ประกาศกระทรวงอุตสาหกรรม

ฉบับที่ ๔๖๐๒ (พ.ศ. ๒๕๕๗)
ออกตามความในพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม
พ.ศ. ๒๕๑๑
เรื่อง ยกเลิกมาตรฐานผลิตภัณฑ์อุตสาหกรรม
ข้อกำหนดทั่วไปสำหรับหน่วยรับรองคุณภาพผลิตภัณฑ์
และกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม
การตรวจสอบและรับรอง - ข้อกำหนดสำหรับหน่วยรับรองผลิตภัณฑ์ กระบวนการ และการบริการ

โดยที่เป็นการสมควรแก้ไขปรับปรุงมาตรฐานผลิตภัณฑ์อุตสาหกรรมข้อกำหนดทั่วไปสำหรับหน่วยรับรองคุณภาพผลิตภัณฑ์ มาตรฐานเลขที่ มอก. 5065 - 2540

อาศัยอำนาจตามความในมาตรา ๑๕ แห่งพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ. ๒๕๑๑ รัฐมนตรีว่าการกระทรวงอุตสาหกรรมออกประกาศยกเลิกประกาศกระทรวงอุตสาหกรรม ฉบับที่ ๒๒๖๒ (พ.ศ. ๒๕๔๐) ออกตามความในพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ. ๒๕๑๑ เรื่อง กำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรมข้อกำหนดทั่วไปสำหรับหน่วยรับรองคุณภาพผลิตภัณฑ์ ลงวันที่ ๕ มิถุนายน ๒๕๔๐ และออกประกาศกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม การตรวจสอบและรับรอง - ข้อกำหนดสำหรับหน่วยรับรองผลิตภัณฑ์ กระบวนการ และการบริการ มาตรฐานเลขที่ มอก. 17065 - 2556 ขึ้นใหม่ ดังมีรายละเอียดต่อท้ายประกาศนี้

ทั้งนี้ ให้มีผลตั้งแต่วันประกาศในราชกิจจานุเบกษาเป็นต้นไป

ประกาศ ณ วันที่ ๗ มกราคม พ.ศ. ๒๕๕๗
ประเสริฐ บุญชัยสุข
รัฐมนตรีว่าการกระทรวงอุตสาหกรรม

มาตรฐานผลิตภัณฑ์อุตสาหกรรม

การตรวจสอบและรับรอง – ข้อกำหนดสำหรับหน่วยรับรองผลิตภัณฑ์ กระบวนการและการบริการ

บทนำ

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้ กำหนดขึ้นโดยรับ ISO/IEC 17065:2012 Conformity assessment – Requirements for bodies certifying products, processes and services มาใช้ในระดับเหมือนกันทุกประการ (identical) โดยใช้ ISO/IEC ฉบับภาษาอังกฤษเป็นหลัก

ขอบข่าย

มาตรฐานนี้ประกอบด้วยข้อกำหนดเกี่ยวกับความสามารถ ความสม่ำเสมอในการดำเนินการ และความเป็นกลางของหน่วยรับรองผลิตภัณฑ์ กระบวนการ และการบริการ (ซึ่งต่อไปในมาตรฐานนี้จะเรียกว่า “หน่วยรับรอง”) หน่วยรับรองที่ดำเนินการตามมาตรฐานนี้ไม่จำเป็นต้องเสนอการให้บริการรับรองผลิตภัณฑ์ กระบวนการ และการบริการทุกประเภท

การรับรองผลิตภัณฑ์ กระบวนการ และการบริการ (ซึ่งต่อไปในมาตรฐานนี้จะเรียกว่า “การรับรอง”) เป็นกิจกรรมการตรวจสอบและรับรองโดยบุคคลที่สาม (ดู ISO/IEC 17000 : 2004 ข้อ 5.5)

ในมาตรฐานนี้ต่อไปคำว่า “ผลิตภัณฑ์” สามารถแทนด้วยคำว่า “กระบวนการ” หรือ “การบริการ” ยกเว้นกรณีที่มีการระบุข้อกำหนดแยกไว้สำหรับ “กระบวนการ” หรือ “การบริการ” เป็นการเฉพาะ (ดู ภาคผนวก ข)

เอกสารอ้างอิง

ISO/IEC 17000 Conformity assessment – Vocabulary and general principles

ISO/IEC 17020 Conformity assessment – Requirements for the operation of various types of bodies performing inspection

ISO/IEC 17021 Conformity assessment – Requirements for bodies providing audit and certification of management system

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

เอกสารอ้างอิงฉบับข้างต้นมีความสำคัญต่อการนำมาตรฐานนี้ไปใช้ สำหรับเอกสารที่มีการอ้างอิงโดยระบุปีให้ใช้เอกสารฉบับตามปีที่ระบุไว้ สำหรับเอกสารที่มีการอ้างอิงโดยไม่ระบุปี ให้ใช้เอกสารฉบับล่าสุด (รวมถึงการเพิ่มเติมต่างๆ)

รายละเอียดให้เป็นไปตาม ISO/IEC 17065: 2011 ข้อ 2

คำศัพท์และบทนิยาม

ความหมายของคำศัพท์และบทนิยามที่ใช้ในมาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้ ให้เป็นไปตาม มอก. 17000 และที่กำหนดเพิ่มเติม

รายละเอียดให้เป็นไปตาม ISO/IEC 17065: 2012 ข้อ 3

ข้อกำหนดทั่วไป

มีข้อกำหนดระบุไว้ 6 หัวข้อหลัก คือ

กฎหมายและสัญญา หน่วยรับรองต้องเป็นนิติบุคคล และมีข้อตกลงที่สามารถบังคับใช้ทางกฎหมายในการรับรองลูกค้า ต้องรับผิดชอบและคงไว้ซึ่งอำนาจในการตัดสินให้การรับรอง รวมถึงการใช้ใบอนุญาต ใบรับรอง และเครื่องหมาย

การจัดการความเป็นกลาง หน่วยรับรองต้องดำเนินกิจกรรมการรับรองด้วยความเป็นกลาง ระบุ และจัดการกับความเสี่ยงต่อความเป็นกลางที่เกิดขึ้น หรือที่มีโอกาสเกิดขึ้น ผู้บริหารระดับสูงของหน่วยรับรองต้องมีความมุ่งมั่นต่อความเป็นกลางและบริหารการขัดแย้งกันของผลประโยชน์ (conflict of interest) ทั้งที่มาจากภายในหน่วยรับรอง หรือจากกิจกรรมของบุคคล หน่วยงาน หรือองค์กรอื่น

หน่วยรับรองและหน่วยงานที่อยู่ภายใต้นิติบุคคลเดียวกัน หรือภายใต้การควบคุมองค์กรเดียวกัน ต้องไม่ดำเนินกิจกรรมใดๆที่มีส่วนเกี่ยวข้องกับผลิตภัณฑ์ที่ให้การรับรอง

ความรับผิดและการเงิน หน่วยรับรองต้องมีการจัดการด้านความรับผิดที่อาจเกิดขึ้นจากกิจกรรมการรับรองอย่างเพียงพอ มีสถานะการเงินที่มั่นคงและมีทรัพยากรที่จำเป็นต่อการดำเนินกิจกรรมการรับรอง

เงื่อนไขการไม่เลือกปฏิบัติ หน่วยรับรองต้องมีนโยบายและขั้นตอนการดำเนินงานที่ไม่เลือกปฏิบัติต่อลูกค้า ให้ผู้ยื่นคำขอทุกรายที่มีกิจกรรมอยู่ภายใต้ขอบข่ายการให้บริการสามารถเข้าถึงบริการการรับรอง

การรักษาความลับ หน่วยรับรองต้องมีข้อตกลงที่บังคับใช้ได้ตามกฎหมายในการรักษาความลับของลูกค้า และต้องแจ้งให้ลูกค้าทราบล่วงหน้าถึงข้อมูลที่ต้องการเผยแพร่สู่สาธารณะ กรณีที่กฎหมายหรือผู้ที่มีอำนาจตามข้อตกลงกำหนดให้หน่วยรับรองต้องเปิดเผยข้อมูลที่เป็นความลับของลูกค้า ต้องแจ้งให้ลูกค้าหรือผู้เกี่ยวข้องทราบล่วงหน้า เว้นแต่มีกฎหมายห้ามไว้

ข้อมูลที่มีไว้ให้แก่สาธารณชน หน่วยรับรองต้องพร้อมให้ข้อมูลต่อไปนี้เมื่อมีการร้องขอ ได้แก่ รูปแบบการรับรอง รวมถึงกระบวนการรับรอง หลักเกณฑ์และเงื่อนไขการรับรอง คำอธิบายแหล่งที่มาของเงินทุนสนับสนุนหน่วยรับรอง ค่าใช้จ่ายที่เรียกเก็บกับผู้ยื่นคำขอหรือลูกค้า คำอธิบายถึงสิทธิและหน้าที่ของผู้ยื่นคำขอและลูกค้า ขั้นตอนการดำเนินงานในการจัดการข้อร้องเรียนและข้ออุทธรณ์

