.
- Minimum criteria for US TAGs include: Openness, balance, due process and an appeals mechanism.

Ref: Annex B: "Criteria for Development and Coordination of U.S. Positions in the International Standardization Activities of the ISO and IEC
Ref: USNC/IEC Guidance Bulletin 1

Overview of EN Standards Development Process



- The three European Standardization Organizations*, CEN, CENELEC and ETSI are officially recognized for voluntary technical standardization.
- Development of EN Standards is governed by the principles of:
  - consensus, openness, transparency, national commitment and technical coherence
- The (EU) Regulation (1025/2012) sets the legal framework. Adopted by the European Parliament and Council of the EU, and entered into force on 1 January 2013.

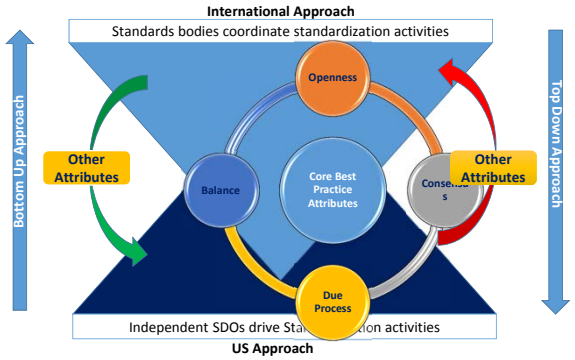
Ref: CEN – European Committee for Standardization - https://www.cen.eu/work/ENdev/Pages/default.aspx available as at 8 March 2018

Overview of ISO Standards Development Process

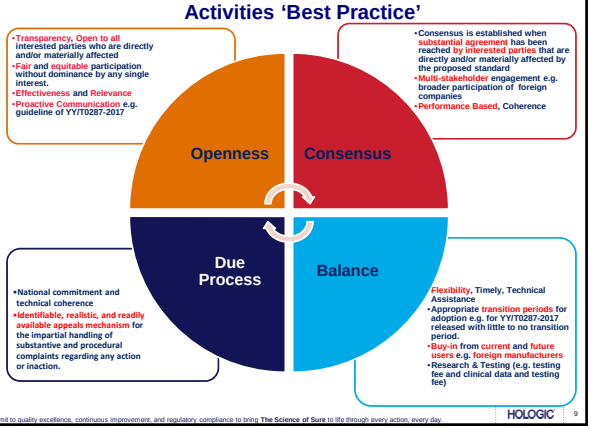
- Like a Symphony Orchestra
- Key drivers and attributes:
  - Market Need, Expert Opinion, Multi-stakeholders, Consensus

Ref: ISO Organization Website: https://www.iso.org/files/live/sites/isoorg/files/developing_standards/iso_deliverables/img/schema-iso-deliverables_EN.jpg as of 8 March 2018

Overlap of 'Best Practice' Core-Attributes



Recommendations for Effective Standards Development Activities 'Best Practice'



Conclusion

- There are two primary approaches to standards development 'best practice'
- Despite the differing best- practice approaches (US/EU/ISO), there are at least four 'core-attributes' that are shared amongst the different SDOs:
  - Openness,
  - balance,
  - consensus, and
  - due process (including appeals mechanism).
- Proactive communications, appropriate transition timelines, and buy-in/broader input from foreign manufacturers is important in 'best-practice' standards development process

HOLOGIC®
The Science of Sure

Thank You!

George Odero
Director, Corporate Regulatory Affairs, Systems & Standards

HOLOGIC®
The Science of Sure

美中标准研习会及合格评定合作新项目

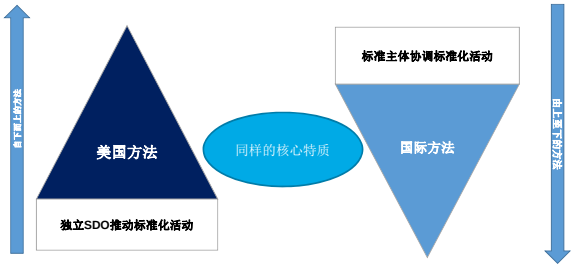
标准开发流程：“最佳实践”方法&核心特质

北京、上海 2018年3月26日

议程

- 标准开发的两种首要最佳实践方法
- 最佳实践总览（美/欧/国际标准化组织）
- 高效标准开发活动“最佳实践”推荐
- 结论
- 问题

“最佳实践”标准化的两种首要方法



什么是标准开发流程？

标准开发是一种记录流程、原则、技术需求和建议的方法，通过权威、惯例或征得同意后建立。

美国标准开发流程总览

- 美国依赖美国标准“策略”。ANSI（美国国家标准协会）是监管美国标准开发的主体
- “策略”概述了十二条标准开发的世界通用原则
  - 透明、公开、公正
  - 有效性、相关性、一致同意、绩效、一惯性
  - 正当程序，技术辅助，
  - 灵活，适时，平衡
- OMB通告A-119：由管理和预算办公司依据国家技术转移和进步法案（NTTAA））（OMB）向美国联邦机构提供的指导——公法104-113

