ISO 9001: 2015 OVERVIEW & EXPECTATIONS

Presenter Name

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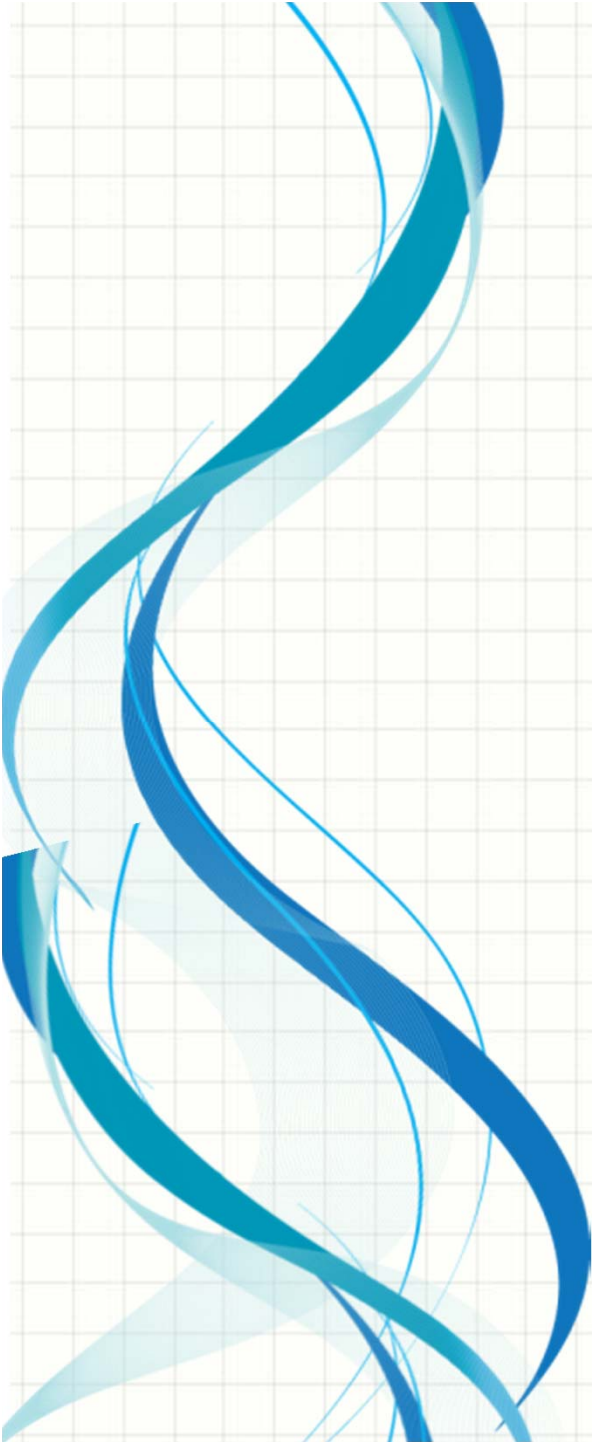
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Purpose Of Presentation

**To provide an overview
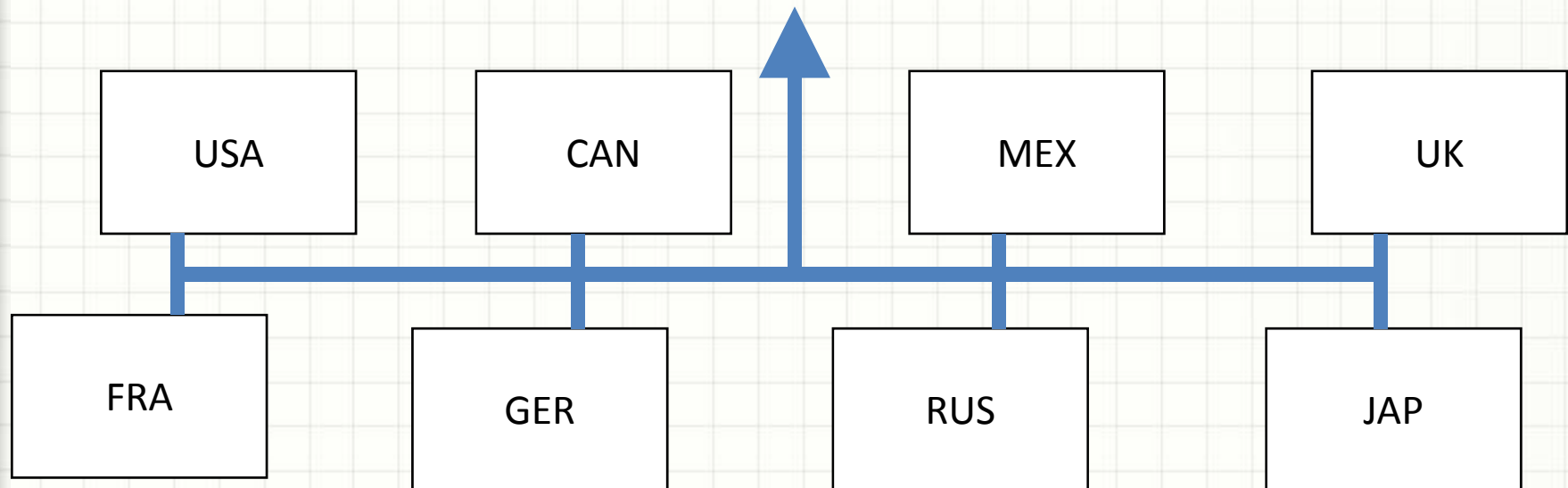9000:2015
9001:2015**

Estimated Release 12/15/15

ISO Facts?