รายละเอียดให้เป็นไปตาม ISO/IEC 17065: 2012 ข้อ 4

โครงสร้าง

มีข้อกำหนดระบุไว้ 2 หัวข้อหลัก คือ

โครงสร้างองค์กรและผู้บริหารระดับสูง หน่วยรับรองต้องกำหนดโครงสร้างองค์กรและอำนาจหน้าที่ของบุคลากรทั้งจากภายในและภายนอกรวมทั้งคณะกรรมการต่างๆ

คณะกรรมการเพื่อความเป็นกลาง โครงสร้างของหน่วยรับรองต้องประกอบด้วยคณะกรรมการเพื่อความเป็นกลาง หน่วยรับรองต้องจัดทำเอกสารองค์ประกอบ ขอบข่ายงาน ความสามารถ หน้าที่ความรับผิดชอบของคณะกรรมการเพื่อความเป็นกลางและอนุมัติโดยผู้บริหารสูงสุด

รายละเอียดให้เป็นไปตาม ISO/IEC 17065: 2012 ข้อ 5

ทรัพยากร

มีข้อกำหนดระบุไว้ 2 หัวข้อหลัก คือ

บุคลากรของหน่วยรับรอง หน่วยรับรองต้องมีบุคลากรที่มีความสามารถในการปฏิบัติงานตามหน้าที่ และมีจำนวนที่เพียงพอต่อการดำเนินการให้เป็นไปตามที่กำหนดในรูปแบบการรับรอง บุคลากรในทุกระดับต้องรักษาความลับข้อมูลของลูกค้า และให้มีการลงนามในสัญญารักษาความลับ และแจ้งถึงการมีส่วนเกี่ยวข้องหรือความขัดแย้งผลประโยชน์ที่เกิดขึ้นหรืออาจเกิดขึ้น

หน่วยรับรองต้องมีการดำเนินการที่ทำให้มั่นใจว่าบุคลากรที่เกี่ยวข้องกับขั้นตอนการรับรองมีความสามารถในงานที่ทำ โดยการกำหนดหลักเกณฑ์ความสามารถสำหรับแต่ละหน้าที่ตามที่กำหนดในรูปแบบการรับรอง ระบุความจำเป็นและจัดให้มีการฝึกอบรม มีการประเมินผลความสามารถของบุคลากร มีการแต่งตั้งและมอบหมายงานและมีการเฝ้าระวังความสามารถและผลการดำเนินงาน รวมถึงต้องมีการจัดเก็บประวัติบุคลากร

ทรัพยากรในการประเมินผล ในการประเมินผลของหน่วยรับรองอาจใช้ทรัพยากรของหน่วยรับรองเอง หรือใช้ทรัพยากรที่อยู่ภายใต้การควบคุมของหน่วยรับรอง หรือทำการจ้างเหมาช่วง โดยต้องเป็นไปตามข้อกำหนดมาตรฐานนี้ และตามรูปแบบการรับรองที่กำหนดไว้ โดยหน่วยรับรองต้องรับผิดชอบต่อกิจกรรมทั้งหมดที่ได้จ้างเหมาช่วงไปและต้องมั่นใจว่าหน่วยงานและบุคลากรของหน่วยงานที่รับเหมาช่วงมีความสามารถ

รายละเอียดให้เป็นไปตาม ISO/IEC 17065: 2012 ข้อ 6

กระบวนการ

มีข้อกำหนดระบุไว้ 13 หัวข้อหลัก คือ

ข้อกำหนดทั่วไป หน่วยรับรองต้องดำเนินกิจกรรมการรับรองตามรูปแบบการรับรอง ข้อกำหนดที่ใช้ในการประเมินผลิตภัณฑ์ของลูกค้าต้องเป็นข้อกำหนดตามมาตรฐานที่ระบุไว้และเอกสารกฎเกณฑ์อื่นๆ หากต้องมีคำอธิบายในการใช้มาตรฐาน ต้องจัดทำโดยบุคคลหรือคณะกรรมการที่เกี่ยวข้อง เป็นกลาง และมีความสามารถทางด้านวิชาการ

การรับคำขอ ในการรับคำขอ หน่วยรับรองต้องให้ได้ข้อมูลทั้งหมดที่จำเป็นสำหรับกระบวนการรับรองตามรูปแบบการรับรองที่เกี่ยวข้อง

การทบทวนคำขอ หน่วยรับรองต้องดำเนินการทบทวนข้อมูลที่ได้จากการรับคำขอ เพื่อให้มั่นใจว่าหน่วยรับรองมีความสามารถ และมีทรัพยากรในการดำเนินกิจกรรมการรับรอง

การประเมินผล หน่วยรับรองต้องมีการวางแผนสำหรับกิจกรรมการประเมินเพื่อให้มีการจัดการสำหรับการเตรียมการที่จำเป็น ต้องแจ้งให้ลูกค้าทราบถึงข้อบกพร่องทั้งหมดที่พบ หากลูกค้ายังคงต้องการขอรับการรับรองต้องให้มีการประเมินเพิ่มเติมเพื่อทำการทวนสอบการแก้ไขข้อบกพร่อง ผลจากการประเมินทั้งหมดต้องจัดทำเป็นเอกสารและนำเข้าสู่การทบทวน

การทบทวนผล หน่วยรับรองต้องมอบหมายบุคลากรที่ไม่มีส่วนเกี่ยวข้องในกระบวนการประเมินเพื่อทบทวนข้อมูลทั้งหมดรวมถึงผลการประเมิน ข้อเสนอในการตัดสินการรับรองที่มาจากการทบทวนผลต้องจัดทำเป็นเอกสาร

การตัดสินการรับรอง หน่วยรับรองต้องรับผิดชอบและคงไว้ซึ่งอำนาจในการการตัดสินการรับรอง การตัดสินการรับรองต้องดำเนินการโดยบุคคลหรือกลุ่มบุคคลที่ไม่มีส่วนเกี่ยวข้องในกระบวนการประเมิน และต้องแจ้งให้ลูกค้าทราบถึงการตัดสินการไม่อนุญาตให้การรับรอง และต้องระบุถึงเหตุผลสำหรับการตัดสินนั้น

เอกสารการรับรอง หน่วยรับรองต้องให้เอกสารการรับรองอย่างเป็นทางการแก่ลูกค้า

บัญชีรายชื่อผลิตภัณฑ์ที่ได้รับการรับรอง หน่วยรับรองต้องเก็บรักษาข้อมูลผลิตภัณฑ์ที่ได้รับการรับรอง

การตรวจติดตามผล ถ้ารูปแบบการรับรองกำหนดให้ต้องมีการตรวจติดตามผล หน่วยรับรองต้องดำเนินการตรวจติดตามผลผลิตภัณฑ์ภายใต้ขอบข่ายการรับรอง โดยให้เป็นไปตามรูปแบบการรับรอง

การเปลี่ยนแปลงที่มีผลต่อการรับรอง หากมีการปรับปรุงแก้ไขรูปแบบการรับรองที่มีผลต่อลูกค้า หน่วยรับรองต้องแจ้งการเปลี่ยนแปลงเหล่านี้แก่ลูกค้า และต้องทวนสอบการนำข้อกำหนดที่เปลี่ยนแปลงไปปฏิบัติของลูกค้า และให้มีปฏิบัติการที่จำเป็นตามที่รูปแบบการรับรองกำหนดไว้ และต้องพิจารณาการเปลี่ยนแปลงอื่นๆ ที่มีผลต่อการรับรอง รวมถึงการเปลี่ยนแปลงที่เกิดขึ้นจากลูกค้า และต้องตัดสินใจปฏิบัติการตามความเหมาะสม

การยุติ ลดขอบข่าย พักใช้ หรือเพิกถอนการรับรอง หน่วยรับรองต้องพิจารณาและตัดสินใจดำเนินการที่เหมาะสมเมื่อพบความไม่เป็นไปตามข้อกำหนดการรับรองจากการตรวจติดตามผลหรืออื่นๆ หากยกเลิกการรับรอง (โดยการร้องขอของลูกค้า) พักใช้ หรือเพิกถอน หน่วยรับรองต้องดำเนินการตามที่รูปแบบการรับรองกำหนด และให้มีการปรับเปลี่ยนเอกสารการรับรองที่จำเป็น หากมีการคืนสถานะการรับรอง หรือการลดขอบข่ายการรับรอง หน่วยรับรองต้องปรับเปลี่ยนเอกสารการรับรอง เพื่อมั่นใจว่ามีการบ่งชี้ที่เหมาะสมถึงการได้รับการรับรองของผลิตภัณฑ์

บันทึก หน่วยรับรองต้องจัดเก็บบันทึกที่แสดงให้เห็นว่าได้มีการดำเนินการตามข้อกำหนดกระบวนการรับรองที่ระบุในมาตรฐานนี้ และในรูปแบบการรับรองอย่างมีประสิทธิผล

ข้อร้องเรียนและอุทธรณ์ หน่วยรับรองต้องมีเอกสารกระบวนการในการรับ ประเมิน และตัดสินข้อร้องเรียนและอุทธรณ์ และต้องแจ้งผู้ร้องเรียนและผู้อุทธรณ์ให้ทราบถึงการดำเนินการและผลการดำเนินการ

