

Regulatory Approaches for Vendor Inspections

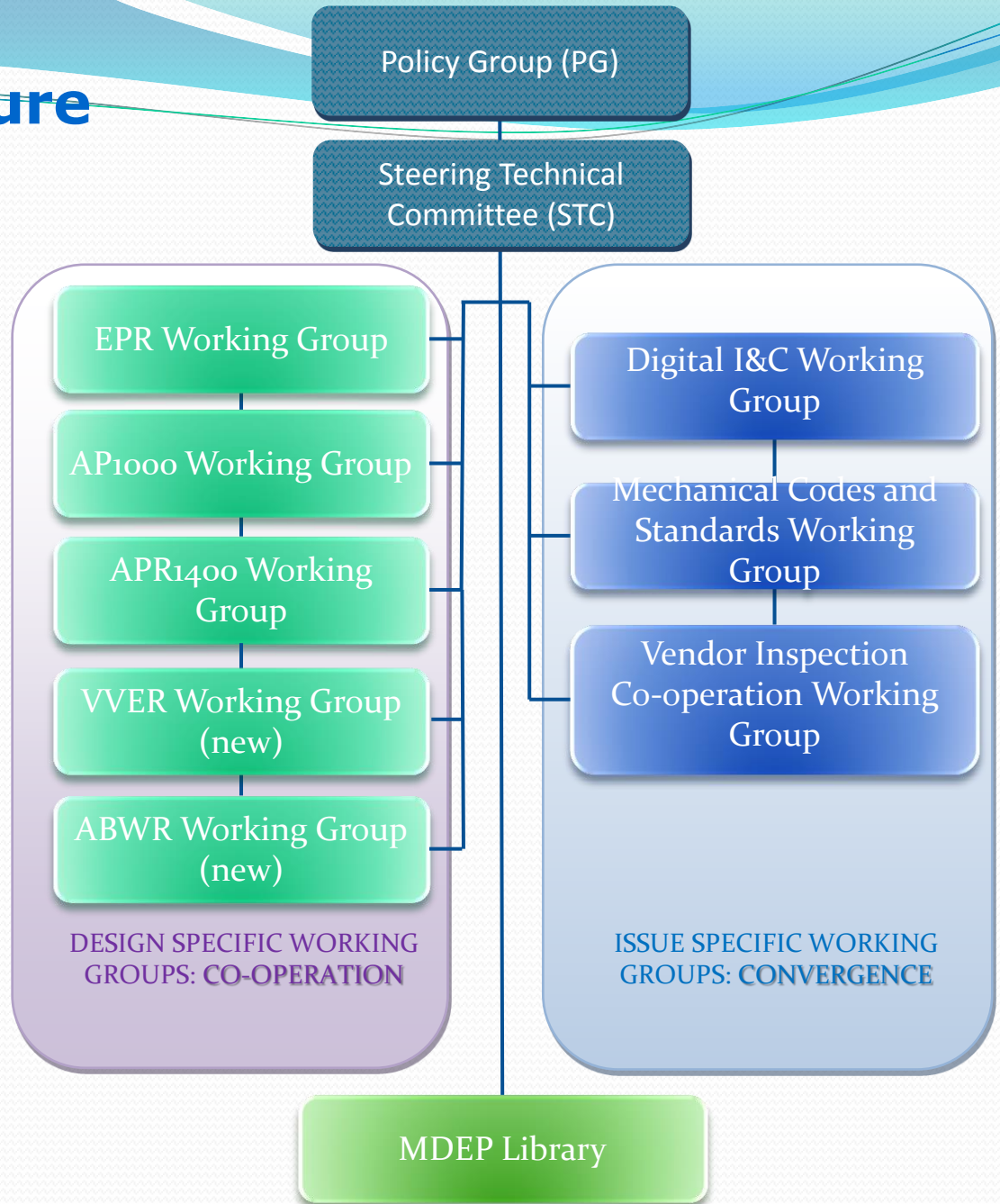
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MDEP Structure