参考：ANSI基本要求：附件B:美国临时国家标准开发（ANS）或ANS的一项临时修正案所采取的流程

美国参与国际标准开发，如：ISO、通过TAGs参与的IEC

- ANSI监管ISO/IEC的美国秘书处
- 美国TAGs（技术咨询组）通过建立合伙人标准开发组织（PSDO）协议在全球推动美国技术。
- TAG成员包括企业、技术和贸易组织、政府机构、学术界和个人
- 美国TAGs的准则包括：公开、平衡、正当程序和申诉机制

参考：附件B：“发展和协调美国在ISO和IEC的国际标准化活动中的地位所需要的标准
参考：USNC/IEC指导手册1

欧洲标准开发流程总览

- 三家欧洲标准化组织*，CEN、CENELEC和ETSI均正式经过志愿技术标准化认证。
- 欧洲标准开发受限于以下原则：
  - 一致同意、公开、透明、国家承诺和技术联接
- （EU）条例（1025/2012）规定了法律框架。被欧洲议会和欧盟理事会采用，于2013年1月1日正式实施。

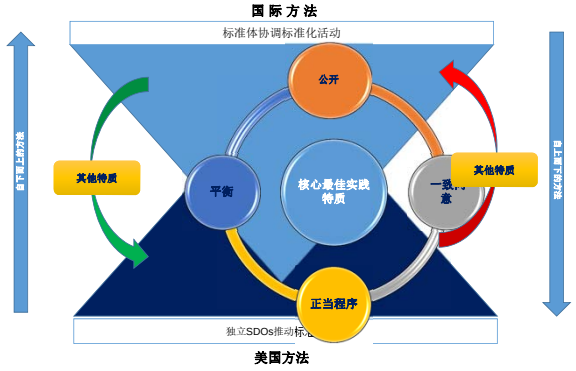
参考：CEN-欧洲标准化委员会-https://www.cen.eu/work/ENdev/Pages/default.aspx 2018年3月8日有效

ISO标准开发流程总览

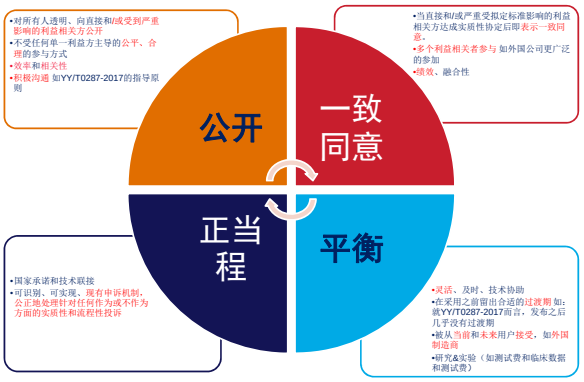
- 类似交响乐团
- 主要推动因素和特质
  - 市场需要、专家观点、多方利益相关者、一致同意

参考：ISO组织网站：https://www.iso.org/files/live/sites/isoorg/files/developing_standards/iso_deliverables/img/schema-iso-deliverables_EN.jpg 2018年3月8日有效

“最佳实践”核心特质的重叠



高效标准开发活动“最佳实践”的推荐



结论

- 标准开发“最佳实践”的两种主要方法
- 虽然最佳实践方式有所不同（美国/欧洲/国际），在不同的SDO之间至少有四种“核心特质”相同：
  - 公开
  - 公平
  - 一致同意，和
  - 正当程序（包括申诉机制）
- 积极沟通，合理的过渡时间表，和外国制造商的接受/广泛的建议在“最佳实践”标准开发流程中很重要。