รายละเอียดให้เป็นไปตาม ISO/IEC 17065: 2012 ข้อ 7

ระบบการบริหารงานสำหรับหน่วยรับรอง

มีข้อกำหนดระบุไว้ 8 หัวข้อหลัก คือ

ทางเลือก หน่วยรับรองมี 2 ทางเลือก ได้แก่ ทางเลือกที่ 1 จัดทำ และรักษาไว้ซึ่งระบบการบริหารงานทั่วไป ซึ่งประกอบด้วย เอกสารระบบบริหารงานทั่วไป การควบคุมเอกสาร การควบคุมบันทึก การทบทวนของฝ่ายบริหาร การตรวจประเมินภายใน ปฏิบัติการแก้ไข และปฏิบัติการป้องกัน หรือทางเลือกที่ 2 จัดทำ และรักษาไว้ซึ่งระบบการบริหารงานคุณภาพตาม ISO 9001

เอกสารระบบการบริหารงานทั่วไป (ทางเลือกที่ 1) หน่วยรับรองต้องจัดทำเอกสารระบบการบริหารงานทั่วไป ให้มีการนำไปปฏิบัติ และรักษาไว้

การควบคุมเอกสาร (ทางเลือกที่ 1) หน่วยรับรองต้องจัดทำขั้นตอนการดำเนินงาน ควบคุมเอกสาร ทั้งเอกสารภายในและเอกสารภายนอก

การควบคุมบันทึก (ทางเลือกที่ 1) หน่วยรับรองต้องจัดทำขั้นตอนการดำเนินงาน เพื่อระบุการควบคุมที่จำเป็นสำหรับการบ่งชี้ การเก็บรักษา การป้องกัน การเรียกคืน ระยะเวลาการจัดเก็บและการทำลายบันทึก

การทบทวนของฝ่ายบริหาร (ทางเลือกที่ 1) หน่วยรับรองต้องจัดทำขั้นตอนการดำเนินงาน การทบทวนของฝ่ายบริหาร และให้มีการดำเนินการทบทวนของฝ่ายบริหารอย่างน้อยปีละครั้ง จัดเก็บบันทึกการทบทวนของฝ่ายบริหาร

การตรวจประเมินภายใน (ทางเลือกที่ 1) หน่วยรับรองต้องจัดทำขั้นตอนการดำเนินงาน การตรวจประเมินภายในเพื่อทวนสอบความสอดคล้องตามข้อกำหนดของมาตรฐานระหว่างประเทศนี้ และการนำระบบการบริหารงานไปปฏิบัติอย่างมีประสิทธิผลและรักษาไว้ โดยต้องดำเนินการตรวจประเมินภายในอย่างน้อยทุก 12 เดือนต่อครั้ง

ปฏิบัติการแก้ไข (ทางเลือกที่ 1) หน่วยรับรองต้องจัดทำขั้นตอนการดำเนินงาน เพื่อระบุและจัดการกับข้อบกพร่องในการดำเนินงาน โดยกำจัดสาเหตุที่ทำให้เกิดข้อบกพร่อง เป็นการป้องกันการเกิดซ้ำของข้อบกพร่อง

ปฏิบัติการป้องกัน (ทางเลือกที่ 1) หน่วยรับรองต้องจัดทำขั้นตอนการดำเนินงาน ปฏิบัติการป้องกัน เพื่อกำจัดสาเหตุของแนวโน้มข้อบกพร่อง

รายละเอียดให้เป็นไปตาม ISO/IEC 17065: 2012 ข้อ 8

ภาคผนวก ก

หลักการสำหรับหน่วยรับรองผลิตภัณฑ์ และกิจกรรมการรับรองผลิตภัณฑ์

อธิบายถึงหลักการในการสร้างความเชื่อมั่นในการรับรองผลิตภัณฑ์ ได้แก่ หลักการทั่วไป ความเป็นกลาง ความสามารถ การรักษาความลับและการเปิดเผยข้อมูล และความรับผิดชอบ

รายละเอียดให้เป็นไปตาม ISO/IEC 17065: 2012 Annex A

ภาคผนวก ข

การนำมาตรฐานไปใช้กับกระบวนการ และการบริการ

อธิบายถึงการนำมาตรฐานนี้ไปใช้กับกระบวนการ และการบริการ

รายละเอียดให้เป็นไปตาม ISO/IEC 17065: 2012 Annex B

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft International Standards are circulated to the national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC 17065 was prepared by the ISO Committee on conformity assessment (CASCO).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This first edition of ISO/IEC 17065 cancels and replaces ISO/IEC Guide 65:1996, which has been technically revised.

The following major changes have been made compared with ISO/IEC Guide 65:1996:

— restructuring of this International Standard based on the common structure adopted by ISO/CASCO;

— modifications based on ISO/PAS 17001, ISO/PAS 17002, ISO/PAS 17003, ISO/PAS 17004 and ISO/PAS 17005;

— introduction of the ISO/IEC 17000 functional approach in the process requirements of Clause 7;

— information on the application of this International Standard for processes and services in Annex B;

— revision of the terms and definitions in Clause 3;

— improvement of the impartiality requirements (mechanism);

— consolidation of the management system requirements in Clause 8;

— inclusion of principles for product certification bodies and their activities in Annex A;

— improvement by taking into account IAF GD 5;

— inclusion of a reference to certification schemes, for which further information is provided in ISO/IEC 17067.

Introduction

The overall aim of certifying products, processes or services is to give confidence to all interested parties that a product, process or service fulfils specified requirements. The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfilment of specified requirements by a third party. Parties that have an interest in certification include, but are not limited to:

a) the clients of the certification bodies;

b) the customers of the organizations whose products, processes or services are certified;

c) governmental authorities;

d) non-governmental organizations; and

e) consumers and other members of the public.

Interested parties can expect or require the certification body to meet all the requirements of this International Standard as well as when relevant, those of the certification scheme.

Certification of products, processes or services is a means of providing assurance that they comply with specified requirements in standards and other normative documents. Some product, process or service certification schemes may include initial testing or inspection and assessment of its suppliers' quality management systems, followed by surveillance that takes into account the quality management system and the testing or inspection of samples from the production and the open market. Other schemes rely on initial testing and surveillance testing, while still others comprise type testing only.

This International Standard specifies requirements, the observance of which is intended to ensure that certification bodies operate certification schemes in a competent, consistent and impartial manner, thereby facilitating the recognition of such bodies and the acceptance of certified products, processes and services on a national and international basis and so furthering international trade. This International Standard can be used as a criteria document for accreditation or peer assessment or designation by governmental authorities, scheme owners and others.

The requirements contained in this International Standard are written, above all, to be considered as general criteria for certification bodies operating product, process or service certification schemes; they may have to be amplified when specific industrial or other sectors make use of them, or when particular requirements such as health and safety have to be taken into account. Annex A contains principles relating to certification bodies and certification activities that they provide.

This International Standard does not set requirements for schemes and how they are developed and is not intended to restrict the role or choice of scheme owners, however scheme requirements should not contradict or exclude any of the requirements of this International Standard.

Statements of conformity to the applicable standards or other normative documents can be in the form of certificates and/or marks of conformity. Schemes for certifying particular products or product groups, processes and services to specified standards or other normative documents will, in many cases, require their own explanatory documentation.

While this International Standard is concerned with third parties providing product, process or service certification, many of its provisions may also be useful in first- and second-party product conformity assessment procedures.

In this International Standard, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

Conformity assessment — Requirements for bodies certifying products, processes and services

1 Scope

This International Standard contains requirements for the competence, consistent operation and impartiality of product, process and service certification bodies. Certification bodies operating to this International Standard need not offer all types of products, processes and services certification. Certification of products, processes and services is a third-party conformity assessment activity (see ISO/IEC 17000:2004, definition 5.5).

In this International Standard, the term “product” can be read as “process” or “service”, except in those instances where separate provisions are stated for “processes” or “services” (see Annex B).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17020, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

ISO/IEC 17021, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following apply.

3.1
client
organization or person responsible to a certification body for ensuring that **certification requirements** (3.7), including **product requirements** (3.8), are fulfilled

NOTE Whenever the term “client” is used in this International Standard, it applies to both the “applicant” and the “client”, unless otherwise specified.

3.2
consultancy
participation in

a) the designing, manufacturing, installing, maintaining or distributing of a certified product or a product to be certified, or

b) the designing, implementing, operating or maintaining of a certified process or a process to be certified, or

c) the designing, implementing, providing or maintaining of a certified service or a service to be certified

NOTE In this International Standard, the term “consultancy” is used in relation to activities of certification bodies, personnel of certification bodies and organizations related or linked to certification bodies.

3.3
evaluation
combination of the selection and determination functions of conformity assessment activities

NOTE The selection and determination functions are specified in ISO/IEC 17000:2004, Clauses A.2 and A.3.

3.4
product
result of a process

NOTE 1 Four generic product categories are noted in ISO 9000:2005:

— services (e.g. transport) (see definition in 3.6);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine, mechanical part);

— processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element.

