

MDEP Vendor Inspection Cooperation Working Group

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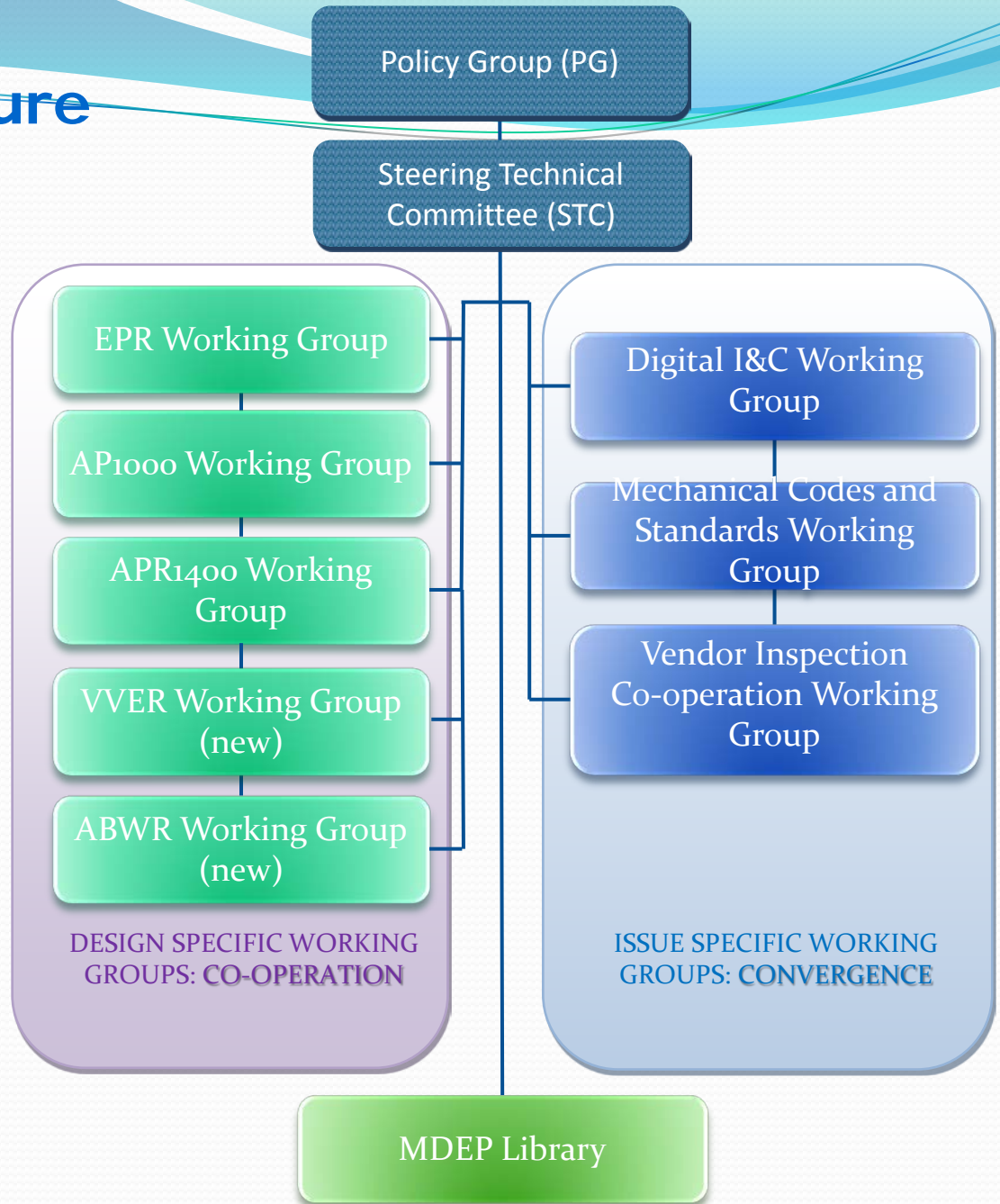
Working Group Overview

- Objectives
- Protocol Document
- Types of Engagement
- Logistical Issues
- VICWG Inspections
- Benefits

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 leverage inspection resources
- To understand Quality Assurance/Management (QA/QM) Requirements for MDEP countries
- To facilitate good practices
- To harmonize the vendor inspection practices
- To continue joint and witnessed inspections and perform multinational inspections

MDEP Protocol

VICWG-01

Purpose and Scope

- The purpose of this protocol is to provide guidance to regulators that wish to carry out vendor inspections or participate in or witness other regulators' vendor inspections or to conduct multinational inspections. It also provides guidance for the sponsoring regulator with regard to its interactions with inspecting, witnessing or participating regulators.

Current Inspection Types

- **Witnessed inspection** – an activity in which a regulator conducts an inspection according to its own regulatory framework and one or more regulators witnesses 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
- Requires leadership by one country and technical support from participating inspectors
- Pilot – Valinox Nucléaire, July 2014

Key Logistical Issues

- Inspection table maintained on the MDEP website
- Sponsoring Regulator determines language
- Records governed by Sponsoring Regulator
- Witnessing regulators provide feedback to MDEP library

VICWG Inspections

- 2011 - 7 witnessed inspections and 1 joint inspection
- 2012 - 7 witnessed inspections and 1 joint inspection
- 2013 - 12 witnessed inspections and 1 joint inspection

Benefits

- 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

VICWG members

Regulatory authorities of:

Full members:



Canada



China



Finland



France



India



Japan



Republic of Korea



Russian Federation



South Africa



Sweden



United Kingdom



United States

Associate members:



Turkey



United Arab Emirates

**THANK YOU FOR
YOUR ATTENTION!
Question?**