- Canada
- Finland
- France
- Japan
- India
- The Peoples Republic of China
- The Republic of Korea
- Russian Federation
- South Africa
- Sweden
- The United Kingdom
- The United States

Associate Members

- Turkey
- The United Arab Emirates



VICWG Objectives

- To maximize the use of the results obtained from other regulator's efforts in inspecting vendors
- To understand the similarities and differences between MDEP national regulators' Quality Assurance/Management (QA/QM) Requirements in order to reach a consensus on the potential for harmonization
- To facilitate the adoption of good vendor oversight practices by national regulators
- To harmonize the vendor inspection practices among MDEP regulators for inspections under the MDEP protocol
- To continue joint, witnessed, multinational inspections of vendors according to the common QA/QM requirements

MDEP Member Regulatory Approaches

- Status of Vendors
 - Licensed
 - Not Licensed
 - Qualified by Regulator
- Regulator Oversight
 - Direct Oversight of Vendors
 - Oversight of Licensee Oversight
 - Use of Inspection Bodies
 - Use of Hold Points
- Quality Requirements
 - Prescriptive
 - Non-Prescriptive

Common QA Criteria

- 1. Quality management system
- 2. Grading
- 3. Documentation of the quality management system
- 4. Control of documents and records
- 5. Responsibility and Leadership
- 6. Human resources
- 7. Process Implementation
- 8. Control of planning and implementation changes
- 9. Purchasing (including aspects of CSFI)
- 10. Control of implementation including Control of special processes
- 11. Monitoring and measurement of product and service
- 12. Assessment
- 13. Non-conformances
- 14. Corrective and preventive actions
- 15. Safety culture

MDEP Inspection Types

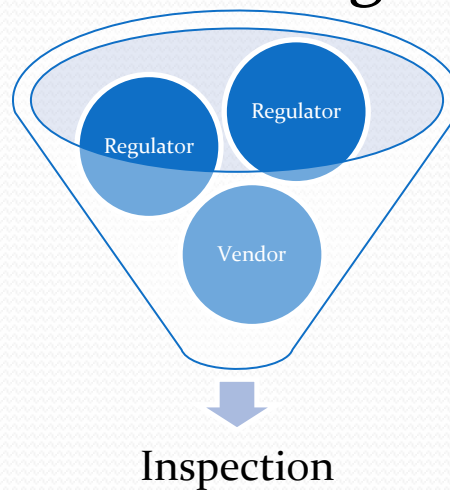
- **Witnessed inspection** – an activity in which a regulator conducts an inspection according to its own regulatory framework and one or more regulators witness it.
- **Joint inspection** – an activity in which one regulator conducts an inspection according to its own regulatory framework with the participation of one or more other regulators' inspectors.
- **Multinational Inspection** - an inspection performed by multiple regulators to the VICWG Common QA Requirements.

Benefits of MDEP Participation

- Regulators
 - Greater Ability Understand the Results of Foreign Inspections
 - The ability to Prioritize Inspections Based on Foreign Inspections
 - The Ability to Leverage Foreign Inspectors
 - Increased Communication Regarding Vendor Issues
- Vendors
 - Reduced Inspections Because Regulators are Sharing Results

Challenges

- Inspection Practices
- Relevance of vendors change as projects progress
- Coordination



- Access Restrictions
- Language Issues

Inspection Selection Considerations

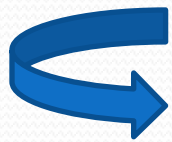
- Prior Inspection Experience
- NUPIC Results
- Scope of Supply
- Complexity of Product or Service
- Susceptibility to Counterfeiting or Cyber Security Issues
- Industry Experience with Product or Service
- New or Advanced Technology
- Oversight by Other Entities (ASME, Foreign Regulators)
- Significance to Pending Regulatory Actions

Inspection Focus Areas

- Focus on activities in progress:
 - product design
 - fabrication
 - testing
 - qualification
- Use of technical specialists
- Use risk as a guide

Take Away Points

- Identify countries sharing interests
- Understand regulatory differences
- Consider project schedules



Leverage Resources