NOTE 2 Products include results of natural processes, such as growth of plants and formation of other natural resources.

NOTE 3 Adapted from ISO/IEC 17000:2004, definition 3.3.

3.5
process
set of interrelated or interacting activities which transforms inputs into outputs

EXAMPLES Welding engineering processes; heat treatment processes; manufacturing processes requiring confirmation of process capability (e.g. operating or producing product within specified tolerances); food production processes; plant growth processes.

NOTE Adapted from ISO 9000:2005, definition 3.4.1.

3.6
service
result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally intangible

NOTE 1 Provision of a service can involve, for example, the following:

— an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);

— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);

— the creation of ambience for the customer (e.g. in hotels and restaurants).

NOTE 2 Adapted from ISO 9000:2005, definition 3.4.2.

3.7
certification requirement
specified requirement, including **product requirements** (3.8), that is fulfilled by the **client** (3.1) as a condition of establishing or maintaining certification

NOTE Certification requirements include requirements imposed on the client by the certification body [usually via the certification agreement (see 4.1.2)] to meet this International Standard, and can also include requirements imposed on the client by the certification scheme. “Certification requirements”, as used in this International Standard, do not include requirements imposed on the certification body by the certification scheme.

EXAMPLE The following are certification requirements that are not product requirements:

— completing the certification agreement;

— paying fees;

— providing information about changes to the certified product;

— providing access to certified products for surveillance activities.

3.8
product requirement
requirement that relates directly to a product, specified in standards or in other normative documents identified by the certification scheme

NOTE Product requirements can be specified in normative documents such as regulations, standards and technical specifications.

3.9
certification scheme
certification system related to specified products, to which the same specified requirements, specific rules and procedures apply

NOTE 1 Adapted from ISO/IEC 17000:2004, definition 2.8.

NOTE 2 A “certification system” is a “conformity assessment system”, which is defined in ISO/IEC 17000:2004, definition 2.7.

NOTE 3 The rules, procedures and management for implementing product, process and service certification are stipulated by the certification scheme.

NOTE 4 General guidance for the development of schemes is given in ISO/IEC 17067, in combination with ISO/IEC Guide 28 and ISO/IEC Guide 53.

3.10
scope of certification
identification of

— the product(s), process(es) or service(s) for which the certification is granted,

— the applicable certification scheme, and

— the standard(s) and other normative document(s), including their date of publication, to which it is judged that the product(s), process(es) or service(s) comply

3.11
scheme owner
person or organization responsible for developing and maintaining a specific **certification scheme** (3.9)

NOTE The scheme owner can be the certification body itself, a governmental authority, a trade association, a group of certification bodies or others.

3.12
certification body
third-party conformity assessment body operating certification schemes

NOTE A certification body can be non-governmental or governmental (with or without regulatory authority).

3.13
impartiality
presence of objectivity

NOTE 1 Objectivity is understood to mean that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the body.

NOTE 2 Other terms that are useful in conveying the element of impartiality are independence, freedom from conflicts of interest, freedom from bias, freedom from prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment and balance.

4 General requirements

4.1 Legal and contractual matters

4.1.1 Legal responsibility

The certification body shall be a legal entity, or a defined part of a legal entity, such that the legal entity can be held legally responsible for all its certification activities.

NOTE A governmental certification body is deemed to be a legal entity on the basis of its governmental status.

4.1.2 Certification agreement

4.1.2.1 The certification body shall have a legally enforceable agreement for the provision of certification activities to its clients. Certification agreements shall take into account the responsibilities of the certification body and its clients.

4.1.2.2 The certification body shall ensure its certification agreement requires that the client comply at least, with the following:

a) the client always fulfils the certification requirements (see 3.7), including implementing appropriate changes when they are communicated by the certification body (see 7.10);

b) if the certification applies to ongoing production, the certified product continues to fulfil the product requirements (see 3.8);

c) the client makes all necessary arrangements for

   1) the conduct of the evaluation (see 3.3) and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and client's subcontractors;

   2) investigation of complaints;

   3) the participation of observers, if applicable;

d) the client makes claims regarding certification consistent with the scope of certification (see 3.10);

e) the client does not use its product certification in such a manner as to bring the certification body into disrepute and does not make any statement regarding its product certification that the certification body may consider misleading or unauthorized;

f) upon suspension, withdrawal, or termination of certification, the client discontinues its use of all advertising matter that contains any reference thereto and takes action as required by the certification scheme (e.g. the return of certification documents) and takes any other required measure;

g) if the client provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme;

h) in making reference to its product certification in communication media such as documents, brochures or advertising, the client complies with the requirements of the certification body or as specified by the certification scheme;

i) the client complies with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity, and on information related to the product;

NOTE See also ISO/IEC 17030, ISO/IEC Guide 23 and ISO Guide 27.

j) the client keeps a record of all complaints made known to it relating to compliance with certification requirements and makes these records available to the certification body when requested, and

1) takes appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification;

2) documents the actions taken;

NOTE Verification of item j) by the certification body can be specified in the certification scheme.

k) the client informs the certification body, without delay, of changes that may affect its ability to conform with the certification requirements.

NOTE Examples of changes can include the following:

— the legal, commercial, organizational status or ownership,

— organization and management (e.g. key managerial, decision-making or technical staff),

— modifications to the product or the production method,

— contact address and production sites,

— major changes to the quality management system.

4.1.3 Use of license, certificates and marks of conformity

4.1.3.1 The certification body shall exercise the control as specified by the certification scheme over ownership, use and display of licenses, certificates, marks of conformity, and any other mechanisms for indicating a product is certified.

NOTE 1 Guidance on the use of certificates and marks permitted by the certification body can be obtained from ISO/IEC Guide 23.

NOTE 2 ISO/IEC 17030 provides requirements for the use of third-party marks.

4.1.3.2 Incorrect references to the certification scheme, or misleading use of licenses, certificates, marks, or any other mechanism for indicating a product is certified, found in documentation or other publicity, shall be dealt with by suitable action.

NOTE Such actions are addressed in ISO Guide 27 and can include corrective actions, withdrawal of certificate, publication of the transgression and, if necessary, legal action.

4.2 Management of impartiality

4.2.1 Certification activities shall be undertaken impartially.

4.2.2 The certification body shall be responsible for the impartiality of its certification activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.2.3 The certification body shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, from its relationships, or from the relationships of its personnel (see 4.2.12). However, such relationships may not necessarily present a certification body with a risk to impartiality.

NOTE 1 A relationship presenting a risk to impartiality of the certification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc.

NOTE 2 Identifying risks does not imply risk assessments as stated in ISO 31000.

4.2.4 If a risk to impartiality is identified, the certification body shall be able to demonstrate how it eliminates or minimizes such risk. This information shall be made available to the mechanism specified in 5.2.

4.2.5 The certification body shall have top management commitment to impartiality.

4.2.6 The certification body and any part of the same legal entity and entities under its organizational control (see 7.6.4) shall not:

a) be the designer, manufacturer, installer, distributer or maintainer of the certified product;

b) be the designer, implementer, operator or maintainer of the certified process;

c) be the designer, implementer, provider or maintainer of the certified service;

d) offer or provide consultancy (see 3.2) to its clients;

e) offer or provide management system consultancy or internal auditing to its clients where the certification scheme requires the evaluation of the client’s management system.

NOTE 1 This does not preclude the following:

— the possibility of exchange of information (e.g. explanations of findings or clarifying requirements) between the certification body and its clients;

— the use, installing and maintaining of certified products which are necessary for the operations of the certification body.

NOTE 2 “Management system consultancy” is defined in ISO/IEC 17021:2011, definition 3.3.

4.2.7 The certification body shall ensure that activities of separate legal entities, with which the certification body or the legal entity of which it forms a part has relationships, do not compromise the impartiality of its certification activities.

NOTE See 4.2.3, Note 1.

4.2.8 When the separate legal entity in 4.2.7 offers or produces the certified product (including products to be certified) or offers or provides consultancy (see 3.2), the certification body's management personnel and personnel in the review and certification decision-making process shall not be involved in the activities of the separate legal entity. The personnel of the separate legal entity shall not be involved in the management of the certification body, the review, or the certification decision.

NOTE For the evaluation personnel, impartiality requirements are stipulated in Clause 6 and additional requirements are given in the other relevant International Standards cited in 6.2.1 and 6.2.2.1.

4.2.9 The certification body's activities shall not be marketed or offered as linked with the activities of an organization that provides consultancy (see 3.2). A certification body shall not state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.

4.2.10 Within a period specified by the certification body, personnel shall not be used to review or make a certification decision for a product for which they have provided consultancy (see 3.2).

NOTE 1 The period can be specified in the certification scheme or, if specified by the certification body, it reflects a period that is long enough to ensure that the review or decision does not compromise impartiality. A specified period of two years is often used.

NOTE 2 For the evaluation personnel, impartiality requirements are stipulated in Clause 6 and additional requirements are given in the other relevant International Standards cited in 6.2.1 and 6.2.2.1.

