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Overview of activities and outputs of IAF/ISO 9001 Auditing Practices Group (APG) and Accreditation Auditing Practices Group (AAPG)

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Content

- What are APG & AAPG guidance documents?
- Marketplace Context
- History and overview of APG topics
- APG Topics
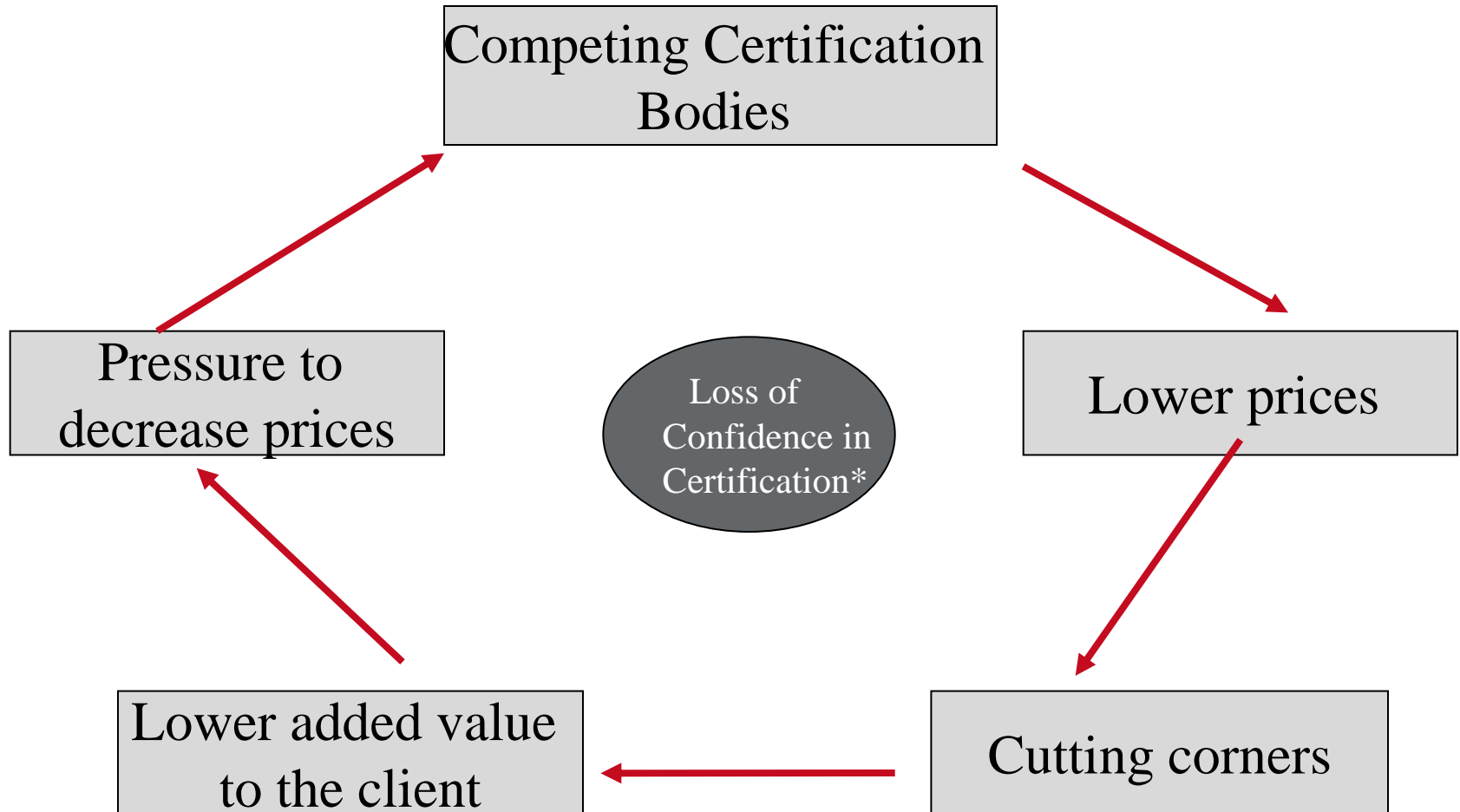- AAPG Topics
- Recognition
- Conclusions

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What are APG &AAPG guidance documents?

