

Changes to Standards: Revision Approval and Announcement System

Following guidance provided by the Board of Governors (BoG), AATB is introducing a new schedule for the approval and announcement of changes to standards pertaining to the 14th Edition and the 2nd Edition of the NT Standards (collectively referred to as “Standards”). The highlights of the new Revision Approval and Announcement System effective January 1, 2019 are as follows:

1. **Standards Committee Approval and Presentation to the BoG**

Changes to Standards approved by the Standards Committees are going to be presented to the Board of Governors for approval on a **quarterly** basis.

2. **Announcement Schedule**

Changes to Standards approved by the Board of Governors are going to be announced **biannually** as follows:

- On **January 31** - changes approved by the BoG in the third and fourth quarter of the previous year.
- On **July 31** – changes approved by the BoG in the first and second quarter of the current year.

3. **Implementation Period.**

The Implementation Period of changes to Standards is going to be fixed at **6 months starting on the day of the announcement**, i.e. changes announced on **January 31** will be effective on **July 31** of the current year, and changes announced on **July 31** will be effective on **January 31** of the following year.

- Changes to Standards recommended as **urgent** by the Standards Committee and approved as such by the Board of Governors may be announced on a midterm basis, i.e. April 30 or October 31, or when approved by the Board of Governors. Such changes may be effective **immediately** as of the date of the Bulletin announcement.

4. **Bulletin Announcement.**

All changes to Standards approved by the BoG during the 3rd and the 4th quarter of 2018 announced in Bulletin No. 19-1, as well as future changes, except those approved as “urgent”, are going to be announced biannually through AATB-issued Bulletins titled “*Changes to AATB Standards*”. The specific changes to Standards (amendments) are going to be presented **by Section** with the following requisite information:

- a) **Description of Amendment(s).** Sections containing amended standards are going to be presented in the AATB Bulletins with brief descriptions of the amendment(s) and links to the redlined versions of each amended Section. Each amended standard will appear with a blue-font preamble “*Current*” showing the current verbiage before the amendment, followed by the redlined version with a preamble “*With amendments*”, and a clean amended version with a preamble “*As amended*”. The clean “As amended” version is going to be followed by a postscript note in blue font showing the announcement date, AATB Bulletin number, effective date and implementation period. (see postscript example in the box below)

Announcement Date: January 31, 2019 (Bulletin No. 19-1)
Effective Date: July 31, 2019 (6-month implementation period)

- b) **NT-Standards.** Sections in the NT-Standards amended **after the publication of the 2nd Edition for NTAD**, are going to be announced in the same way as the amendments to the 14th Edition with “*Current*”, “*With amendments*”, and “*As amended*” versions and description of amendments.

5. **Table of Contents.** Standards amended after the publication of the 14th Edition are going to appear in the Table of Contents with the effective dates of their most recent amendments in blue font italics. (see excerpt from the Table of Contents below)

D5.000 RECOVERY, COLLECTION, AND ACQUISITION
D5.100 Reagents, Supplies, Materials and Equipment (*amended 5-31-18*)
D5.110 Stock Rotation
D5.200 Donor Identification
D5.210 Verification Procedures (*amended 4-19-17*)
D5.211 Confirmation
D5.212 Donor Identity

6. **Amended Standards.** In addition to the “last amended” notes in the Table of Contents, standards amended after the publication of the 14th Edition (2016) will appear in their respective Sections with a blue-font note showing the effective date of their last amendment.

J5.300 Qualification and Maintenance (*last amended July 9, 2018*)

Instruments, apparatus, gauges, and recording devices shall be calibrated or verified and routinely maintained, inspected, monitored, cleaned, decontaminated, sterilized (when applicable), and repaired per the manufacturer’s requirements and recommendations. When equipment, instruments, apparatus, gauges, and recording devices are found out of tolerance, there shall be provisions for remedial action to evaluate whether there was any adverse effect on quality.

J5.310 Requalification/Recalibration (*last amended July 9, 2018*)

Following repairs and system upgrades, equipment should be recalibrated or verified according to procedures in the SOPM that have been designed to be in compliance with the manufacturer’s requirements and recommendations.

If you have any questions, please contact Roman Hitchhev at hitchevr@aatb.org.