

# Exclusions to ISO 9001:2008

From The Registrar's Point of View

Presented by:  
Melody Sands  
Staff Auditor  
Platinum Registration, Inc.



# Exclusions to ISO 9001:2008

- 1.2 Application states:
  - Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.
  - Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

# Exclusions to ISO 9001:2008

- Justification – appropriate?
  - Who is the customer?
  - What is the product
  - What are the requirements (stated and not stated) related to the product?
- Expressed in the Quality Manual
  - Per sub-clause 4.2.2 of ISO 9001:2008
- Exclusions of partial clauses in 7, i.e., 7.5.1.f post delivery activities

# Exclusions to ISO 9001:2008

- Not acceptable justifications for exclusion:
  - We've always excluded it
  - We outsource it
  - Regulatory agencies don't demand compliance but the requirements affect ability to meet customer requirements

Platinum Registration, Inc.  
3955 East Exposition Ave., Suite 206,  
Denver, CO  
303-639-9001

# Exclusions to ISO 9001:2008

- Examples:

## Exclusion for Design of services:

- Small consulting firm performing internal audits
- Methodology and tools were based on guidance ISO 19011:2002
- Customized service - the output is a written audit report and supporting data
- Wishes to exclude 7.3 Design and Development with justification that, as a service provided, it cannot have any design and development activities

Platinum Registration, Inc.  
3955 East Exposition Ave., Suite 206,  
Denver, CO  
303-639-9001

# Exclusions to ISO 9001:2008

## Analysis/Conclusion –

- Not justified exclusion
- Has developed customized service to meet customer requirements
- Developed methodologies and tools, including delivery of written report

Platinum Registration, Inc.  
3955 East Exposition Ave., Suite 206,  
Denver, CO  
303-639-9001

# Exclusions to ISO 9001:2008

- Exclusion of Validation of Processes
  - *Small machine shop, providing finished metal parts to customers requirements as stated on prints*
  - *Includes plating, passivation, paint, etc... requirements*
  - *Wishes to exclude 7.5.2 Validation of Processes because they outsource the plating, passivation, painting, etc... to vendors identified and/or required by the customer*

# Exclusions to ISO 9001:2008

- *Analysis/Conclusion*
  - *Exclusion is not justified*
  - *The organization is responsible for the final product and are required by the ISO 9001:2008 standard to control the processes that cannot be measured, including outsourced processes*

# Exclusions to ISO 9001:2008

- Monitoring and Measuring Devices
  - *Small training organization*
  - *Trains people upgrading their skills*
  - *Participants learns the use of monitoring and measuring equipment*
  - *Product is skills development and not the crafted items produced*
  - *Wishes to exclude 7.6 Control of monitoring and measuring devices*

Platinum Registration, Inc.  
3955 East Exposition Ave., Suite 206,  
Denver, CO  
303-639-9001

# Exclusions to ISO 9001:2008

- Analysis/Conclusion:
  - The measuring devices are a diversion and not the focus when considering exclusion of 7.6
  - Training is the product which should be evaluated
  - Organization should be controlling monitoring/measuring devices such as:
    - Tests
    - Student satisfaction surveys
    - Reports related to students finding jobs
  - Control may be demonstrated through verification or validation of the devices such as through test pilot testing of the survey questionnaires
  - Exclusion may be justified to the requirements of 7.6 which deal with calibration of measuring equipment bullets (a) to (e)
  - If the training includes providing students with ability to check accuracy of their equipment then the bullets (a) to (e) could not be excluded

# Exclusions to ISO 9001:2008

- Customer Property
  - Bank is implementing QMS only for Internet banking services
  - Bank is excluding sub-clause 7.5.4 Customer property
  - Justification is that they do not have possession of any customer property

# Exclusions to ISO 9001:2008

- Analysis/Conclusion:
  - Not Justified
  - Bank receives customer information – personal and confidential
  - The note of sub-clause *7.5.4 Customer property*, clearly indicates “*Customer property can include intellectual property and personal data*”
  - Therefore the bank has to address the requirements for customer property in its QMS

# Exclusions to ISO 9001:2008

- Summary
  - Exclusions are allowed – down to sub-clauses and even portions of those sub-clauses
  - Exclusions are being looked at for validity more closely with the release of the new standard, even if you are not upgrading yet
  - This is NOT a change, only clarification on the requirement as originally written in the ISO 9001:2000 standard

Platinum Registration, Inc.  
3955 East Exposition Ave., Suite 206,  
Denver, CO  
303-639-9001

# Exclusions to ISO 9001:2008

- Read the guidelines:
- ISO 9000 Introduction and Support Package Module: Guidance on ISO 9001:2008 Sub-clause 1.2 'Application' Document: ISO/TC 176/SC 2/524R6 15 October 2008
- On the web at:  
<http://isotc.iso.org/livelink/livelink/3554792/1.2Application.doc?func=doc.Fetch&nodeid=3554792>

# Exclusions to ISO 9001:2008

## Thank you!

Melody Sands

Platinum Registration

303-639-9001

Platinum Registration, Inc.  
3955 East Exposition Ave., Suite 206,  
Denver, CO  
303-639-9001