4.2.11 The certification body shall take action to respond to any risks to its impartiality, arising from the actions of other persons, bodies or organizations, of which it becomes aware.

4.2.12 All certification body personnel (either internal or external) or committees who could influence the certification activities shall act impartially.

4.3 Liability and financing

4.3.1 The certification body shall have adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations.

4.3.2 The certification body shall have the financial stability and resources required for its operations.

4.4 Non-discriminatory conditions

4.4.1 The policies and procedures under which the certification body operates, and the administration of them, shall be non-discriminatory. Procedures shall not be used to impede or inhibit access by applicants, other than as provided for in this International Standard.

4.4.2 The certification body shall make its services accessible to all applicants whose activities fall within the scope of its operations.

4.4.3 Access to the certification process shall not be conditional upon the size of the client or membership of any association or group, nor shall certification be conditional upon the number of certifications already issued. There shall not be undue financial or other conditions.

NOTE A certification body can decline to accept an application or maintain a contract for certification from a client when fundamental or demonstrated reasons exist, such as the client participating in illegal activities, having a history of repeated non-compliances with certification/product requirements, or similar client-related issues.

4.4.4 The certification body shall confine its requirements, evaluation, review, decision and surveillance (if any) to those matters specifically related to the scope of certification.

4.5 Confidentiality

4.5.1 The certification body shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of certification activities. Except for information that the client makes publicly available, or when agreed between the certification body and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential. The certification body shall inform the client, in advance, of the information it intends to place in the public domain.

4.5.2 When the certification body is required by law or authorized by contractual arrangements to release confidential information, the client or person concerned shall, unless prohibited by law, be notified of the information provided.

4.5.3 Information about the client obtained from sources other than the client (e.g. from the complainant or from regulators) shall be treated as confidential.

4.6 Publicly available information

The certification body shall maintain (through publications, electronic media or other means), and make available upon request, the following:

a) information about (or reference to) the certification scheme(s), including evaluation procedures, rules and procedures for granting, for maintaining, for extending or reducing the scope of, for suspending, for withdrawing or for refusing certification;

b) a description of the means by which the certification body obtains financial support and general information on the fees charged to applicants and to clients;

c) a description of the rights and duties of applicants and clients, including requirements, restrictions or limitations on the use of the certification body's name and certification mark and on the ways of referring to the certification granted;

d) information about procedures for handling complaints and appeals.

5 Structural requirements

5.1 Organizational structure and top management

5.1.1 Certification activities shall be structured and managed so as to safeguard impartiality.

5.1.2 The certification body shall document its organizational structure, showing duties, responsibilities and authorities of management and other certification personnel and any committees. When the certification body is a defined part of a legal entity, the structure shall include the line of authority and the relationship to other parts within the same legal entity.

5.1.3 The management of the certification body shall identify the board, group of persons, or person having overall authority and responsibility for each of the following:

a) development of policies relating to the operation of the certification body;

b) supervision of the implementation of the policies and procedures;

c) supervision of the finances of the certification body;

d) development of certification activities;

e) development of certification requirements;

f) evaluation (see 7.4);

g) review (see 7.5);

h) decisions on certification (see 7.6);

i) delegation of authority to committees or personnel, as required, to undertake defined activities on its behalf;

j) contractual arrangements;

k) provision of adequate resources for certification activities;

l) responsiveness to complaints and appeals;

m) personnel competence requirements;

n) management system of the certification body (see Clause 8).

5.1.4 The certification body shall have formal rules for the appointment, terms of reference and operation of any committees that are involved in the certification process (see Clause 7). Such committees shall be free from any commercial, financial and other pressures that might influence decisions. The certification body shall retain authority to appoint and withdraw members of such committees.

5.2 Mechanism for safeguarding impartiality

5.2.1 The certification body shall have a mechanism for safeguarding its impartiality. The mechanism shall provide input on the following:

a) the policies and principles relating to the impartiality of its certification activities;

b) any tendency on the part of a certification body to allow commercial or other considerations to prevent the consistent impartial provision of certification activities;

c) matters affecting impartiality and confidence in certification, including openness.

NOTE 1 Other tasks or duties (e.g. taking part in the decision-making process) can be assigned to the mechanism, provided these additional tasks or duties do not compromise its essential role of ensuring impartiality.

NOTE 2 A possible mechanism can be a committee established by one or more certification bodies, a committee implemented by a scheme owner, a governmental authority or an equivalent party.

NOTE 3 A single mechanism for several certification schemes can satisfy this requirement.

NOTE 4 If the certification body also provides management systems certification, a committee that fulfils ISO/IEC 17021:2011, 6.2, can also fulfil this subclause (5.2) providing that all the requirements of 5.2 have been met.

5.2.2 The mechanism shall be formally documented to ensure the following:

a) a balanced representation of significantly interested parties, such that no single interest predominates (internal or external personnel of the certification body are considered to be a single interest, and shall not predominate);

b) access to all the information necessary to enable it to fulfil all its functions.

5.2.3 If the top management of the certification body does not follow the input of this mechanism, the mechanism shall have the right to take independent action (e.g. informing authorities, accreditation bodies, stakeholders). In taking appropriate action, the confidentiality requirements of 4.5 relating to the client and certification body shall be respected.

Input that is in conflict with the operating procedures of the certification body or other mandatory requirements should not be followed. Management should document the reasoning behind the decision to not follow the input and maintain the document for review by appropriate personnel.

5.2.4 Although every interest cannot be represented in the mechanism, a certification body shall identify and invite significantly interested parties.

NOTE 1 Such interested parties can include clients of the certification body, customers of clients, manufacturers, suppliers, users, conformity assessment experts, representatives of industry trade associations, representatives of governmental regulatory bodies or other governmental services, and representatives of non-governmental organizations, including consumer organizations. It can be sufficient to have one representative of each interested party in the mechanism.

NOTE 2 These interests can be limited, depending on the nature of the certification scheme.

6 Resource requirements

6.1 Certification body personnel

6.1.1 General

6.1.1.1 The certification body shall employ, or have access to, a sufficient number of personnel to cover its operations related to the certification schemes and to the applicable standards and other normative documents.

NOTE The personnel include those normally working for the certification body, as well as persons working under an individual contract or a formal agreement that places them within the management control and systems/procedures of the certification body (see 6.1.3).

6.1.1.2 The personnel shall be competent for the functions they perform, including making required technical judgments, defining policies and implementing them.

6.1.1.3 Personnel, including any committee members, personnel of external bodies, or personnel acting on the certification body's behalf, shall keep confidential all information obtained or created during the performance of the certification activities, except as required by law or by the certification scheme.

6.1.2 Management of competence for personnel involved in the certification process

6.1.2.1 The certification body shall establish, implement and maintain a procedure for management of competencies of personnel involved in the certification process (see Clause 7). The procedure shall require the certification body to:

a) determine the criteria for the competence of personnel for each function in the certification process, taking into account the requirements of the schemes;

b) identify training needs and provide, as necessary, training programmes on certification processes, requirements, methodologies, activities and other relevant certification scheme requirements;

c) demonstrate that the personnel have the required competencies for the duties and responsibilities they undertake;

d) formally authorize personnel for functions in the certification process;

e) monitor the performance of the personnel.

6.1.2.2 The certification body shall maintain the following records on the personnel involved in the certification process (see Clause 7):

a) name and address;

b) employer(s) and position held;

c) educational qualification and professional status;

d) experience and training;

e) the assessment of competence;

f) performance monitoring;

g) authorizations held within the certification body;

h) date of most recent updating of each record.

6.1.3 Contract with the personnel

The certification body shall require personnel involved in the certification process to sign a contract or other document by which they commit themselves to the following:

a) to comply with the rules defined by the certification body, including those relating to confidentiality (see 4.5) and independence from commercial and other interests;

b) to declare any prior and/or present association on their own part, or on the part of their employer, with:

   1) a supplier or designer of products, or

   2) a provider or developer of services, or

   3) an operator or developer of processes

   to the evaluation or certification of which they are to be assigned;

c) to reveal any situation known to them that may present them or the certification body with a conflict of interest (see 4.2).

Certification bodies shall use this information as input into identifying risks to impartiality raised by the activities of such personnel, or by the organizations that employ them (see 4.2.3).

6.2 Resources for evaluation

6.2.1 Internal resources

When a certification body performs evaluation activities, either with its internal resources or with other resources under its direct control, it shall meet the applicable requirements of the relevant International Standards and, as specified by the certification scheme, of other documents. For testing, it shall meet the applicable requirements of ISO/IEC 17025; for inspection, it shall meet the applicable requirements of ISO/IEC 17020; and for management system auditing, it shall meet the applicable requirements of ISO/IEC 17021. The impartiality requirements of the evaluation personnel stipulated in the relevant standard shall always be applicable.

NOTE Examples of reasons as to why some requirements are not applicable include the following:

— expertise is available within the certification body when using the results of the evaluation activity;

— the extent of control the certification body has over testing (including witnessing the testing), inspection (e.g. specifying inspection methods or parameters) or management system assessment (e.g. requiring specific details of a management system);

— a particular requirement is covered in an equivalent way by this International Standard, or is not needed to give confidence in the certification decision.

