

ANAB Update on Transitions and Business Opportunities

Transitions

ISO 13485:2016: All ANAB ISO 13485 accredited CBs have transitioned to ISO 13485:2016.

ISO/IEC 27006:2015: Over 50% of ANAB ISO/IEC 27001 accredited CBs still need to transition to ISO/IEC 27006:2015. The transition must be completed by 30 September 2017.

ISO 9001:2015: Organizations are transitioning very slowly to ISO 9001:2015 due to limited resources and perceived overwhelming changes. An estimated 15-20% of organizations have transitioned, as of 15 April 2017.

ANAB and IAF are extremely concerned about the slow pace of transitions and the availability of CB resources. According to IAF, the 14 September 2018 deadline will not be extended. IAF has requested that ABs provide the following information on CB transition activity at the September meeting in Vancouver and that ABs also require CBs to update information every quarter:

- # companies that have started transition
- # companies that have transitioned
- # companies deciding NOT to transition and drop certification

ANAB has only witnessed 16 ISO 9001:2015 audits. Based on feedback from ANAB assessors, some of the requirements CB auditors are struggling with are 4.1, 4.2, 5.1.1(d), and 6.1. During the witnessed audits, multiple CBs have documented findings against the following requirements: 4.4.1, 7.2, 8.4.1, 9.1.2, 9.2.5, 9.3.2, and 10.2.1.

Business Opportunities

ISO/IEC 20000-1: Per ISO Survey there was no increase in the number of certificates in 2015. ANAB does not foresee any business opportunity for this standard.

ISO/IEC 27001: Per ISO Survey there was a 20% growth in number of certifications in 2015. ANAB has received very few inquiries from potential clients, but there is still considerable interest in this program. Most inquiries are from consultants.

ISO 37001: ANAB has received applications from 2 international CBs. ANAB has received inquiries from organizations requesting an American based CB. There is considerable opportunity for this standard.