- ISO is the International Organization for Standardization:

  — *ISO is based in Geneva-Switzerland,*
  — *Over 160 nations participate, with*
  — *Approximately 20,000 standards, and*
  — *Are consensus based.*

- ISO standards are usually developed by Technical Committees (TCs) or their Sub-Committees (SC), or by Project Committees (PC).

- ISO work involves experts nominated by their national standards bodies (e.g., ANSI/ASQ).

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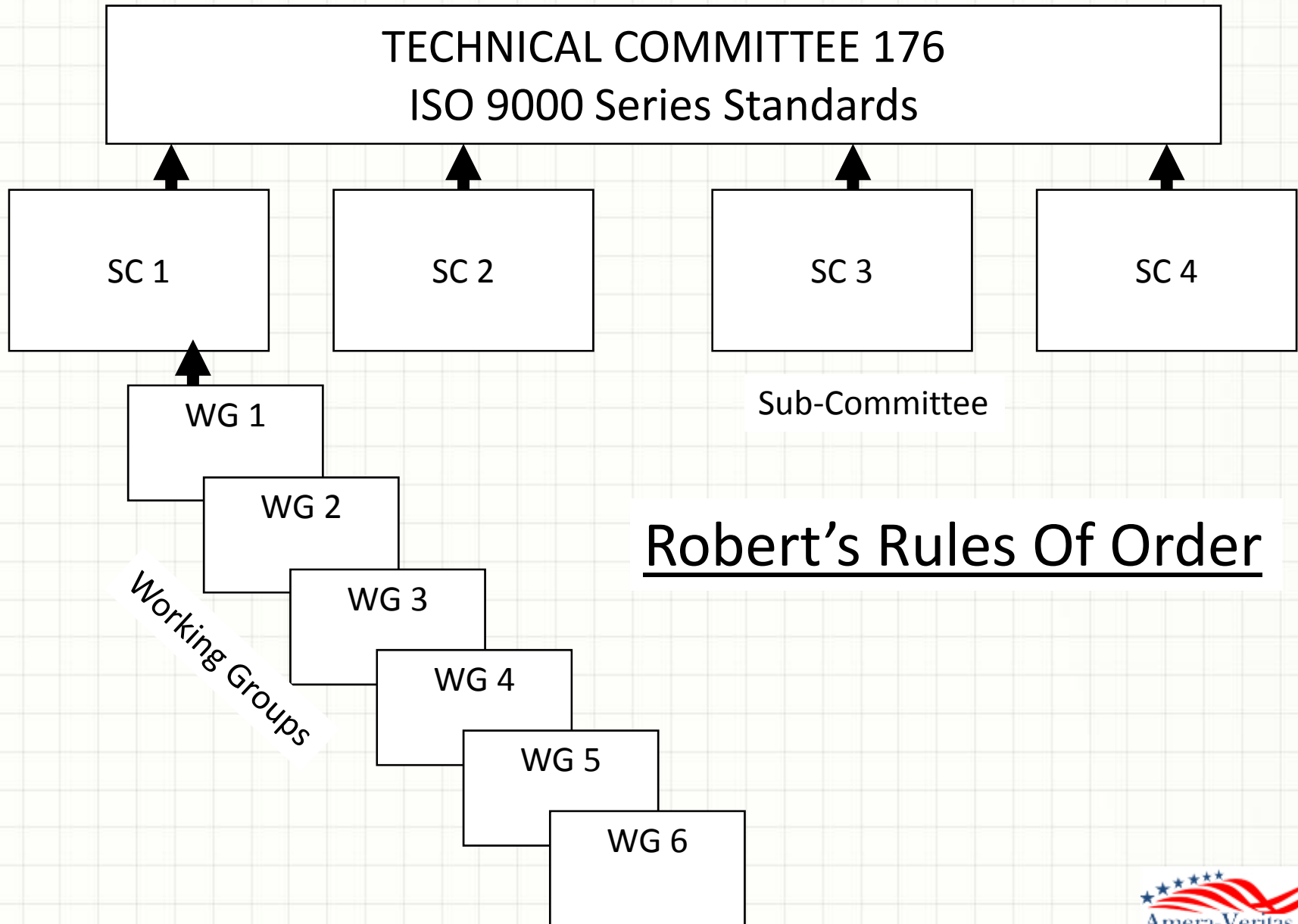*Experts in Quality, Risk & Safety Management Systems*

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TECHNICAL COMMITTEE'S

TC- 56   TC-69   TC-176   TC-207

| USA | CAN | MEX | UK |

| FRA | GER | RUS | JAP |

"One Country – One Vote"

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TECHNICAL COMMITTEE 176
ISO 9000 Series Standards

SC 1

SC 2

SC 3

SC 4

Sub-Committee

WG 1

WG 2

WG 3

WG 4

WG 5

WG 6

Working Groups

Robert's Rules Of Order

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ISO DEVELOPMENT PROCESS

- An international ballot agreed the need for revision

- There are several distinct stages when developing an ISO standard; the key ones being:

