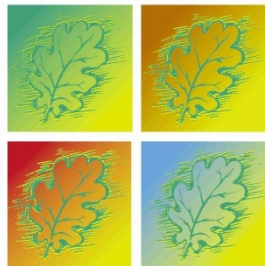
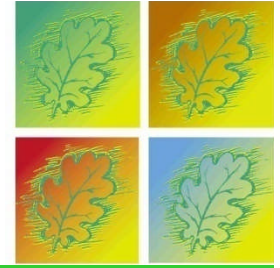


# How to fix your QMS for ISO 9001:2008



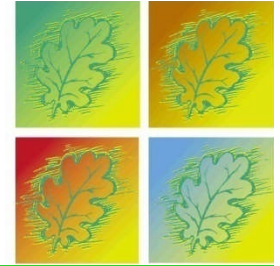
Colin Gray  
Cavendish Scott, Inc.

# Cavendish Scott, Inc.



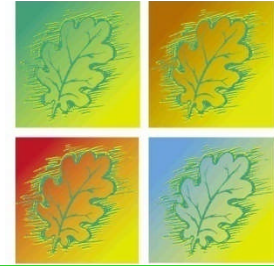
- ISO Consulting, Training and Auditing Since 1985
- Consulting with Guarantee of Successful Registration
- Accredited ISO training, public and on site
- **Internal auditing for your system (to ISO 9001:2008)**
- Probably 2000 successful ISO registrations
- 1000's of auditors trained
- All IRCA/RABQSA registered auditors
- 9001, AS9100B & C, ISO 14001, ISO 27001,, TL, TS, Etc.

# Colin Gray



- Consulting, training and auditing for 20 years
- RABQSA and IRCA QMS Lead Auditor
- IRCA Accredited trainer
- MBA, IAMdip, CIMdip, IQM

# The Changes



INTERNATIONAL  
STANDARD

**ISO  
9001**

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Fourth edition 2008-11-15

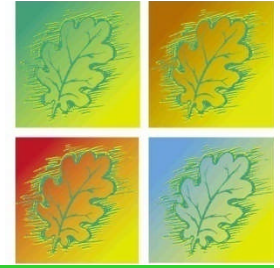
**Quality management systems**

—

**Requirements**

*Systèmes de management de la qualité — Exigences*

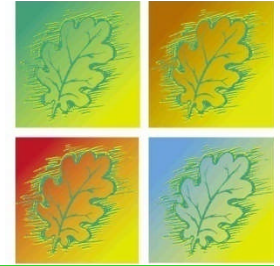
# Fixing the Errors



- ISO 9001:2008 Technical Corrigendum 1 was published on July 15, 2009 with corrections to Annex A and Annex B of the ISO 9001:2008 standard published on November 15, 2008.

The corrections were limited to Tables A.1 and A.2, the ISO 9001:2008 and ISO 14001:2004 cross-reference tables, and Table B.1, the ISO 9001:2000 to ISO 9001:2008 changes table.

# Annex A, Table A.1, Correspondence between ISO 9001:2008 and ISO 14001:2004

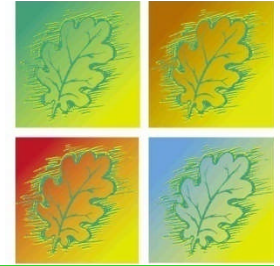


- Page 15
  - 5.1: Add clause 4.6, Management review, under the ISO 14001 column.
  - 5.2: Remove the 4.6 entry under the ISO 14001 column.
  - 5.5.1: Remove the 4.1 entry under the ISO 14001 column.

Page 17

8.4: Add clause 4.5.3, Nonconformity, corrective action, and preventive action under ISO 14001 column.

# Annex A, Table A.2, Correspondence between ISO 14001:2004 and ISO 9001:2008

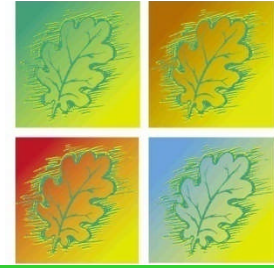


- Page 18  
4.1: Remove the entries for clauses 5.5 and 5.5.1 under the ISO 9001 column.

Page 19

4.4.6: Remove the clause 7.5 entry under the ISO 9001 column.

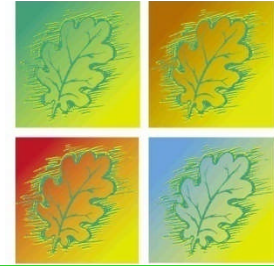
# Annex B, Table B.1, Changes between ISO 9001:2000 and ISO 9001:2008



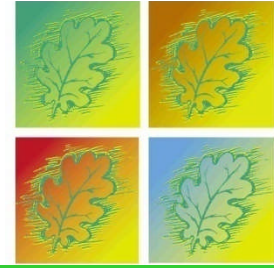
- Page 20, Annex B, Table B.1, seventh row: The entire sentence should be shown as a strike-through. In other words, include "Annexes A" as part of the deleted sentence.