HOLOGIC®
The Science of Sure

谢谢！

George Odero
全球法规、体系&标准总监

International Best Practice of Medical Devices Test

Daniel Chen
Philips Global Regulations & Standards
March 26, 2018

innovation + you

PHILIPS

The importance of medical device testing

- Important part of medical devices quality assurance
  - input for product design
  - safe guard the quality of the manufacturing
- Important evidence for the competence authority to grant the market access
  - Requirement on manufacturer: the product must be in compliance with the regulations
  - Requirement on the test lab: be trustworthy

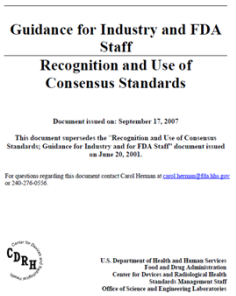
Requirement from EU → Show the conformity with the Regulation

- ANNEX X CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION
  - The notified body shall:
  - (a) examine the application by using staff with proven knowledge and experience regarding the technology concerned and its clinical application. The notified body may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the relevant requirements of this Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests;


Official Journal L 117
of the European Union
Legislation
EN

Requirement of US → show the substantial equivalence (e.g. for 510(k))

- A manufacturer may base declarations of conformity on the manufacturer's own testing and analysis or on that of a third party, such as a testing laboratory or certification body. Falsifying a declaration of conformity is a prohibited act under 21 U.S.C. 331(x). Any device for which a declaration of conformity has been falsified is adulterated under 21 U.S.C. 351(e)(2).


Guidance for Industry and FDA Staff
Recognition and Use of Consensus Standards
Document issued on: September 17, 2007
This document supersedes the "Recognition and Use of Consensus Standards; Guidance for Industry and for FDA Staff" document issued on June 20, 2003.
For questions regarding this document contact Carol Herman at carol.herman@fda.hhs.gov or 240-276-0556.
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Standards Management Staff
Office of Science and Engineering Laboratories

Requirement of China (1) → testing is dedicated to the test institute

- **Regulations for the Supervision and Administration of Medical Devices**
  - **Article 9** To file a record for Class I medical devices and apply for registration of Class II and Class III medical devices, the following files shall be submitted:
    - (I) Risk analysis report of the product;
    - (II) Technical requirements of the product;
    - (III) Testing report of the product;
    - (IV) Clinical evaluation material;
    - (V) Sample of Instruction for use and label;
    - (VI) Quality management system documents related to research and development and manufacture.
    - (VII) Other necessary documents to demonstrate safety and effectiveness of the product.
  - **Article 11 …** For Class II and Class III medical devices, the testing report shall be type testing report issued by testing institute of medical device; …


中华人民共和国中央人民政府
中华人民共和国国务院令
国务院关于修改《医疗器械监督管理条例》的决定

Requirement of China (2) → Show the compliance with the PRODUCT TECHNICAL REQUIREMENT

- **Provisions for Medical Device Registration**
  - **Article 16** The REGISTRATION TEST shall be conducted to apply registration for Class II and Class III medical device. The testing institutes of medical device shall conduct registration testing according to PRODUCT TECHNICAL REQUIREMENT.
- **CFDA Notice about Better Carrying Out The Medical Device Testing**
  - III, All the medical device test institute shall follow the requirements of *Regulations for the Supervision and Administration of Medical Devices, Provisions for Medical Device Registration* and *Provisions for IVD Registration*, carry out the contracted test according to the PRODUCT TECHNICAL REQUIREMENT, and issue a report for product registration.


国家食品药品监督管理总局 CFDA
《医疗器械注册管理办法》（国家食品药品监督管理总局令第4号）
国家食品药品监督管理总局令

High cost of the product type test

- Many kinds of test to be carried out include but not limited to:
  - Safety test
  - Performance test
  - EMC test
  - Biocompatibility
  - Software test
  - Cybersecurity test
- Long test cycle, resources demanding
  - Long time to prepare a test sample
    - Several months
    - Transportation and custom clearance needed for imported sample
  - Long time to do the test
    - Several months to more than 1 year
  - Human resources allocation
    - team work needed due to specialty of the test engineers
    - Support from R&D personel
  - Lab preparation
    - Installing and disassembling large devices
    - Paticular test site preparation (e.g. EMC)
- Opportunity cost
  - Innovation can't be realized in time
- Psychological cost
  - No cruelty

Finally this will be the cost of the society on medical care

Reform direction of China

General Office of CPC & General Office of the State Council published *Opinions on Deepening the Reform of the Review and Approval System to Encourage the Innovation of Drugs and Medical Devices*