  WD   - Working Drafts

  CD   - Committee Draft

  DIS   - Draft International Standard
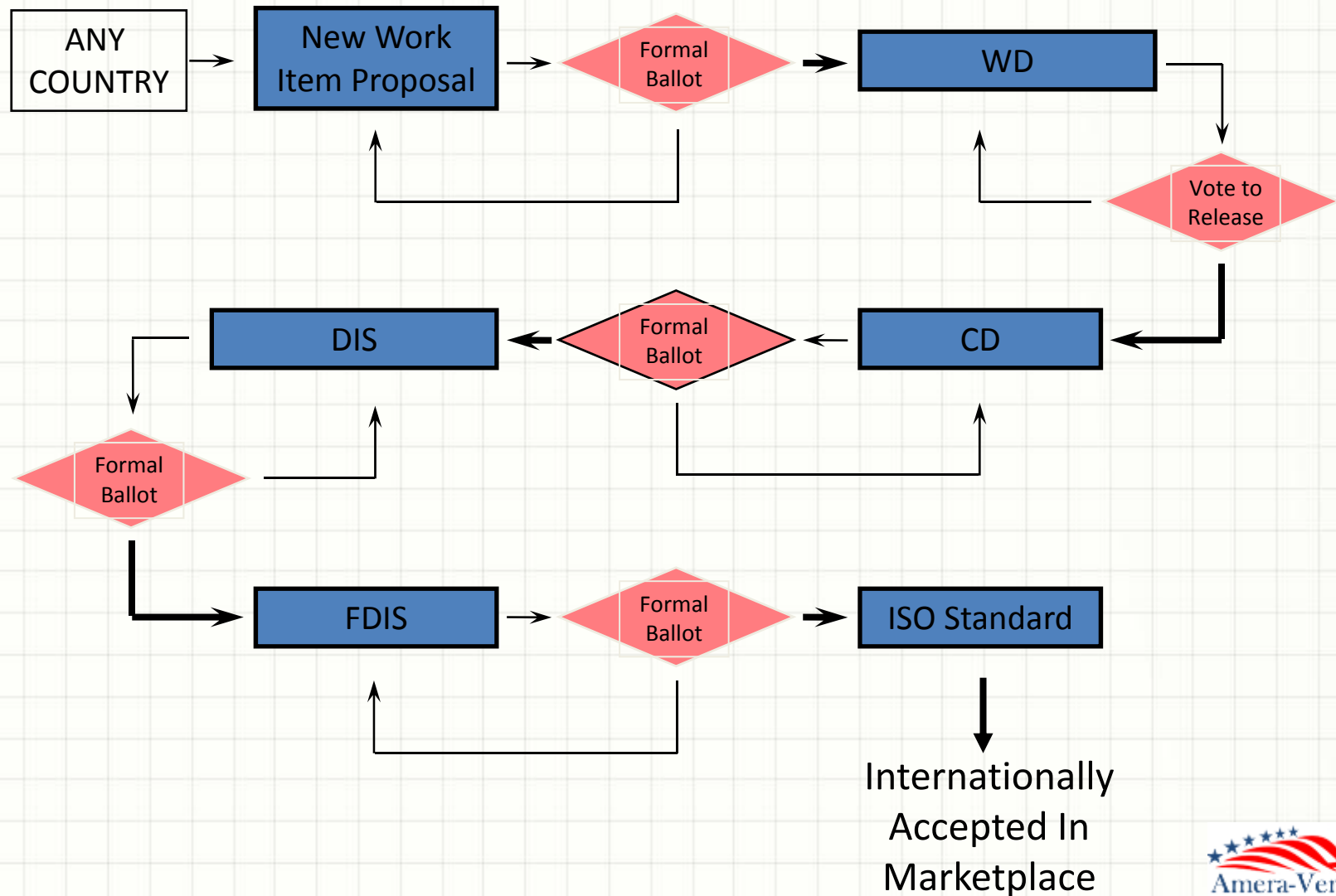
  FDIS - Final Draft International Standard

  IS   - International Standard

Other documents include TS-Technical Specifications, Guidelines, etc.

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ISO DEVELOPMENT PROCESS

Technical Committee's

```
ANY          →   New Work        →   Formal   →        WD
COUNTRY          Item Proposal        Ballot
                      ↑                  |                |
                      └──────────────────┘                ↓
                                                      Vote to
                                                      Release
                                                          ↑
      DIS      ←   Formal   ←           CD    ←───────────┘
                   Ballot
       ↓              ↑                  |
   Formal             └──────────────────┘
   Ballot
       ↓
     FDIS     →    Formal    →      ISO Standard
                   Ballot
       ↑              |                  |
       └──────────────┘                  ↓
                                   Internationally
                                   Accepted In
                                   Marketplace
```

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Why Change?

Impacts Shifts In Our Approach?
Challenges?

WHAT WAS CONSIDERED?

- The results of an extensive web-based user survey,

- The increasing diversity of ISO 9001 users,

- Developments in knowledge and technologies,

- ISO Gods desire to harmonize MSS,

- Broader user interests, and

- Changes in industry.

REVISION CHALLENGES

- Maintain relevance,

- Integrated with other MSS (14000/18000),

- Integrated approach to org. mgmt.,

- A consistent foundation (next 10 years),

- Reflect the increasingly complex environments in which organizations operate,

- Ensure the new standard reflects the needs of all potential user groups, and

- Enhance an organization's ability to satisfy its customers.

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SHIFTS IN APPROACH

- Risk-based thinking throughout the standard supersedes a single clause on preventive action,

- The term 'documented information' replaces 'documents and records',

- The term 'outsourcing' is replaced by 'external provision',

- Increased leadership requirements, and

- No requirement for a management representative.

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SHIFTS IN APPROACH

- Objectives must include reference to who, what, when, where, how,

- Planning of changes,

- Explicit reference to knowledge management,

- No need for a Quality Manual,

- Operational planning includes addressing risks, and

- Greater emphasis on processes achieving requirements for goods or services and customer satisfaction.

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SHIFTS IN APPROACH

- Control of changes,

- Monitoring and measurement,

- Internal audits now require the consideration of related risks, and

- Management review to take into consideration strategic direction of the organization.

