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Last revision published in 2016 and the transition period for migration to this version has not yet ended (due date 31st Mar 2019). This is indeed a unique situation – a new revision to an ISO management system standard started before the transition to the previous version has been completed.

Another Revision of ISO 13485 starts in 2019

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For more information about the changes, see our ISO 13485:2016 factsheet, which is available for download here. The necessary transition of your certificate is as follows: Since the official publication of ISO 13485:2016 on March 1, 2016, the transition of accredited certifications to the new ISO 13485:2016 can now be effected within the scope of a regular surveillance or recertification audit.