- I, The reform of clinical trial administration
- II, Speed up the pre-market review and approval
- III, Promoting the development of drug and generic drugs
- IV, Strengthening the whole life cycle management of medical devices
- V, Upgrading technical support capability
- VI, Strengthen the implementation

Key word Innovation

Speeding up is vital for innovation

- Innovations need to be realized as soon as possible
- The innovation of the medical community needs to come into contact with new technology as soon as possible

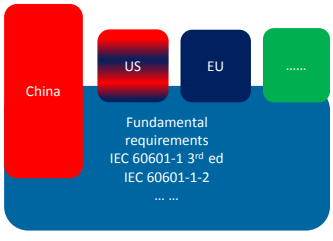
Draft amendment to the *Regulation* (call for comments)

The amendment of the Regulation relates to the inspection of medical devices:

For Class II and Class III medical devices, the testing report ~~shall be type testing report issued by testing institute of medical device~~ is allowed to be a self generated test report from the applicant or a test report issued by an accredited medical device test institution;

Speed up → reduce redundancies

- Global general requirements, one test for all
- Country specifics, particular test for individual



Accreditation of test labs

- Basic requirements
  - Impartiality
  - Competence
  - well organized
- Standard ISO/IEC 17025
  - Title: General requirements for the competence of testing and calibration laboratories
  - Recognized by China as GB/T 27025-2008

Mutual Recognition Arrangement

- ILAC MRA
  - Ensure the impartiality and competence of the test lab
  - Remove barriers to global trade: Tested or inspected once, accepted every where.
- China National Accreditation Service for Conformity Assessment (CNAS)

Outlook

- Global harmonization of the standards
  - Same standard being recognized
  - Same standard with the same version being used
- Recognition both result from manufacturers and accredited labs
  eg.:
  - Compliance with standards is checked by accredited test lab.
    - For the part regarding standards, there is mutual recognition. The redundant test is thus avoided.
  - High end performance part, being tested by the manufacturer, and recognized by the competence authority
    - eg. some medical devices are too specialized to have a test setup in an accredited test lab only for this manufacturer.

Summarize

- The competence authorities are serious about the type tests on medical devices
- China is reforming its system toward more innovation friendly
- We hope the approach by recognizing both the test result from the manufacturer and the test labs to be adopted
  - reduce the redundant labor and reduce the cost to the society.

PHILIPS

医疗器械检测
国际最佳实践

谌达宇
飞利浦全球法规与标准部门
2018年3月26日

innovation + you

PHILIPS

医疗器械检验的重要性

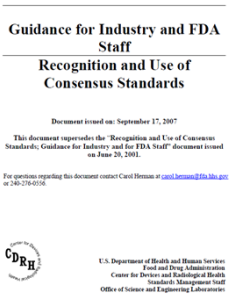
- 医疗器械质量保障的重要环节
  - 对产品设计提供输入
  - 对产品制造予以把关
- 监管者给予市场准入的重要依据
  - 一方面要求生产厂商的产品符合法规要求
  - 另一方面要求检验实验室值得信赖

欧盟的要求 → 证明符合法规

- 附录 10， 基于型式检验的符合性评价
  - 公告机构应：
  - (a) 针对相应的技术及其临床应用，调集确有知识与经验的员工对申请予以审查。为了对本法规的符合性作出评价，公告机构可以要求补充进一步的检验，或提供进一步的证据以使申请更完整。针对这个器械，公告机构应进行充分的物理或实验室测试或者要求制造商来完成相应的测试。
  - (b) …

美国的要求 → 证明实质性等同 (以510(k)为例)

- 进行符合性声明时，制造商提供的依据可以来自于制造商本身的测试与分析，也可以来自第三方，比如某个检测实验室或认证机构。针对符合性声明的造假行为是法律条文21 U.S.C. 331(x)禁止的。假造符合性声明所涉及的任何器械，根据21 U.S.C. 351(e)(2)法律条文，属于假造器械。


Guidance for Industry and FDA Staff

Recognition and Use of Consensus Standards

Document issued on: September 17, 2007

This document supersedes the "Recognition and Use of Consensus Standards; Guidance for Industry and for FDA Staff" document issued on June 20, 2001.

For questions regarding this document contact Carol Herman at carol.herman@fda.hhs.gov or 240-276-0556.