6.2.2 External resources (outsourcing)

6.2.2.1 The certification body shall outsource evaluation activities only to bodies that meet the applicable requirements of the relevant International Standards and, as specified by the certification scheme, of other documents. For testing, it shall meet the applicable requirements of ISO/IEC 17025; for inspection, it shall meet the applicable requirements of ISO/IEC 17020; and for management system auditing, it shall meet the applicable requirements of ISO/IEC 17021. The impartiality requirements of the evaluation personnel stipulated in the relevant standard shall always be applicable.

NOTE 1 Examples of reasons as to why some requirements are not applicable include the following:

— expertise is available within the certification body when using the results of the evaluation activity;

— the extent of control the certification body has over testing (including witnessing the testing), inspection (e.g. specifying inspection methods or parameters) or management system assessment (e.g. requiring specific details of a management system);

— a particular requirement is covered in an equivalent way by this International Standard, or is not needed to give confidence in the certification decision.

NOTE 2 This can include outsourcing to other certification bodies. Use of external personnel under contract is not outsourcing.

NOTE 3 For the purposes of this International Standard, the terms “outsourcing” and “subcontracting” are considered to be synonyms.

6.2.2.2 Where evaluation activities are outsourced to non-independent bodies (e.g. client laboratories), the certification body shall ensure that the evaluation activities are managed in a manner which provides confidence in the results, and that records are available to justify the confidence.

6.2.2.3 The certification body shall have a legally binding contract with the body that provides the outsourced service, including provisions for confidentiality and conflict of interest as specified in 6.1.3, item c).

6.2.2.4 The certification body shall:

a) take responsibility for all activities outsourced to another body;

b) ensure that the body that provides outsourced services, and the personnel that it uses, are not involved, either directly or through any other employer, in such a way that the credibility of the results could be compromised;

c) have documented policies, procedures and records for the qualification, assessing and monitoring of all bodies that provide outsourced services used for certification activities;

d) maintain a list of approved providers of outsourced services;

e) implement corrective actions for any breaches of the contract in 6.2.2.3 or other requirements in 6.2.2 of which it becomes aware;

f) inform the client in advance of outsourcing activities, in order to provide the client with an opportunity to object.

NOTE If the qualification, assessing and monitoring of the bodies that provide outsourced services are performed by other organizations (e.g. by accreditation bodies, peer assessment bodies or governmental authorities), the certification body can take this qualification and monitoring into account provided that:

— it is provided for within the scheme requirements;

— the scope is applicable to the work being undertaken;

— the validity of the qualification, assessing and monitoring arrangements is verified at a periodicity determined by the certification body.

7 Process requirements

7.1 General

7.1.1 The certification body shall operate one or more certification scheme(s) covering its certification activities.

NOTE 1 The elements of such schemes can be coupled with surveillance of production, or with the assessment and surveillance of the client's management system, or both.

NOTE 2 General guidance on the development of schemes is given in ISO/IEC 17067, in combination with ISO/IEC Guide 28 and ISO/IEC Guide 53.

7.1.2 The requirements against which the products of a client are evaluated shall be those contained in specified standards and other normative documents.

NOTE Guidance for developing normative documents suitable for this purpose is contained in ISO/IEC 17007.

7.1.3 If explanations are required as to the application of these documents (see 7.1.2) for a specific certification scheme, they shall be formulated by relevant and impartial persons or committees, possessing the necessary technical competence, and shall be made available by the certification body upon request.

7.2 Application

For application, the certification body shall obtain all the necessary information to complete the certification process in accordance with the relevant certification scheme.

NOTE 1 The following are examples of necessary information:

— the product(s) to be certified;

— the standards and/or other normative documents for which the client is seeking certification (see 7.1.2);

— the general features of the client, including its name and the address(es) of its physical location(s), significant aspects of its process and operations (if required by the relevant certification scheme), and any relevant legal obligations;

— general information concerning the client, relevant to the field of certification for which the application is made, such as the client's activities, its human and technical resources, including laboratories and/or inspection facilities, and its functions and relationship in a larger corporation, if any;

— information concerning all outsourced processes used by the client that will affect conformity to requirements; if the client has identified a legal entity/entities for producing the certified product(s) that is different from the client, then the certification body can establish appropriate contractual controls over the legal entity/entities concerned, if necessary for effective surveillance; if such contractual controls are needed, they can be established prior to providing formal certification documentation (see 7.7);

— all other information needed in accordance with the relevant certification requirements, such as information for initial evaluation and surveillance activities, e.g. the locations where the certified product(s) are produced and contact personnel at these locations.

NOTE 2 A variety of media and mechanisms can be used to collect this information at various times, including an application form. Such information gathering can be in conjunction with, or separate from, the completion of the legally binding agreement (the certification agreement) specified in 4.1.2.

NOTE 3 Application for an extension of the certification scope could involve similar products, different locations, etc.

7.3 Application review

7.3.1 The certification body shall conduct a review of the information obtained (see 7.2) to ensure that:

a) the information about the client and the product is sufficient for the conduct of the certification process;

b) any known difference in understanding between the certification body and the client is resolved, including agreement regarding standards or other normative documents;

c) the scope of certification (see 3.10) sought is defined;

d) the means are available to perform all evaluation activities;

e) the certification body has the competence and capability to perform the certification activity.

7.3.2 The certification body shall have a process to identify when the client's request for certification includes

— a type of product, or

— a normative document, or

— a certification scheme

with which the certification body has no prior experience,

NOTE Products can be considered to be of the same type when the knowledge of the requirements, characteristics and technology related to one product is sufficient to understand the requirements, characteristics and technology of another product.

7.3.3 In these cases (see 7.3.2), the certification body shall ensure it has the competence and capability for all the certification activities it is required to undertake, and it shall maintain a record of the justification for the decision to undertake certification.

7.3.4 The certification body shall decline to undertake a specific certification if it lacks any competence or capability for the certification activities it is required to undertake.

7.3.5 If the certification body relies on certifications it has already granted to the client, or has already granted to other clients, to omit any activities, then the certification body shall reference the existing certification(s) in its records. If requested by the client, the certification body shall provide justification for omission of activities.

7.4 Evaluation

7.4.1 The certification body shall have a plan for the evaluation activities to allow for the necessary arrangements to be managed.

NOTE Depending on the characteristics of the certification scheme and the product requirements, the plan can be either a generic plan applicable to all activities, including evaluation of the quality management system, when applicable, or a specific one for a particular activity, or a combination of both.

7.4.2 The certification body shall assign personnel to perform each evaluation task that it undertakes with its internal resources (see 6.2.1).

NOTE Outsourced tasks are completed by personnel usually assigned by the organization to which the task is outsourced. Such personnel are not normally assigned by the certification body.

7.4.3 The certification body shall ensure all necessary information and/or documentation is made available for performing the evaluation tasks.

NOTE The evaluation tasks can include activities such as design and documentation review, sampling, testing, inspection and audit.

7.4.4 The certification body shall carry out the evaluation activities that it undertakes with its internal resources (see 6.2.1) and shall manage outsourced resources (see 6.2.2) in accordance with the evaluation plan (see 7.4.1). The products shall be evaluated against the requirements covered by the scope of certification and other requirements specified in the certification scheme.

7.4.5 The certification body shall only rely on evaluation results related to certification completed prior to the application for certification, where it takes responsibility for the results and satisfies itself that the body that performed the evaluation fulfils the requirements contained in 6.2.2 and those specified by the certification scheme.

NOTE This can include work carried out under recognition agreements between certification bodies.

7.4.6 The certification body shall inform the client of all nonconformities.

7.4.7 If one or more nonconformities have arisen, and if the client expresses interest in continuing the certification process, the certification body shall provide information regarding the additional evaluation tasks needed to verify that nonconformities have been corrected.

7.4.8 If the client agrees to completion of the additional evaluation tasks, the process specified in 7.4 shall be repeated to complete the additional evaluation tasks.

7.4.9 The results of all evaluation activities shall be documented prior to review (see 7.5).

NOTE 1 This documentation can provide an opinion as to whether product requirements (including requirements such as those for the quality management system under which the product is produced, if required by the certification scheme) have been fulfilled.

NOTE 2 The certification scheme can indicate whether the evaluation is performed by the certification body, under its responsibility, or is performed prior to the application (see 7.2) for the certification process. In the latter case, the requirements of 7.4 are not applicable.

7.5 Review

7.5.1 The certification body shall assign at least one person to review all information and results related to the evaluation. The review shall be carried out by person(s) who have not been involved in the evaluation process.

7.5.2 Recommendations for a certification decision based on the review shall be documented, unless the review and the certification decision are completed concurrently by the same person.

7.6 Certification decision

7.6.1 The certification body shall be responsible for, and shall retain authority for, its decisions relating to certification.

7.6.2 The certification body shall assign at least one person to make the certification decision based on all information related to the evaluation, its review, and any other relevant information. The certification decision shall be carried out by a person or group of persons [e.g. a committee (see 5.1.4)] that has not been involved in the process for evaluation (see 7.4).