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EXPECT

- All MSS must use of the High Level Structure (HLS),

- Expected to improve applicability for service organizations,

- There are fewer prescribed requirements,

- There is an increased emphasis on organizational context,

- QMS boundaries must now be defined, and
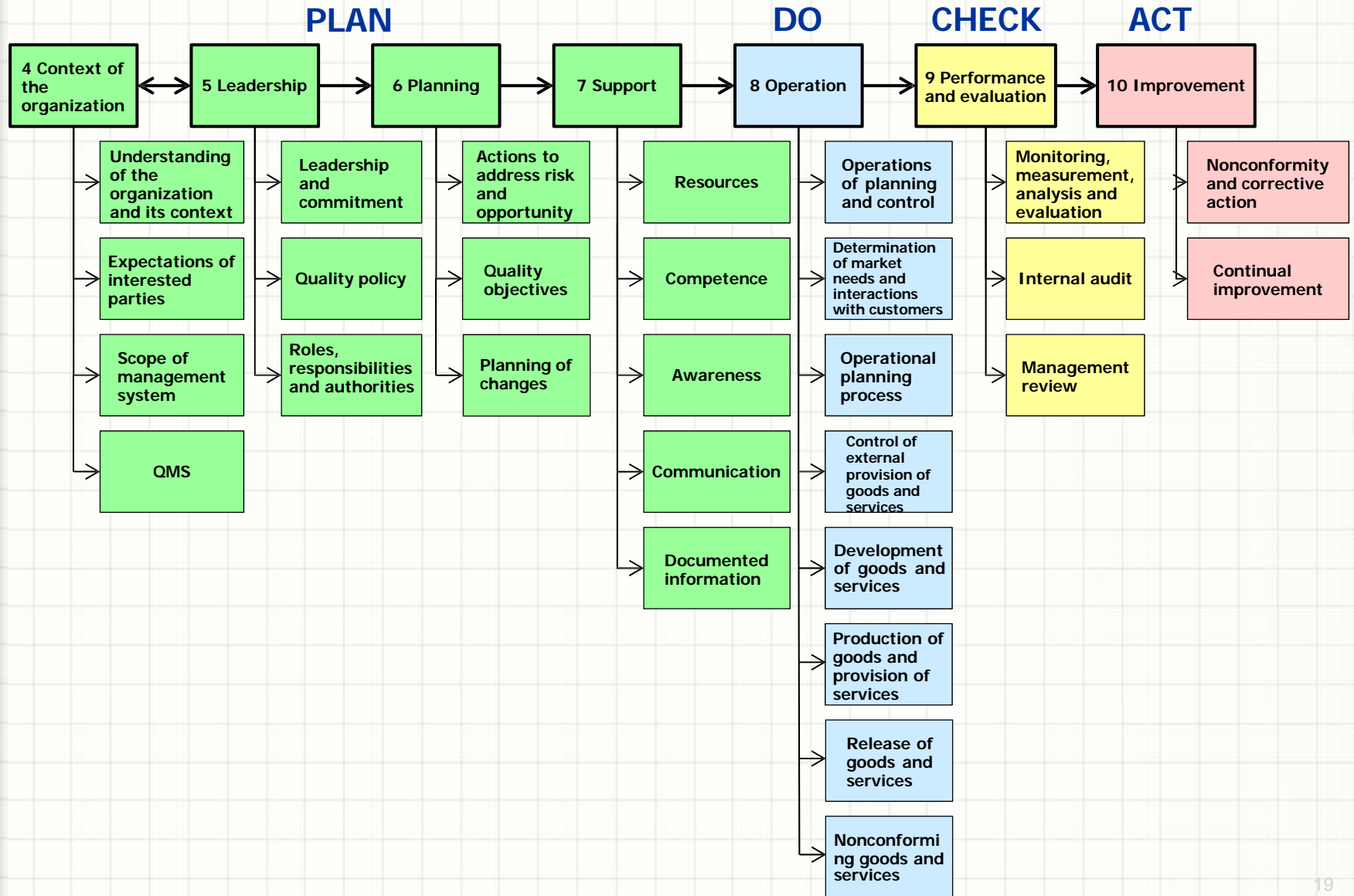
- New consideration of exclusions.

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Result =
New Format

MSS Common Definitions

3.01 organization
3.02 interested party
3.03 Requirement
3.04 management system
3.05 top management
3.06 effectiveness
3.07 Policy
3.08 objective
3.09 risk
3.10 competence
3.11 documented information

3.12 process
3.13 performance
3.14 outsource
3.15 monitoring
3.16 measurement process
3.17 audit
3.18 conformity
3.19 nonconformity
3.20 correction
3.21 corrective action
3.22 continual improvement

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New Structure

- A new common format has been developed for use in all management system standards

  — *standardized core text and structure*

  — *standardized core definitions*

Organizations implementing multiple management systems (e.g. quality, environmental, information security) can achieve better integration and easier implementation

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QMS Structure

PLAN **DO** **CHECK** **ACT**

4 Context of the organization	5 Leadership	6 Planning	7 Support	8 Operation	9 Performance and evaluation	10 Improvement

PLAN

- 4 Context of the organization
  - Understanding of the organization and its context
  - Expectations of interested parties
  - Scope of management system
  - QMS

- 5 Leadership
  - Leadership and commitment
  - Quality policy
  - Roles, responsibilities and authorities

- 6 Planning
  - Actions to address risk and opportunity
  - Quality objectives
  - Planning of changes

- 7 Support
  - Resources
  - Competence
  - Awareness
  - Communication
  - Documented information

DO

- 8 Operation
  - Operations of planning and control
  - Determination of market needs and interactions with customers
  - Operational planning process
  - Control of external provision of goods and services
  - Development of goods and services
  - Production of goods and provision of services
  - Release of goods and services
  - Nonconforming goods and services

CHECK

- 9 Performance and evaluation
  - Monitoring, measurement, analysis and evaluation
  - Internal audit
  - Management review

ACT

- 10 Improvement
  - Nonconformity and corrective action
  - Continual improvement