- By November 2016:
  * 40 APG documents
  * 12 AAPG documents

- Auditing practice available at
  http://www.iso.org/tc176/ISO9001AuditingPracticesGroup

- Concerned with effective value auditing of Quality Management Systems

- Some additional graphics and illustrations

- Not subject to a formal endorsement process by ISO and IAF , but produced by experts, auditors and practitioners drawn from the ISO Technical Committee 176 and IAF

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Marketplace Context

- Certification shall be conducted by a **competent audit team**, **with adequate resources** and following a **consistent process**, with the **results reported in a consistent manner.**
- **The value of certification is the degree of public confidence and trust that is established by an impartial and competent assessment by a third-party.**

Marketplace Context

Competing Certification Bodies

Pressure to decrease prices

Loss of Confidence in Certification*

Lower prices

Lower added value to the client

Cutting corners

The certification death spiral

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Marketplace Context

- The ISO 9000 Advisory Group identified auditor competence and the competent use of these auditors as a critical issue when ensuring the credibility of ISO 9001 certification.

- Auditing Practices Group established in February 2003.

Marketplace Context

- The *Accreditation Auditing Practices Group* is constituted as an informal group of accreditation experts, auditors and practitioners, drawn from the ISO Policy Committee for *Conformity Assessment* (ISO/CASCO), the ISO Technical Committee 176 *Quality Management and Quality Assurance* (ISO/TC 176) and the International Accreditation Forum (IAF). It was established following the success of the *ISO 9001 Auditing Practices Group*, and following a request from the IAF's Technical Committee.

- The Co-Conveners of the *Accreditation Auditing Practices Group* are Mr Fei Yang (Deputy Director, CNAS, China) and Mr Alex Ezrakhovich (Managing Director, AEConformity Pty Ltd, Australia).

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Participants

Experts nominated by:-

- IAF (CABs, ABs, Industry)

- ISO TC/176(WG Interpretations, SC1, SC2, SC3)

- ISO CASCO

- IATCA (now IPC)

Aims of the Group

1. Development of examples of good auditing practices related to requirements of ISO9001 and guidelines of ISO19011

2. Development of a website where papers and examples of auditing practice against the requirements of ISO 9001 are posted and available to the public without charge.

3. The information provided by the Group does not constitute IAF or ISO endorsed benchmarks or interpretations of the preferred way conformance to ISO 9001 is audited.