NOTE The review and the certification decision can be completed concurrently by the same person or group of persons.

7.6.3 The person(s) [excluding members of committees (see 5.1.4)] assigned by the certification body to make a certification decision shall be employed by, or shall be under contract with, one of the following:

— the certification body (see 6.1);

— an entity under the organizational control of the certification body (see 7.6.4).

7.6.4 A certification body's organizational control shall be one of the following:

— whole or majority ownership of another entity by the certification body;

— majority participation by the certification body on the board of directors of another entity;

— a documented authority by the certification body over another entity in a network of legal entities (in which the certification body resides), linked by ownership or board of director control.

NOTE For governmental certification bodies, other parts of the same government can be considered to be "linked by ownership" to the certification body.

7.6.5 The persons employed by, or under contract with, entities under organizational control shall fulfil the same requirements of this International Standard as persons employed by, or under contract with, the certification body.

7.6.6 The certification body shall notify the client of a decision not to grant certification, and shall identify the reasons for the decision.

NOTE If the client expresses interest in continuing the certification process, the certification body can resume the process for evaluation from 7.4.

7.7 Certification documentation

7.7.1 The certification body shall provide the client with formal certification documentation that clearly conveys, or permits identification of the following:

a) the name and address of the certification body;

b) the date certification is granted (the date shall not precede the date on which the certification decision was completed);

c) the name and address of the client;

d) the scope of certification (see 3.10);

NOTE Where the standard(s) or other normative document(s) (see 7.1.2) to which conformity is being certified include reference to other standards or normative documents, these do not need to be included in the formal certification documentation.

e) the term or expiry date of certification, if certification expires after an established period;

f) any other information required by the certification scheme.

7.7.2 The formal certification documentation shall include the signature or other defined authorization of the person(s) of the certification body assigned such responsibility.

NOTE The name and title of an individual whose agreement to be responsible for certification documentation is on record at the certification body is an example of a “defined authorization” other than a signature.

7.7.3 Formal certification documentation (see 7.7) shall only be issued after, or concurrent with, the following:

a) the decision to grant or extend the scope of certification (see 7.6.1) has been made;

b) certification requirements have been fulfilled;

c) the certification agreement (see 4.1.2) has been completed/signed.

7.8 Directory of certified products

The certification body shall maintain information on certified products which contains at least the following:

a) identification of the product;

b) the standard(s) and other normative document(s) to which conformity has been certified;

c) identification of the client.

The parts of this information that need to be published or made available upon request in a directory (through publications, electronic media or other means) are stipulated by the relevant scheme(s). As a minimum, the certification body shall provide information, upon request, about the validity of a given certification.

NOTE Where the certification body provides the information to a scheme, the scheme directory would satisfy this requirement.

7.9 Surveillance

7.9.1 If surveillance is required by the certification scheme, or as specified in 7.9.3 or 7.9.4, the certification body shall initiate surveillance of the product(s) covered by the certification decision in accordance with the certification scheme.

NOTE 1 ISO/IEC 17067 provides examples of surveillance activities in certification schemes.

NOTE 2 The criteria and process for surveillance activities are defined by each certification scheme.

7.9.2 When surveillance utilizes evaluation, review or a certification decision, the requirements in 7.4, 7.5 or 7.6, respectively, shall be fulfilled.

7.9.3 When continuing use of a certification mark is authorized for placement on a product (or its packaging, or information accompanying it) (for process or service, see 7.9.4) of a type which has been certified, surveillance shall be established and shall include periodic surveillance of marked products to ensure ongoing validity of the demonstration of fulfilment of product requirements.

7.9.4 When continuing use of a certification mark is authorized for a process or service, surveillance shall be established and shall include periodic surveillance activities to ensure ongoing validity of the demonstration of fulfilment of process or service requirements.

7.10 Changes affecting certification

7.10.1 When the certification scheme introduces new or revised requirements that affect the client, the certification body shall ensure these changes are communicated to all clients. The certification body shall verify the implementation of the changes by its clients and shall take actions required by the scheme.

NOTE Contractual arrangements with clients can be necessary to ensure implementation of these requirements. A model of a license agreement for the use of certification, including the aspects related to a notice of changes, as far as applicable, is given in ISO/IEC Guide 28:2004, Annex E.

7.10.2 The certification body shall consider other changes affecting certification, including changes initiated by the client, and shall decide upon the appropriate action.

NOTE Changes affecting certification can include new information related to the fulfilment of certification requirements obtained by the certification body after certification has been established.

7.10.3 The actions to implement changes affecting certification shall include, if required, the following:

— evaluation (see 7.4);

— review (see 7.5);

— decision (see 7.6);

— issuance of revised formal certification documentation (see 7.7) to extend or reduce the scope of certification;

— issuance of certification documentation of revised surveillance activities (if surveillance is part of the certification scheme).

These actions shall be completed in accordance with applicable parts of 7.4, 7.5, 7.6, 7.7 and 7.8. Records (see 7.12) shall include the rationale for excluding any of the above activities (e.g. when a certification requirement that is not a product requirement changes, and no evaluation, review or decision activities are necessary).

7.11 Termination, reduction, suspension or withdrawal of certification

7.11.1 When a nonconformity with certification requirements is substantiated, either as a result of surveillance or otherwise, the certification body shall consider and decide upon the appropriate action.

NOTE Appropriate action can include the following:

a) continuation of certification under conditions specified by the certification body (e.g. increased surveillance);

b) reduction in the scope of certification to remove nonconforming product variants;

c) suspension of the certification pending remedial action by the client;

d) withdrawal of the certification.

7.11.2 When the appropriate action includes evaluation, review or a certification decision, the requirements in 7.4, 7.5 or 7.6, respectively, shall be fulfilled.

7.11.3 If certification is terminated (by request of the client), suspended or withdrawn, the certification body shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified. If a scope of certification is reduced, the certification body shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

7.11.4 If certification is suspended, the certification body shall assign one or more persons to formulate and communicate the following to the client:

— actions needed to end suspension and restore certification for the product(s) in accordance with the certification scheme;

— any other actions required by the certification scheme.

These persons shall be competent in their knowledge and understanding of all aspects of the handling of suspended certifications (see 6.1).

7.11.5 Any evaluations, reviews or decisions needed to resolve the suspension, or that are required by the certification scheme, shall be completed in accordance with the applicable parts of 7.4, 7.5, 7.6, 7.7.3, 7.9 and 7.11.3.

7.11.6 If certification is reinstated after suspension, the certification body shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications exist that the product continues to be certified. If a decision to reduce the scope of certification is made as a condition of reinstatement, the certification body shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

7.12 Records

7.12.1 The certification body shall retain records to demonstrate that all certification process requirements (those in this International Standard and those of the certification scheme) have been effectively fulfilled (see also 8.4).

7.12.2 The certification body shall keep records confidential. Records shall be transported, transmitted and transferred in a way that ensures confidentiality is maintained (see also 4.5).

7.12.3 If the certification scheme involves complete re-evaluation of the product(s) within a determined cycle, records shall be retained at least for the current and the previous cycle. Otherwise, records shall be retained for a period defined by the certification body.

NOTE In defining retention times, legal circumstances and recognition arrangements can be considered.

7.13 Complaints and appeals

7.13.1 The certification body shall have a documented process to receive, evaluate and make decisions on complaints and appeals. The certification body shall record and track complaints and appeals, as well as actions undertaken to resolve them.

7.13.2 Upon receipt of a complaint or appeal, the certification body shall confirm whether the complaint or appeal relates to certification activities for which it is responsible and, if so, shall address it.

7.13.3 The certification body shall acknowledge receipt of a formal complaint or appeal.

7.13.4 The certification body shall be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.

7.13.5 The decision resolving the complaint or appeal shall be made by, or reviewed and approved by, person(s) not involved in the certification activities related to the complaint or appeal.

7.13.6 To ensure that there is no conflict of interest, personnel (including those acting in a managerial capacity) who have provided consultancy (see 3.2) for a client, or been employed by a client, shall not be used by the certification body to review or approve the resolution of a complaint or appeal for that client within two years following the end of the consultancy or employment.

7.13.7 Whenever possible, the certification body shall give formal notice of the outcome and the end of the complaint process to the complainant.

7.13.8 The certification body shall give formal notice of the outcome and the end of the appeal process to the appellant.

7.13.9 The certification body shall take any subsequent action needed to resolve the complaint or appeal.

8 Management system requirements

8.1 Options

8.1.1 General

The certification body shall establish and maintain a management system that is capable of achieving the consistent fulfilment of the requirements of this International Standard in accordance with either Option A or Option B.

8.1.2 Option A

The management system of the certification body shall address the following:

— general management system documentation (e.g. manual, policies, definition of responsibilities, see 8.2);

— control of documents (see 8.3);

— control of records (see 8.4);

— management review (see 8.5);

— internal audit (see 8.6);

— corrective actions (see 8.7);

— preventive actions (see 8.8).

8.1.3 Option B

A certification body that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of this International Standard, fulfils the management system clause requirements (see 8.2 to 8.8).