19
Date:

New Structure

4. Context of the organization

4.1 Understanding the organization and its context

4.2 Understanding needs/expectations of interested parties

4.3 Determining the scope of the QMS

4.4 Quality management system

5. Leadership

5.1 Leadership and commitment

5.2 Policy

5.3 Organizational roles, responsibilities/authorities

6. Planning

6.1 Actions to address risks and opportunities

6.2 Quality objectives and planning to achieve them

7. Support

7.1 Resources

7.1.1 Infrastructure

7.1.2 Work environment

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented information

7.5.1 General

7.5.2 Creating and updating

7.5.3 Control of documented Information

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8. Operation

8.1 Operational planning and control

8.2.Planning of product realization

8.3   Customer-related processes

8.3.1 Determination of req. related to the product

8.3.2 Review of req. related to the product

8.3.3 Customer communication

8. Operation

8.4 Design and development

8.4.1 Design and development planning

8.4.2 Design and development inputs

8.4.3 Design and development outputs

8.4.4 Design and development review

8.4.5 Design and development verification

8.4.6 Design and development validation

8.4.7 Control of design and development changes

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8. Operation

8.5 Purchasing

8.5.1 Purchasing process

8.5.2 Purchasing information

8.5.3 Verification of purchased product

8.6   Production and service provision

8.6.1 Control of production and service provision

8.6.2 Validation of processes for production and service provision

8.6.3 Identification and traceability

8.6.4 Customer property

8.6.5 Preservation of product

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9. Performance Evaluation

9.1 Monitoring, meas., analysis and evaluation

9.1.1 Customer satisfaction

9.1.2 Monitoring and measurement of processes

9.1.3 Monitoring and measurement of product

9.1.4 Control of monitoring and measuring equip.

9.2 Internal Audit

9.3 Management review

10. Improvement

10.1 Nonconformity and corrective action

10.2 Continual improvement

10.2.1 Analysis of data

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Major Changes

4. Context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcome(s) of its quality management system.

4.2 Understanding the needs and expectations of interested parties

The organization shall determine the:

- Interested parties that are relevant to the quality management system, and
- Requirements of these interested parties.

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4.3 Determining the scope of the QMS

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider
- The external and internal issues referred to in 4.1, and
- The requirements referred to in 4.2.

The scope shall be available as documented information

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5. Leadership

5.1 Leadership and commitment

Top mgmt. shall demonstrate leadership and commitment with respect to the quality management system by:

a) Ensuring that policies and objectives are established for the quality management system and are compatible with the strategic direction of the organization,

b) Ensuring the integration of the quality management system requirements into the organization's business processes,

c) Ensuring that the resources needed for the quality management system are available,

d) Communicating the importance of effective quality management and of conforming to the quality management system requirements,

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5. Leadership

5.1 Leadership and commitment (Continued)

Top mgmt. shall demonstrate leadership and commitment with respect to the quality management system by:

e) Ensuring that the quality management system achieves its intended outcome(s),

f) Directing and supporting persons to contribute to the effectiveness of the quality management system,

g) Ensuring that customer requirements are determined and are met with the aim of enhancing customer satisfaction,

h) Promoting continual improvement, and

i) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

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6. Planning
6.1 Actions to address risks and opportunities

When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to

- Assure the quality management system can achieve its intended outcome(s),
- Prevent, or reduce, undesired effects, and
- Achieve continual improvement.

The organization shall plan:

1. Actions to address these risks and opportunities, and
2. How to integrate and implement the actions into its quality management system processes and evaluate the effectiveness of these actions.

6.2 Quality objectives & planning to achieve them
The organization shall establish quality objectives at relevant functions/levels. Quality objectives shall,

- Be consistent with the quality policy,
- Be measurable (if practicable),
- Take into account applicable requirements,
- Be monitored,
- Be communicated, and
- Be updated as appropriate.

The org. shall retain documented information on the quality objectives.

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6.2 Quality objectives & planning to achieve them
When planning how to achieve its quality objectives, the organization shall determine:
- What will be done,
- What resources will be required,
- Who will be responsible,
- When it will be completed, and
- How the results will be evaluated.

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7. Support

7.3 Awareness

Persons doing work under the organization's control shall be aware of:

- The quality policy,
- Their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance, and
- The implications of not conforming with the quality management system requirements.

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7. Support

7.4 Communication

The organization shall determine the need for internal and external communications relevant to the quality management system including:

a) On what it will communicate,

b) When to communicate, and

c) With whom to communicate.

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8. Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes needed to meet requirements, and to implement the actions determined in 6.1, by:

a) Establishing criteria for the processes

b) Implementing control of the processes in accordance with the criteria

c) Keeping documented information to the extent necessary to have confidence that the processes have been carried out as planned.

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8. Operation

8.1 Operational planning and control

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

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Major Changes

9. Performance Evaluation

9.1 Monitoring, meas., analysis & evaluation

The organization shall determine

a. What needs to be monitored and measured,

b. The methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results,

c. When the monitoring and measuring shall be performed,

d. When the results from monitoring and measurement shall be analyzed and evaluated.

9. Performance Evaluation

9.1 Monitoring, meas., analysis & evaluation

The organization shall retain appropriate documented information as evidence of the results.

The organization shall evaluate the quality performance and the effectiveness of the quality management system.

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10. Improvement

10.1 Nonconformity and corrective action

When a nonconformity occurs, the organization shall:

a)   React to the nonconformity, and as applicable take action to control and correct it, and

b)   Deal with the consequences.

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ISO 9001: 2015

10. Improvement

10.1 Nonconformity and corrective action

Evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere, by

- Reviewing the nonconformity
- Determining the causes of the nonconformity,
- Determining if similar nonconformities exist, or could potentially occur,
- Implement any action needed,
- Review the effectiveness of any action taken,
- Make changes to the quality management system, if necessary.