APG-Introduction.doc

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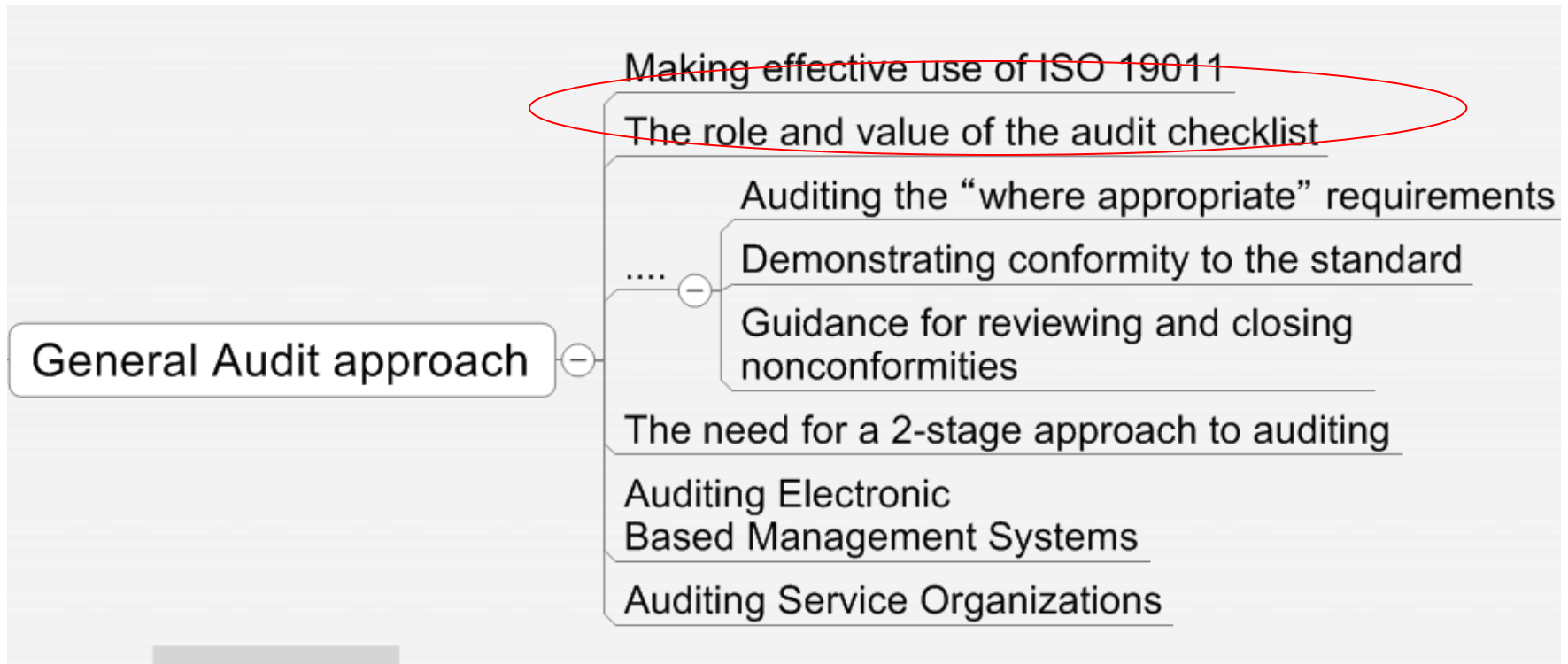Expertise in Conformity Assessment

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Overview of APG Guidance

- In order to give an easy overview, we group guidelines:
    - General audit approach
    - Guidance on auditing specific requirements
        - Sub-group according common elements of type A standards (ISO Guide 72)
    - Professionalism
    - Interpretation and clarification

Overview of APG Guidance:
General audit approach

General Audit approach
- Making effective use of ISO 19011
- The role and value of the audit checklist
  - Auditing the "where appropriate" requirements
  - Demonstrating conformity to the standard
  - Guidance for reviewing and closing nonconformities
- The need for a 2-stage approach to auditing
- Auditing Electronic Based Management Systems
- Auditing Service Organizations

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Overview of APG Guidance:
Guidance on auditing specific requirements

Guidance on auditing specific requirements

Policy
- Policy and principles
  - Auditing Quality Policy, Quality Objectives, and Management Review
  - Linking an audit of a particular task, activity or process to the overall system

Planning
- Identification of needs, requirements and analysis of critical issues
  - Auditing Statutory and Regulatory requirements
  - Auditing Customer Feedback processes
- Identification of resources
  - Auditing the Management of Resources

Implementation and operation
- Management of human resources
  - Auditing competence and the effectiveness of actions taken
- Documentation and its control
  - Auditing a QMS which has minimum documentation
- Communication
  - Auditing Internal Communications
  - Auditing Customer Communications

Improvement
- Preventive action
  - Auditing Preventive Action
- Continual improvement
  - Auditing continual improvement

