

MDEP

Common Position

CP-VICWG-03

Related to: Vendor Inspection Cooperation Working Group activities

Common Position:

Preparation and Performance of Vendor Inspections

Participation

Regulators involved in the MDEP working group discussions:	ASN, CNSC, KINS, ONR, NNSA, NNR, NRA, NRC, STUK, VOSAF.
Regulators which support the present Common Position	All
Regulators with no objection:	N/A
Regulators which disagree:	N/A
Compatible with existing IAEA related documents:	Yes

This Common Position replaces the previous Technical Report (TR-VICWG-05) on Vendor Inspection Good Practices

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Vendor Inspection Cooperation Working Group

Common Position on

Preparation and Performance of Vendor Inspections

I – INTRODUCTION

The aim of this document is to list commendable practices in the preparation and performance of vendor inspections and in addressing any findings.

According to the International Standard ISO 17020:2012-03 [Ref. 1], the term “item” is used below to encompass product, process, service or installation, as appropriate.

II - PREPARATION PHASE

Effective preparation is key to a successful inspection.

1. Planning

- a. When planning for inspections be mindful of inspector availability and work load to allow appropriate preparation and review of documentation in advance.
- b. Plan the inspection date as early as practicable to enable a comprehensive preparation phase with team members.
- c. Consider if the inspection should be timed to align with specific high risk vendor activities

2. Team composition and inspection assignments:

- a. Identify the team leader
- b. Identify the team members including necessary technical expert(s)
- c. Define the team members assignments

3. Inspection scope, regulations and guidance

- a. Precisely define items to be inspected
- b. Identify the applicable regulatory requirements
- c. Identify and request vendor documents to be used for preparation
- d. Gather relevant information from previous inspections related to the same vendor/same scope

- e. Consider the inspection of high risk issues that are outside the scope of the MDEP common QA/QM criteria [Ref. 2] if considered relevant to the vendor, for example CFSI (Counterfeit, Fraudulent and Suspect Items) mitigation methods. However, any findings would have to be referenced against relevant inspection scope, host country regulation, regulator or client requirements or raised as an inspection team observation.

4. Inspection plan/Agenda

- a. Evaluate the duration of inspection time for each item
- b. Document the list of queries to raise during the inspection in a dedicated template to facilitate the recording of data
- c. Prepare a document reference table as a dedicated template to identify those documents reviewed during the inspection
- d. Prepare a dedicated template to record the names and roles of personnel interviewed during the inspection.

5. Announcement

- a. Inform the vendor of the date, time and scope of the planned inspection
- b. Consider the need for a reasonable advance notice

6. Practical and logistical aspects

These aspects should be anticipated sufficiently in advance so inspectors can focus on the inspection on arrival:

- a. Ensure transportation and accommodations are in place.
- b. Identify or reserve parking
- c. Ensure Inspectors will have access to the site/workshop/premises
- d. Organise and require team meetings: who? when? where?
- e. Ask for team members contact details (mobile phone)
- f. Ask for vendor contact details (name, position, telephone)
- g. Obtain required personal protective equipment
- h. Obtain required measurement devices as necessary
- i. Print and bring inspection documents (see below)

III - PERFORMING THE INSPECTION

1. Site entrance

The Team Leader should introduce himself to the identified organisation or site contact

2. Opening Meeting

- a. Thank the vendor staff for receiving the inspection team

- b. Introduce each inspection team member and identify the scope of their review
- c. Request introduction, if necessary, from the vendor representatives
- d. Explain the scope and objectives of the inspection
- e. Identify any specifics:
 - i. Manufacturing operations to be witnessed
 - ii. Documents to be prepared/provided
 - iii. Personnel to be interviewed
- f. Get Agreement on the inspection schedule with regards to:
 - i. Any operations to be witnessed
 - ii. Any personnel to be interviewed
 - iii. Duration of any breaks
 - iv. End of inspection meeting
 - v. Closure of the inspection

3. Handling inspection items and records

- a. Identify and record the items inspected
- b. Record the name and role of each personnel interviewed
- c. Record the references of each document reviewed
- d. Ask the vendor for copies of documents reviewed when necessary
- e. Ask the vendor to provide measurements when necessary and to check the calibration of measurement device
- f. Pay particular attention to the agreed upon schedule to ensure the inspection scope and objectives are met
- g. For each topic and prior to progressing to the next item to be inspected, summarise the findings and the conformity status of the item inspected
- h. Allow time for development of issues and re-evaluation of scope based on risk as necessary

4. Feedback meetings

- a. Consider conducting end-of-the-day meetings to discuss:
 - i. Any potential inspection findings
 - ii. Status of open requests
 - iii. Plans for the next day
- b. Before the end of inspection, team members to meet in a private room to:
 - i. Review the data recorded
 - ii. Discuss the conformity assessment of each item inspected
 - iii. Identify the findings

- c. Before closing the inspection, the Lead Inspector should ensure that participants :
 - i. Present the good points identified during the inspection
 - ii. List the deviations identified during the inspection
 - iii. Raise findings and observations ordered by importance
 - iv. Be sensitive or avoid naming personnel involved in any identified deviations as it can induce direct human consequences on the vendor staff
 - v. Deliver a written outline of the noteworthy deviations identified during the inspection

IV - DELIVERABLES AND FINDING RESOLUTION

1. Inspection report

- a. Consider a peer review of inspection results and findings prior to finalizing the inspection report
- b. Record information that supports the findings and observations in order to ensure appropriate evidence is maintained to substantiate the inspector's report
- c. Complete the inspection report as soon as practicable following the inspection

2. Finding letter

- a. Send a formal letter to the vendor listing the findings and requesting corrective actions
- b. Send the letter as soon as practicable following the inspection

3. Resolution

- a. Ensure recording/archiving of the vendor's answers to the inspectors team requests
- b. Inform the vendor that the inspection process is closed once its answers have been accepted by the inspectors team

V – REFERENCE

1. International Standard ISO 17020:2012-03:
https://webstore.iec.ch/preview/info_isoiec17020%7Bed2.0%7Den.pdf
2. Multinational Design Evaluation Program, "Technical Report: Common QA/QM criteria for the multinational vendor inspection" TR-VICWG-03, 30 January 2014 OECD Nuclear Energy Agency, Paris, France.