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10. Improvement

10.1 Nonconformity and corrective action

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

The organization shall retain documented information as evidence of:

- The nature of the nonconformities and any subsequent actions taken, and
- The results of any corrective action.

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A Shift To Risk Based Thinking

How The ISO 9001:2015 Addresses Risk.

WHAT IS "RISK BASED THINKING?"

- Risk-based thinking is something we all do automatically and often sub-consciously,
- The concept of risk has always been implicit in ISO 9001. However, this revision makes it more explicit and builds it into the whole MS,
- Risk-based thinking is already part of the process approach,
- Risk-based thinking makes preventive action part of the routine, and
- Risk is often thought of only in the negative sense. Risk- based thinking can also help to identify opportunities. This can be considered to be the positive side of risk.

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MAIN OBJECTIVE OF RISK IN 9001

- To provide confidence in the organization's ability to consistently provide customers with conforming goods and services.

- To enhance customer satisfaction.

The concept of "risk" in the context of ISO 9001 relates to the uncertainty in achieving these objectives.

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RISK IN CLAUSES
APPROACH, LEADERSHIP, PLANNING

ISO 9001: 2015

- **Clause 4 -** the organization is required to determine the risks which can affect its ability to meet objectives

- **Clause 5 -** top management is required to commit to ensuring Clause 4 is followed

- **Clause 6 -** the organization is required to take action to address risks and opportunities

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RISK IN CLAUSES
OPERATION-EVALUATION-IMPROVEMENT

- **Clause 8 -** the organization is required to have processes which identify and address risk in its operations

- **Clause 9 -** the organization is required to monitor, measure, analyse and evaluate the risks and opportunities

- **Clause 10 -** the organization is required to improve by responding to changes in risk

WHY ADOPT "RISK BASED" THINKING?

- To improve customer confidence and satisfaction

- To assure consistency of quality of goods and services

- To establish a proactive culture of prevention and improvement

- Successful companies intuitively take a risk-based approach

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WHAT SHOULD I DO?

Use a risk-driven approach in your organizational processes
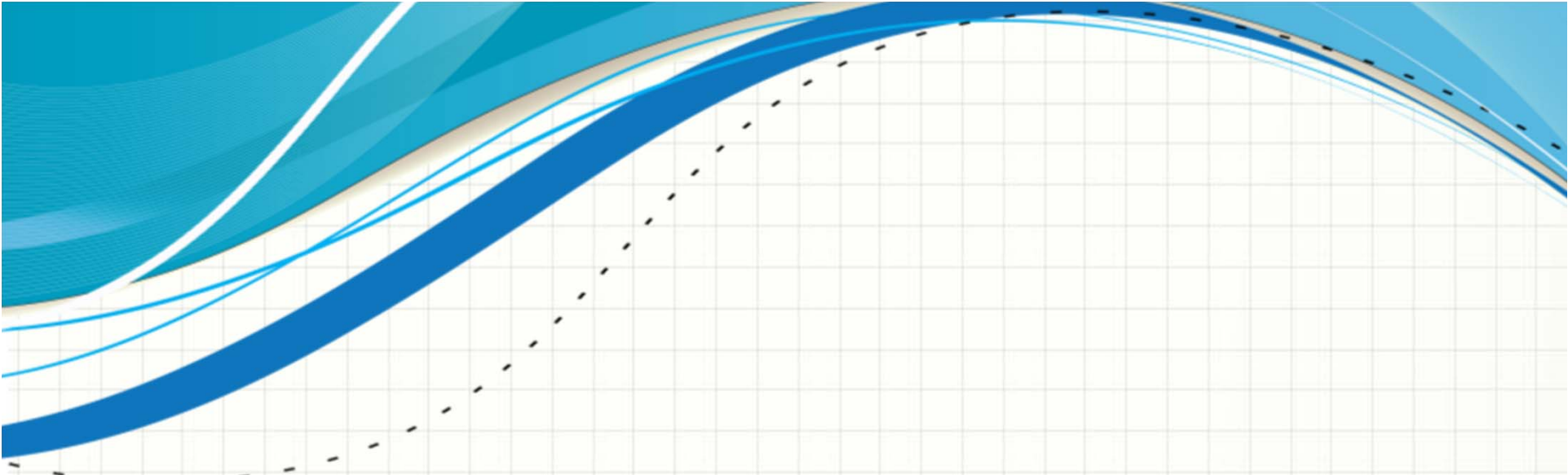
Identify what the risks and opportunities are in your organization – it depends on context

ISO 9001:2015 will not automatically require you to carry out a full, formal risk assessment, or to maintain a "risk register"

ISO 31000 ("Risk management — Principles and guidelines") will be a useful reference (but not mandated)

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WHAT SHOULD I DO?

- **Analyze and prioritize the risks and opportunities in your organization**
  - —*what is acceptable?*
  - —*what is unacceptable?*
- **Plan actions to address the risks**
  - —*how can I avoid or eliminate the risk?*
  - —*how can I mitigate the risk?*
- **Implement the plan – *take action***
- **Check the effectiveness of the actions – *does it work?***
- **Learn from experience – *continual improvement***