Management review
- How to audit top management processes

Performance assessment
- Monitoring and measuring
  - Auditing ISO 9001, Clause 7.6 Control of monitoring and measuring devices
- System audits
  - Auditing the Effectiveness of the Internal Audit
- Measuring QMS effectiveness and improvements

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Overview of APG Guidance: Professionalism Interpretation and clarification

Professionalism
- Third Party Auditor Impartiality and Conflict of Interest
- Documenting a Nonconformity
- How to Add Value during the audit process

Interpretation and clarification
- Understanding the process approach
- Determination of the "where appropriate" processes
- Scope of ISO 9001:2000, Scope of Quality Management System and Defining Scope of Certification

Auditing Practices Group Topics (1)

- **General**
  - ∗ Adding value
  - ∗ Code of Conduct and Ethics
  - ∗ Cultural Aspects
  - ∗ Expected Outcomes
  - ∗ Impartiality
  - ∗ Scope of ISO 9001, Scope of Quality Management System and Scope of Certification
  - ∗ Technical Experts
  - ∗ Two stage initial certification audit

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Auditing Practices Group Topics(2)

- **Auditing General**
  - Added Value Audits versus Consultancy
  - Audit Reports
  - Audit Trail
  - Checklist
  - Deal with consultants
  - Demonstrate conformity to the standard
  - Effective use of ISO 19011
  - Effectiveness
  - Electronic documented information systems
  - Evidence collection
  - Nonconformity – Documenting
  - Nonconformity – Review and closing

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Auditing Practices Group Topics(3)

- **Auditing to ISO 9001:2015 (1)**
  * [Competence](#)
  * [Context](#)
  * [Customer Communications](#)
  * [Customer Complaints](#)
  * [Customer Feedback](#)
  * [Design and Development Process](#)
  * [External providers](#)
  * [Improvement](#)
  * [Internal audit](#)
  * [Internal communication](#)

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Auditing Practices Group Topics

- **Auditing to ISO 9001:2015 (2)**
  - Measurement traceability
  - Monitoring and measuring resources
  - Organizational Knowledge
  - Policy, objectives and management review
  - Processes
  - Resources
  - Risk Based Thinking
  - Service organizations
  - Statutory and Regulatory requirements
  - Top management

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Accreditation Auditing Practices Group Topics

▶ [Introduction to the Accreditation Auditing Practices Group](#)

▶ [The witnessing of CAB audits by an accreditation body](#)

▶ ["Process Approach" based accreditation audits](#)

▶ [Auditor Code of Conduct and Ethics](#)

▶ [Criteria for Competence of AB Assessors and Assessment Teams](#)

▶ [Auditing Accreditation Scopes](#)

▶ [Auditing the CAB Impartiality Committee](#)

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Accreditation Auditing Practices Group Topics

▶ Auditing Certification Body management systems based on ISO 9001 (Option 1 from clause 10 of ISO/IEC 17021)

▶ Deployment of the Expected Outcomes Documents

▶ Control of CABs' foreign or remote locations

▶ The conduct of integrated assessments of a CAB operating more than one MS certification scheme

▶ Possible indicators of CAB Performance

▶ Good practices for AB's and CAB's in the Transition to ISO 9001:2015

The need for a 2 stage approach to auditing

- Auditing to ISO 9001 requires a good understanding of the business and QMS

- The primary purpose of the 1st stage audit

- Activities performed during the 1st stage audit

APG-2stage.doc

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How to audit top management processes