CDRH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Standards Management Staff
Office of Science and Engineering Laboratories

中国的要求 (1)→ 检测限于医疗器械检验机构

- 医疗器械监督管理条例
  - 第九条　第一类医疗器械产品备案和申请第二类、第三类医疗器械产品注册，应当提交下列资料：
    - （一）产品风险分析资料；
    - （二）产品技术要求；
    - （三）产品检验报告；
    - （四）临床评价资料；
    - （五）产品说明书及标签样稿；
    - （六）与产品研制、生产有关的质量管理体系文件；
    - （七）证明产品安全、有效所需的其他资料。
  - 第十一条 … 第二类、第三类医疗器械产品注册申请资料中的产品检验报告应当是医疗器械检验机构出具的检验报告； …

中国的要求 (2) →证明符合产品技术要求

- 医疗器械注册管理办法
  - 第十六条　申请第二类、第三类医疗器械注册，应当进行注册检验。医疗器械检验机构应当依据产品技术要求对相关产品进行注册检验。
- 总局办公厅关于做好医疗器械检验有关工作的通知
  - 三、各医疗器械检验机构要按照《医疗器械监督管理条例》（国务院令第680号）和《医疗器械注册管理办法》（食品药品监管总局令第4号）、《体外诊断试剂注册管理办法》（食品药品监管总局令第5号）等规定，对医疗器械注册申请人委托检验的注册产品依据产品技术要求进行检验，并出具检验报告用于产品注册。

产品型式检验的高成本

- 医疗器械检验所涵盖的种类众多，包含但不限于
  - 安规测试
  - 性能测试
  - 电磁兼容性测试
  - 生物相容性测试
  - 软件测试
  - 网络安全测试

最终将成为社会的医疗成本

- 医疗器械检验周期长，资源耗费高
  - 准备试验样机时间长
    - 数月
    - 进口检验还需要运输通关
  - 完成检验时间周期长
    - 数月甚至一年以上
  - 人员调度
    - 专职检验工程师各自技术背景不同，完成产品检验通常需要多人合作
    - 产品研发人员支持
  - 实验室准备
    - 大型设备架设与拆卸
    - 特殊场地的调配（如EMC）
- 机会成本
  - 创新无法快速实现为产品
- 心理成本
  - No cruelty

中国的改革方向

- 一、改革临床试验管理
- 二、加快上市审评审批
- 三、促进药品创新和仿制药发展
- 四、加强药品医疗器械全生命周期管理
- 五、提升技术支撑能力
- 六、加强组织实施

关键词 创新

加快速度是创新的生命力所在

- 新的想法需要尽快实现为产品
- 医学界的创新需要尽快地接触到新的技术

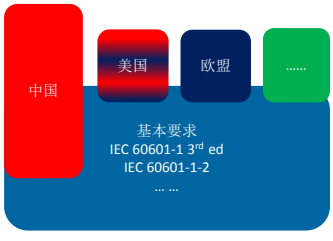
条例修正案征求意见稿

条例的修改涉及到了医疗器械检验

第二类、第三类医疗器械产品注册申请资料中的产品检验报告~~应当是医疗器械检验机构出具的检验报告~~可以是注册申请人的自检报告或者委托有资质的医疗器械检验机构出具的检验报告。

加快速度 → 减少重复劳动

- 全球通用要求，一次检验完成
- 各国差异，针对具体情况完成



实验室资质认定

- 基本要求
  - 公正性
  - 权威性
  - 组织规范
- 标准ISO/IEC 17025
  - 标题：，检测和校准实验室能力的通用要求
  - 等同转化为：GB/T 27025-2008

实验室互认约定

- ILAC 互认约定
  - 确保实验室公正权威
  - 破除贸易壁垒：一次检验，全球接受
- 中国合格评定国家认可委员会 (CNAS)

未来的希望

- 全球标准协调统一
  - 使用相同的标准
  - 同一标准使用相同的版本
- 厂家自测 与 认证实验室相结合
  例如：
  - 公用标准部分 采取认证实验室检测方式
    - 公用标准部分，各认证实验室互相认可，减少或避免重复性测试
  - 高端性能部分 采用厂家自测方式，由认证机构认可
    - 比如：部分医疗器械过于特殊，认证实验室不一定有相应的检测工装，也不值得为了一家的检测去购置

总结

- 医疗器械的型式检验受到各国的重视
- 中国的改革在朝有利于创新的方向发展
- 希望，实验室互认与厂家自测方式相结合
  - 减少重复劳动，降低整体社会的医疗成本