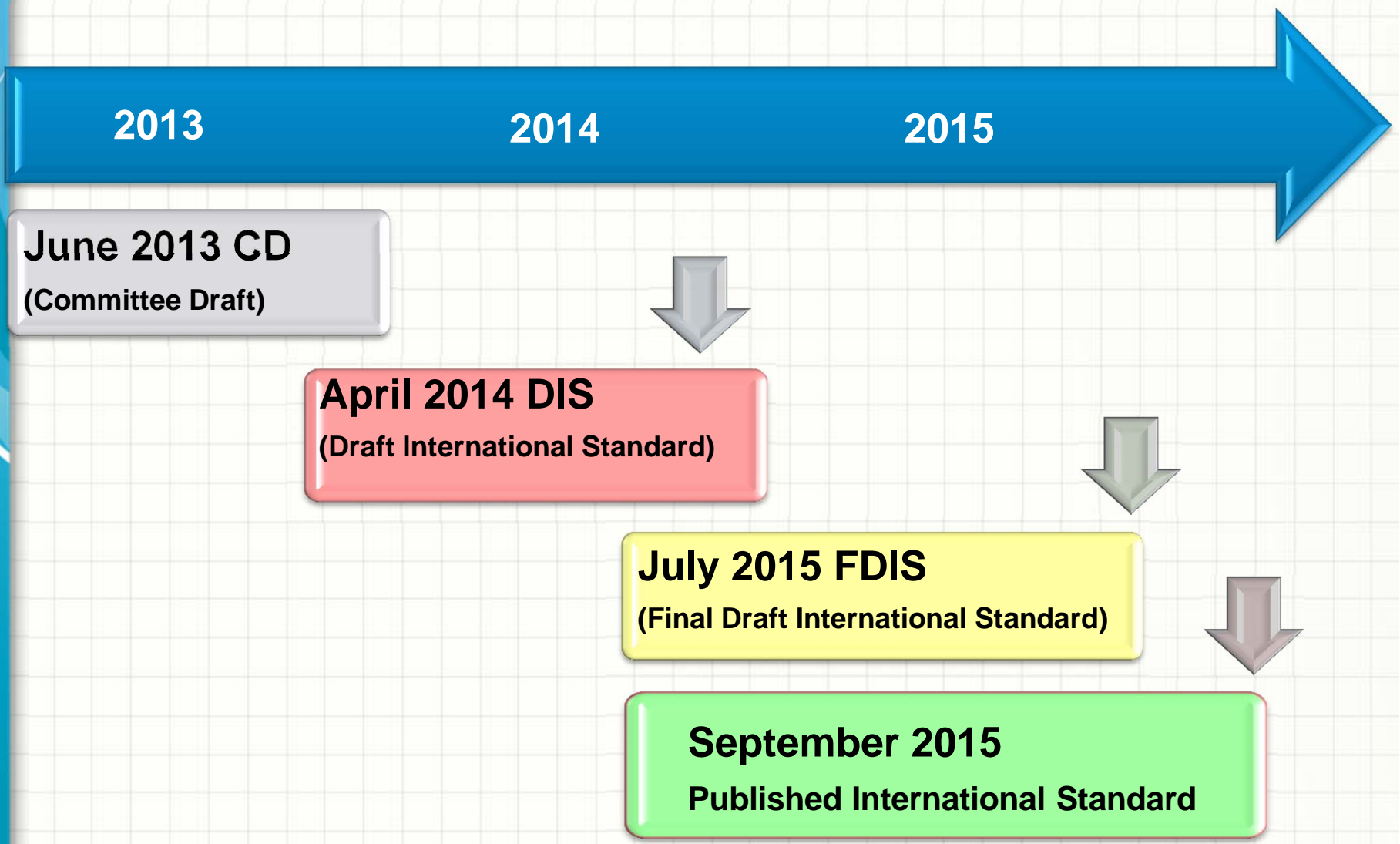ISO 9001: 2015

Summary
& Timeline

SUMMARY OF CHANGES

- Extensive Renumbering,

- New requirements added, some deleted,

- New emphasis on risk-based thinking,

- Increased emphasis on achieving value for all interested parties,

- Increase flexibility on the use of documentation,

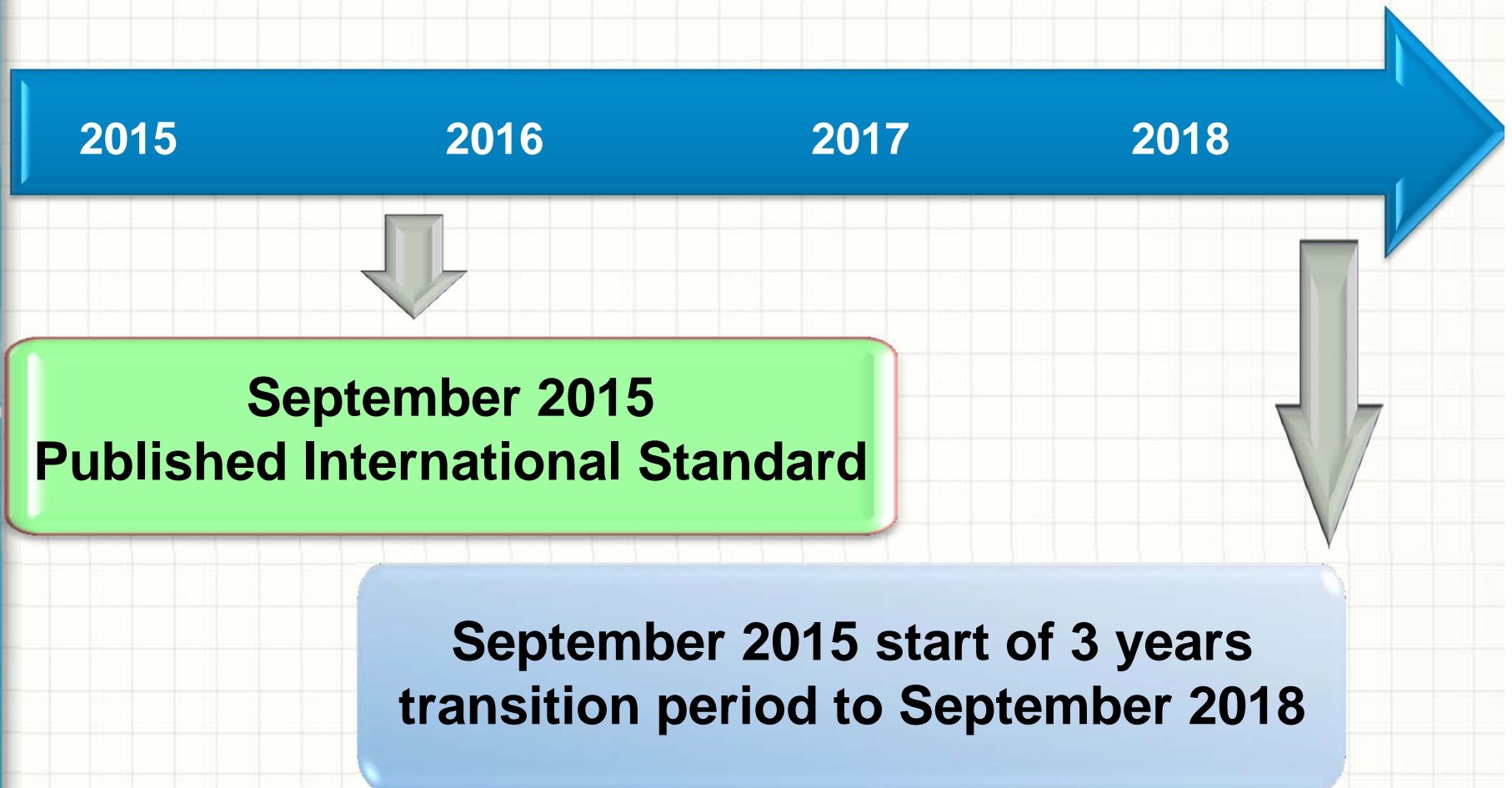- More readily applicable by "service" type org.
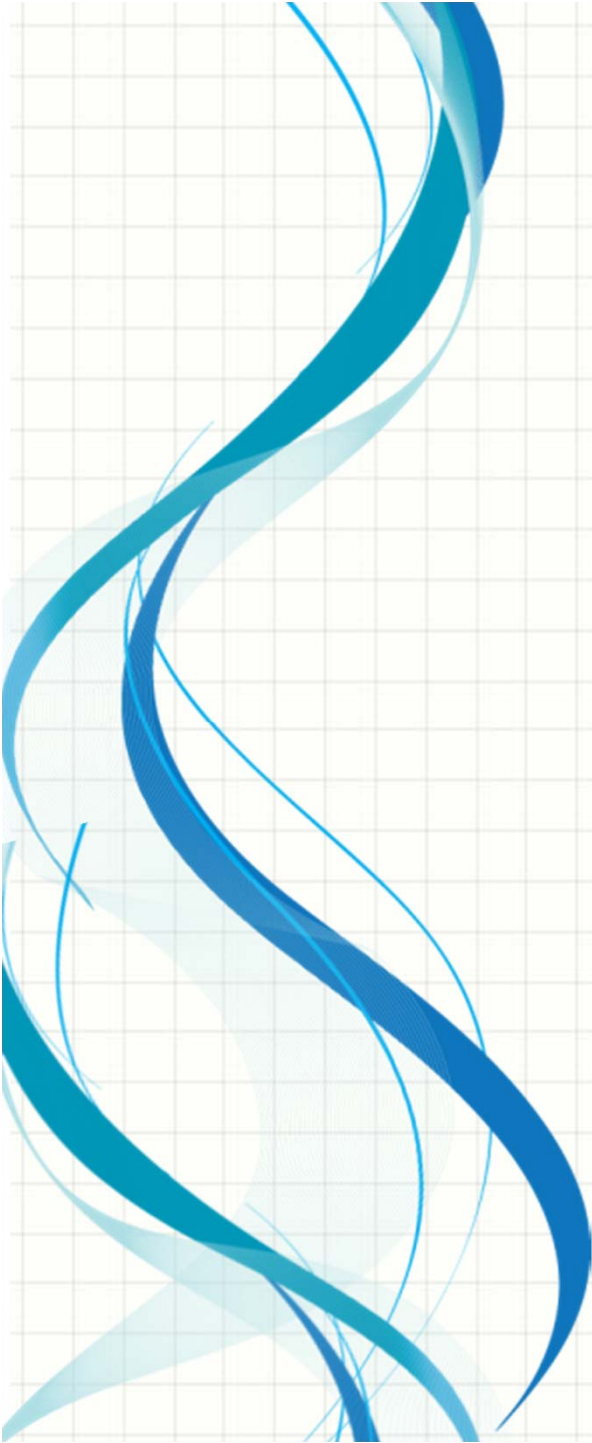
**Customers Remain
The Primary Focus**

ISO 9001:2015 Timeline

ISO 9001: 2015

2013   2014   2015

June 2013 CD
(Committee Draft)

April 2014 DIS
(Draft International Standard)

July 2015 FDIS
(Final Draft International Standard)

September 2015
Published International Standard

What Should I Do?

ENSURE YOUR ORGANIZATION....

- Waits until the DIS version is issued,

- Is aware of the new direction and key changes,

- Fully understands the key concepts,

- Plans to implement the new requirements within the transition period (3 years),

- Continues to stay informed as the revision proceeds forward, and

- Capitalizes on the new revision of ISO 9001.

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INDUSTRY IMPACTS

- Automotive Industry (TS16949)?

- Aerospace Industry (AS 9100)?

- Medical Device Industry (FDA ISO 13485)?

- American Petroleum Industry (API)?

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EXPECT….

- The revision of ISO 9001 will impact on other related standards and documents.

- Expect changes to:

    - industry-specific standards

    - supporting documents

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QUESTIONS?

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