- Identifying top management processes
- Conducting the audit
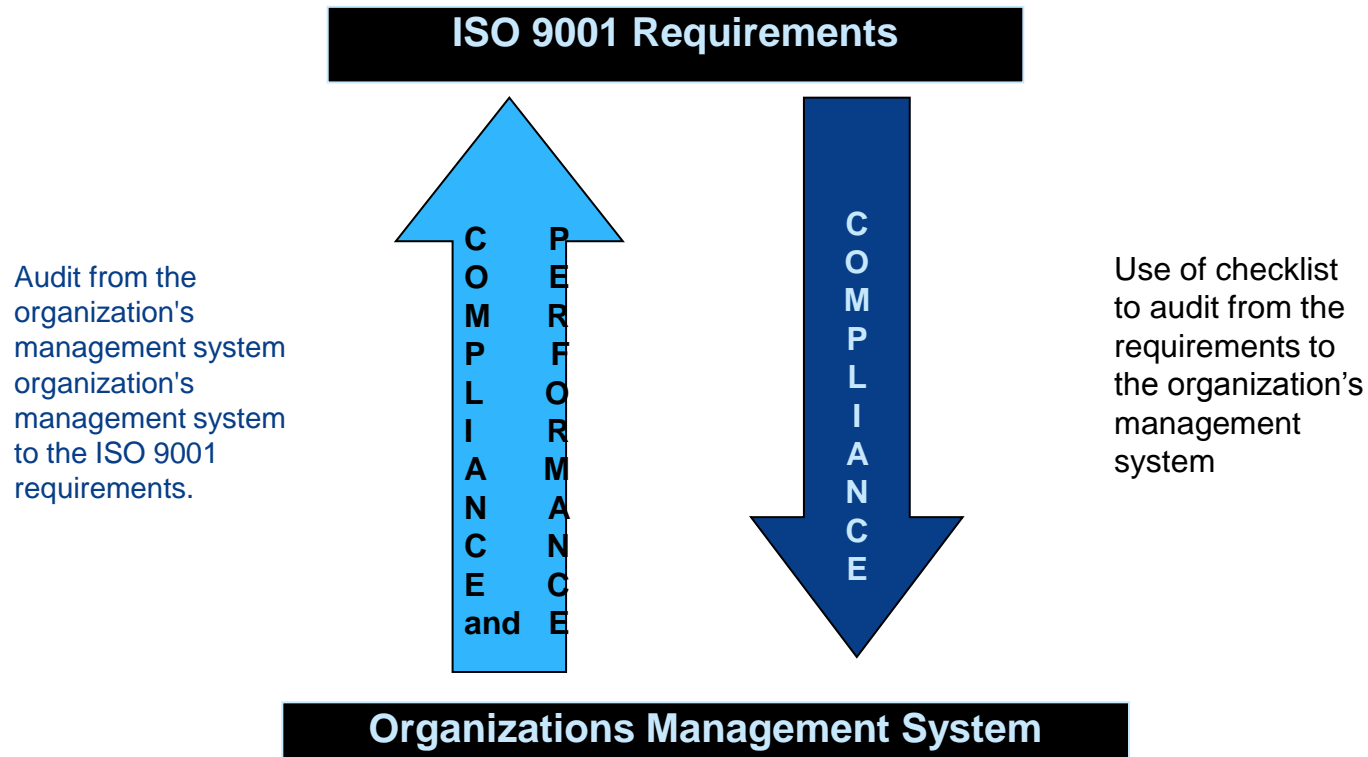- Audit reporting

APG-AuditTopManagement.doc

The role and value of the audit checklist

- Need for checklists
- The use of audit checklists
- Advantages
- Disadvantages
- Conclusion

APG-Checklist.doc

The role and value of the audit checklist

It is beneficial to audit from the organization's quality management system up to the requirements. A checklist may be used to ensure that all relevant ISO 9001 requirements addressed

ISO 9001 Requirements

Audit from the organization's management system organization's management system to the ISO 9001 requirements.

C O M P L I A N C E and **P E R F O R M A N C E**

C O M P L I A N C E

Use of checklist to audit from the requirements to the organization's management system

Organizations Management System

Third party auditor impartiality and conflict of interest

- CAB commitment to impartiality

- Threats to auditor impartiality

- Safeguards to auditor impartiality

- Assessing the level of impartiality risk

- Determining the acceptability of the level of impartiality risk

- Organizational and structural issues

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Auditing the effectiveness of the internal audit

- **Issues to evaluate:**
  - ∗ the competencies that are needed for and applied to the audit
  - ∗ the risk analysis performed by the organization (if any) in planning internal audits
  - ∗ the degree of management involvement in the internal audit process
  - ∗ the way the outcome of the internal audit process is used by the organization to evaluate the effectiveness of its QMS and to identify opportunities for improvements.