NOTE Option B is included to enable a certification body which operates a management system in accordance with ISO 9001 to use that system to demonstrate fulfilment of the management system requirements in 8.2 to 8.8 of this International Standard. Option B does not require that the certification body's management system is certified to ISO 9001.

8.2 General management system documentation (Option A)

8.2.1 The certification body's top management shall establish, document, and maintain policies and objectives for fulfilment of this International Standard and the certification scheme and shall ensure the policies and objectives are acknowledged and implemented at all levels of the certification body’s organization.

8.2.2 The certification body's top management shall provide evidence of its commitment to the development and implementation of the management system and its effectiveness in achieving consistent fulfilment of this International Standard.

8.2.3 The certification body's top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that include the following:

a) ensuring that processes and procedures needed for the management system are established, implemented and maintained;

b) reporting to top management on the performance of the management system and any need for improvement.

8.2.4 All documentation, processes, systems, records, etc. related to the fulfilment of the requirements of this International Standard shall be included, referenced, or linked to documentation of the management system.

8.2.5 All personnel involved in certification activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 Control of documents (Option A)

8.3.1 The certification body shall establish procedures to control the documents (internal and external) that relate to the fulfilment of this International Standard.

8.3.2 The procedures shall define the controls needed to:

a) approve documents for adequacy prior to issue;

b) review and update (as necessary) and re-approve documents;

c) ensure that changes and the current revision status of documents are identified;

d) ensure that relevant versions of applicable documents are available at points of use;

e) ensure that documents remain legible and readily identifiable;

f) ensure that documents of external origin are identified and their distribution controlled;

g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

NOTE Documentation can be in any form or type of medium.

8.4 Control of records (Option A)

8.4.1 The certification body shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this International Standard.

8.4.2 The certification body shall establish procedures for retaining records (see 7.12) for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements.

8.5 Management review (Option A)

8.5.1 General

8.5.1.1 The certification body's top management shall establish procedures to review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this International Standard.

8.5.1.2 These reviews shall be conducted at least once a year. Alternatively, a complete review broken up into segments shall be completed within a 12-month time frame. Records of reviews shall be maintained.

8.5.2 Review inputs

The input to the management review shall include information related to the following:

a) results of internal and external audits;

b) feedback from clients and interested parties related to the fulfilment of this International Standard;

NOTE Interested parties can include scheme owners.

c) feedback from the mechanism for safeguarding impartiality;

d) the status of preventive and corrective actions;

e) follow-up actions from previous management reviews;

f) the fulfilment of objectives;

g) changes that could affect the management system;

h) appeals and complaints.

8.5.3 Review outputs

The outputs from the management review shall include decisions and actions related to the following:

a) improvement of the effectiveness of the management system and its processes;

b) improvement of the certification body related to the fulfilment of this International Standard;

c) resource needs.

8.6 Internal audits (Option A)

8.6.1 The certification body shall establish procedures for internal audits to verify that it fulfils the requirements of this International Standard and that the management system is effectively implemented and maintained.

NOTE ISO 19011 provides guidelines for conducting internal audits.

8.6.2 An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits.

8.6.3 Internal audits shall normally be performed at least once every 12 months, or completed within a 12-month time frame for segmented (or rolling) internal audits. A documented decision-making process shall be followed to change (reduce or restore) the frequency of internal audits or the time frame in which internal audits shall be completed. Such changes shall be based on the relative stability and ongoing effectiveness of the management system. Records of decisions to change the frequency of internal audits, or the time frame in which they will be completed, including the rationale for the change, shall be maintained.

8.6.4 The certification body shall ensure that:

a) internal audits are conducted by personnel knowledgeable in certification, auditing and the requirements of this International Standard;

b) auditors do not audit their own work;

c) personnel responsible for the area audited are informed of the outcome of the audit;

d) any actions resulting from internal audits are taken in a timely and appropriate manner;

e) any opportunities for improvement are identified.

8.7 Corrective actions (Option A)

8.7.1 The certification body shall establish procedures for identification and management of nonconformities in its operations.

8.7.2 The certification body shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence.

8.7.3 Corrective actions shall be appropriate to the impact of the problems encountered.

8.7.4 The procedures for corrective actions shall define requirements for the following:

a) identifying nonconformities (e.g. from complaints and internal audits);

b) determining the causes of nonconformity;

c) correcting nonconformities;

d) evaluating the need for actions to ensure that nonconformities do not recur;

e) determining and implementing the actions needed in a timely manner;

f) recording the results of actions taken;

g) reviewing the effectiveness of corrective actions.

8.8 Preventive actions (Option A)

8.8.1 The certification body shall establish procedures for taking preventive actions to eliminate the causes of potential nonconformities.

8.8.2 Preventive actions taken shall be appropriate to the probable impact of the potential problems.

8.8.3 The procedures for preventive actions shall define requirements for the following:

a) identifying potential nonconformities and their causes;

b) evaluating the need for action to prevent the occurrence of nonconformities;

c) determining and implementing the action needed;

d) recording the results of actions taken;

e) reviewing the effectiveness of the preventive actions taken.

NOTE The procedures for corrective and preventive actions do not necessarily have to be separate.

Annex A
(informative)

Principles for product certification bodies and their certification activities

A.1 General

A.1.1 The overall aim of certification is to give confidence to all interested parties that a product fulfils specified requirements. The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfilment of specified requirements by a third party. Parties that have an interest in certification include, but are not limited to the following:

a) the clients of the certification bodies;

b) the customers of the organizations whose products are certified;

c) governmental authorities;

d) non-governmental organizations;

e) consumers and other members of the public.

A.1.2 The principles for inspiring confidence are those specified in Clauses A.2 to A.6.

A.2 Impartiality

A.2.1 It is necessary for certification bodies and their personnel to be impartial, and to be perceived as impartial, in order to give confidence in their activities and their outcomes.

A.2.2 Risks to impartiality include bias that may arise from the following:

a) self-interest (e.g. overdependence on a contract for service or the fees, or fear of losing the client or fear of becoming unemployed, to an extent that adversely affects impartiality in carrying out conformity assessment activities);

b) self-review (e.g. performing a conformity assessment activity in which the certification body evaluates the results of other services it has already provided, such as consultancy);

c) advocacy (e.g. a certification body or its personnel acting in support of, or in opposition to, a given company which is at the same time its client);

d) over-familiarity, i.e. risks that arise from a certification body or its personnel being overly familiar or too trusting, instead of seeking evidence of conformity (in the product certification context, this risk is more difficult to manage because the need for personnel with very specific expertise often limits the availability of qualified personnel);

e) intimidation (e.g. the certification body or its personnel can be deterred from acting impartiality by risks from, or fear of, a client or other interested party);

f) competition (e.g. between the client and a contracted person).

A.3 Competence

The competence of the personnel supported by the management system of the certification body is necessary in order to deliver certification that provides confidence.

A.4 Confidentiality and openness

A.4.1 General

Managing the balance between requirements related to confidentiality (see A.4.2) and openness (see A.4.3) affects the trust of stakeholders and their perception of value in the conformity assessment activities being performed.

A.4.2 Confidentiality

To gain access to the information needed to conduct effective conformity assessment activities, the certification body needs to provide confidence that confidential information will not be disclosed.

All organizations and personnel have the right to ensure the protection of any proprietary information that they provide, unless the law or the certification scheme that has been applied for requires disclosure of proprietary information (see 4.5).

A.4.3 Openness

A certification body needs to provide access to, and disclosure of, appropriate and timely information about its evaluation and certification processes, as well as about the certification status of any product (i.e. granting, maintaining, extending or reducing the scope of, suspending, withdrawing or refusing certification), in order to gain confidence in the integrity and credibility of certification. Openness is a principle of access to, or disclosure of, appropriate information.

A.4.4 Access to information

Any information held by the certification body on a product that is the subject of an evaluation and/or certification should be made accessible, upon request, to the person or organization that contracted the certification body to undertake the certification activity.

A.5 Responsiveness to complaints and appeals

The effective resolution of complaints and appeals is an important means of protection for the certification body, its clients and other users of conformity assessment against errors, omissions or unreasonable behaviour. Confidence in conformity assessment activities is safeguarded when complaints and appeals are processed appropriately.

A.6 Responsibility

A.6.1 The client, not the certification body, has the responsibility of fulfilling the certification requirements.

A.6.2 The certification body has the responsibility to obtain sufficient objective evidence upon which to base a certification decision. Based on a review of the evidence, it makes a decision to grant certification if there is sufficient evidence of conformity, or a decision not to grant certification if there is not sufficient evidence of conformity, or a decision not to maintain certification.

Annex B
(informative)

Application of this International Standard for processes and services

B.1 Explanations of how to apply this International Standard to the certification of processes

When applying this International Standard to the certification of processes:

— replace “product(s)” with “process(es)”;

— replace “production” with “operation”;

— replace “produced” with “operated”;

— replace “producing” with “operating”.

B.2 Explanations of how to apply this International Standard to the certification of services

When applying this International Standard to the certification of services:

— replace “product(s)” with “service(s)”;

— replace “production” with “provision”;

— replace “produced” with “provided”;

— replace “producing” with “providing”.

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