Page 21, Annex B, Table B.1, second row: The word "are" at the end of the first sentence should have been underlined to indicate it was an addition.

Page 25, Annex B, Table B.1, first row: The second sentence should not have been shown as a strike-through. It replaced the prior deleted sentence and should have been underlined as an addition.

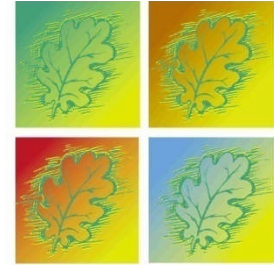


# Official Implementation



- IAF - News Item 3
- <http://www.iaf.nu/>
- Joint IAF-ISO communiqué
- **“ISO 9001:2008 does not contain any new requirements”**
- ANAB
- Heads Up 155 – “no new requirements”

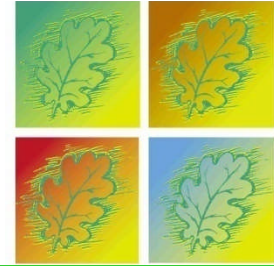
# Nonconformance



## AUDIT REPORT – Corrective Action Request (CAR)

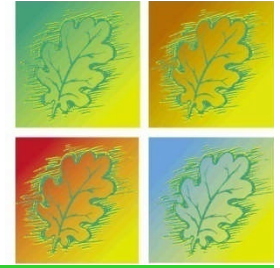
PART 1 Completed by NQA Auditor Complete all sections in Part 1					
Assessor Name	SP	Site:	Denver CO	CAR No.	2
Reference Standard	ISO 9001:2008	Referenced Clause	4.2.3b)	Criticality Ma / mi	mi
<b>Nonconformity</b>					
Requirement Stated: “A documented procedure shall be established to define the controls needed to b) review and update as necessary and re-approve documents”					
Nonconformity Statement: Section 4.1 of the Quality Manual, para. 3, states “Processes necessary to the operation of the QMS have been identified...”. The revised wording of the ISO 9001:2008 standard changes “identify” to “determine” in clause 4.1, which the Quality Manual text is citing.					
PART 2 Organization’s Planned Actions Complete this section and submit to NQA when required (see page 2) May also be completed using the organization’s own forms					
<b>Immediate Containment Actions and Correction Taken</b>					
					Planned completion date
<b>Root Cause Analysis ('how/why did this happen?')</b>					
<b>Corrective Action(s) (to prevent recurrence) w planned completion date</b>					
					Planned completion date
Organization’s Representative					Date:
PART 3 Completed by the Organization The organization’s verification of corrective action’s implementation Must be completed this section prior to the next scheduled audit					
Organization’s Representative					Date:
PART 4 Completed by the NQA Auditor Verification/Closure of the implemented corrective action					
Date:	Accepted: Yes <input type="checkbox"/> No <input type="checkbox"/>		Auditor’s Name:		
Details of Verification and Effectiveness					

# Nonconformance



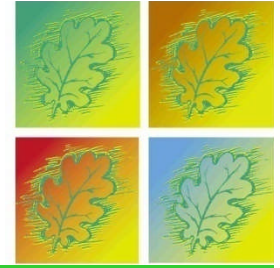
- Requirement Stated: “A documented procedure shall be established to define the controls needed to b) review and update as necessary and re-approve documents”
- Nonconformity Statement: Section 4.1 of the Quality Manual, para. 3, states “Processes necessary to the operation of the QMS have been identified...”. The revised wording of the ISO 9001:2008 standard changes “identify” to “determine” in clause 4.1, which the Quality Manual text is citing.

# Implementation Tasks



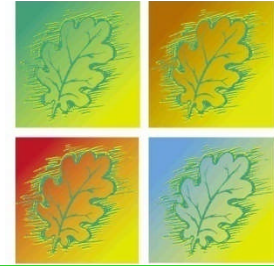
- Relax
- Take about half-one day
- Done by your next audit
- Change your documentation (Discuss)
- Buy Copy (Discuss)
- Ask registrar for their checklist
- Checklist proof
- Internally audit to the new standard
  
- AS9100 (major changes)

# Registrar Implementation Schedule



- a. Did not issue any certificate to ISO 9001:2008 prior to 2008/11/15;
- b. Does not issue any certificate to ISO 9001:2008 until after conducting a surveillance or re-certification audit with an independent decision for certification;
- c. Does not issue any certificate (any new certification or re-certification) to ISO 9001:2000 after 2009/11/15; and
- d. Ensures that there are no certificates to ISO 9001:2000 after 2010/11/15.

# Contact



- Questions about the new standard
- Internal auditing to upgrade your ISO system
- Training, Consulting, Auditing
  
- [Colin@CavendishScott.com](mailto:Colin@CavendishScott.com)
- [www.CavendishScott.com](http://www.CavendishScott.com)
- Cell: 303 668 2500
- Office: 303 480 0111
- Fax: 303 480 9000