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Auditing Electronic-Based Management Systems (EBMS)

- Audit Initiation and Planning
- Document Review
- On-Site Realization Activities
- Auditing the Control of Electronic Documents
- Auditing the Control of Electronic Records
- Organizational Resources
- Internal and External Electronic Communication
- Multi-Site Management Systems
- Auditor Competence

The Witnessing of CAB Audits by an Accreditation Body

- Pre-audit preparations

- During the audit

- Feedback and reporting of results

"Process approach" based accreditation audits

- CAB objectives

- Typical processes of CABs

- Example of questions to be asked by an AB during a process based audit

Auditing the competence of quality management system CAB auditors and audit teams

- Evaluation of auditor qualifications and competence
- Personal attributes
- Generic knowledge and skills
- Processes and products
- Size of Organizations
- Culture and Language
- Legal, statutory, and regulatory requirements
- Evaluation of competence requirements
- Deployment of a team of competent auditors

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Copies of the guidance documents referred to in this presentation can be obtained from:

www.iaf.nu

www.iso.org/tc176/ISO9001AuditingPracticesGroup

Comments on the papers or presentations can be sent to the following email address:

charles.corrie@bsi-global.com

Feedback from users will be used by the *ISO 9001 Auditing Practices Group* to determine whether additional guidance documents should be developed, or if these current ones should be revised.

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Recognition

- The output of these group was used as an input for development of:
  * **ISO/IEC 17021-1**, *Conformity assessment — Requirements for bodies providing audit and certification of management systems - Part 1: Requirements*
  * **ISO/IEC TS 17021-3**, *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 3: Competence requirements for auditing and certification of quality management systems*
  * **ISO 9001:2015,** *Quality management systems — Requirements*
- Utilised in training by:
  - Accreditation Bodies members of IAF
  - *Accredited CABs*
  - *International Automotive Task Force – IATF*
  - *International Aerospace Quality Group – IAQG*
  - *Information Security Management Systems* - ISO/IEC JTC 1/SC27

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Recognition

- **Translated to:**
  - *[Chinese - host: China Quality Certification Centre](#)*
  - *[Italian - host: Associazione Italiana Cultura Qualità](#)*
  - *[Japanese - host: Japan Association of Certification Bodies (JACB)](#)*
  - *[Romanian - host: Romanian Society for Quality Assurance (SRAC)](#)*
  - *[Russian - host: Novoe Kachestvo](#)*
  - *[Serbian- host: Institute for Standardization of Serbia (ISS)](#)*
  - *[Spanish - host: Instituto Colombiano de Normas Técnicas y Certificación (ICONTEC)](#)*

Recognition

- ISO TC176 Resolution 6 (2012) – Auditing Practices Group
  Considering the value of the APG produced papers and considerable experience developed in operation of the APG ISO/TC 176 resolves to:
  Maintain APG as an ad-hoc group and requests SC 1, 2 and 3 to nominate experts to this group.

Conclusions

- APG guidance help to identify typical problem areas in Management systems areas, which need to be addressed

- Many guidance documents are re-usable for ALL Management6 Systems with only minor changes, especially high-level issues

- Auditing a Management System as part of the overall management system leads in some industries to MS specific requirement which are **quality requirements** about services provided to customers

