

China

Update on jurisdictional regulatory developments

Department of medical device supervision
State Food and Drug Administration, China

2013.03.20

Revise

- Regulations for the Supervision and Administration of Medical Devices (State council decree No.276)

----2006, start to revise

----2008, complete the first draft document by SFDA

----2010, a consultation paper by Legislative Affairs Office of state council on their website for advice

Now, still in progress

Adjust

- Classification of some medical devices have been adjusted by SFDA on 2012, mainly reduced classification level

For example:

Most of X-ray equipment (except for use in special part of body diagnostic, such as Angiographic X-ray diagnostic device and so on)

--- From class III to II

Colorful ultrasonic devices (except for include class III probe detector)

--- From class III to II

Details could be found on SFDA's website www.sfda.gov.cn

Release

- YY 0505 standard had been released on 2012, this standard is identical to IEC 60601-1-2:2004 “Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral standard : Electromagnetic compatibility. Requirements and tests”
- It is mandatory standard, implementation from 2014.01.01
- For medical device Registration:
 - from 2014.1.1, class III medical device apply for Initial registration should provide the test report issued by china medical device test center
 - from 2015.1.1, class II, I medical device apply for Initial registration should provide the test report issued by china medical device test center/by itself
 - medical devices which have already been registered before 2014.01.01 (implementation date) should provide test report at re-registration

Prepare

- **GB 9706.1-2007** is identical to IEC 60601-1:1988+A1:1991+A2:1995 <Medical electrical equipment - Part1: General requirements for safety>

Now, it is preparing for revision and implementation, and SFDA had Published the work scheme for the project,

the purpose: new standard will be identical to IEC 60601-1:2005+A1:2012 (Revise the GB 9706.1-2007)

- GB means national level (Not SFDA level standard) in china. So, the standard must acquire the approval of SAC (Standardization Administration of the people's republic of China)
- Now, SFDA is studying the items below:
 - compare the differences between GB 9706.1-2007 and IEC 60601-1:2005+A1:2012
 - evaluate the influence on medical device administration after the new standard implementation
 - investigate the revision plan for related Collateral standards and special standards

According to the work scheme, SFDA will plan to submit the new standard document to SAC in the end of 2014 in accordance with procedure of the standard revision.

- Thank you
- E-mail: yuanpeng@sfda.gov.cn, wanglm@sfda.gov.cn
- Questions ?