

MDEP Vendor Inspection Cooperation Working Group

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Working Group Overview

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

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 and witnessed inspections and perform multinational inspections of vendors according to the common QA/QM requirements

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
- May require training or familiarization
- 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



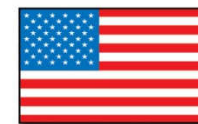
South Africa



Sweden



United Kingdom



United States

Associate members:



Turkey



United Arab Emirates

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