- Emerging integrated management systems need integrated audit practice

INTERACTION OF STAKEHOLDER REQUIREMENTS
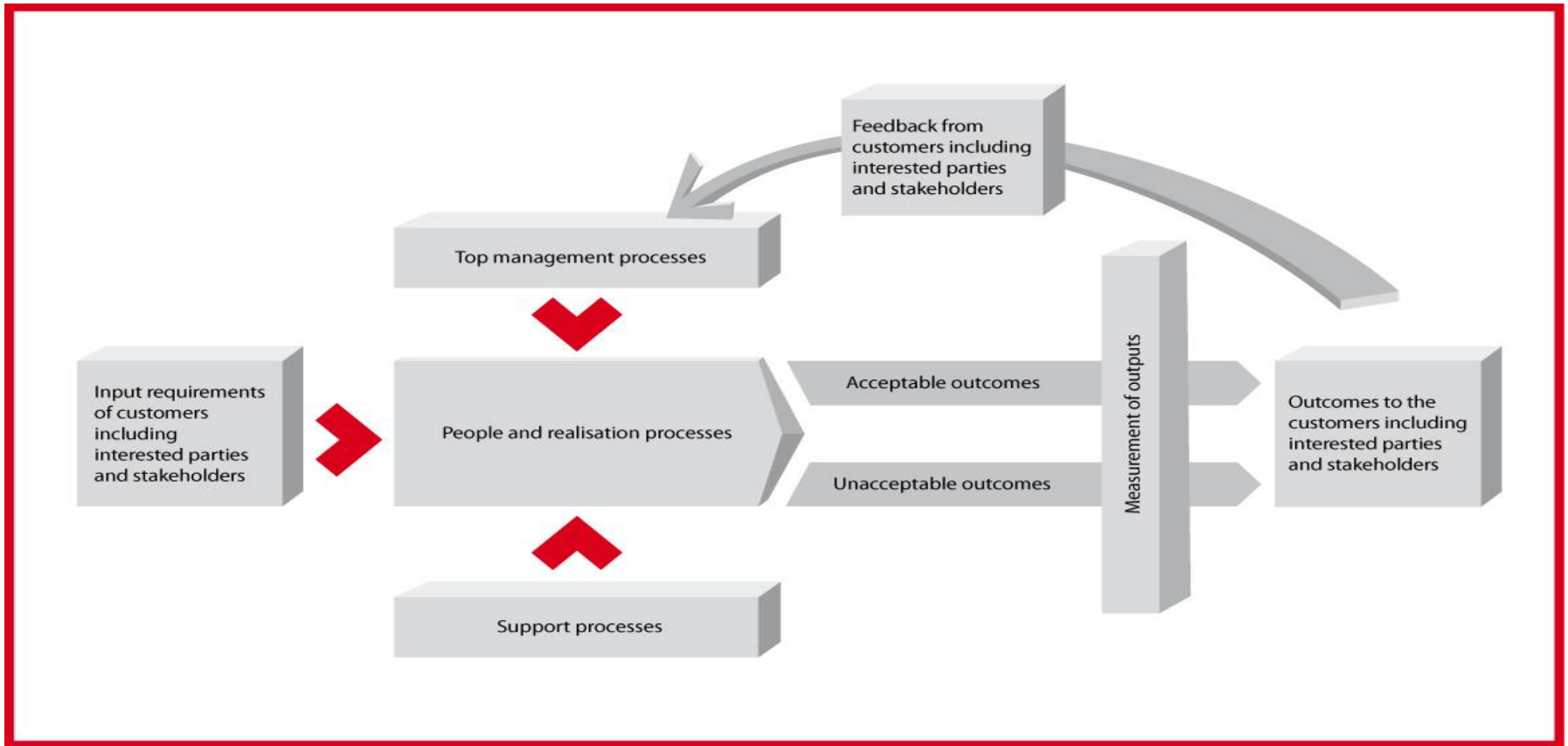
Management Process include, for example: Planning, Reviewing and Allocation of Resources etc.
People and Realisation Process include, for example : Customer and Interested Parties Related Process, Design and Development etc.
Support Processes include, for example: Supply chain, Training, Purchasing, Maintenance etc.