

# **MDEP Protocol**

## **VICWG-01**

Related to: Vendor Inspection Cooperation Working Group activities

**MDEP Protocol:**  
**Witnessed, Joint, and Multinational**  
**Vendor Inspection Protocol**

***Multi-National Design Evaluation Programme  
Vendor Inspection Cooperation Working Group***

**1) Background**

The Multinational Design Evaluation Programme (MDEP) was launched in 2006 by the US Nuclear Regulatory Commission (NRC) and the French Nuclear Safety Authority (ASN) with the aim of developing innovative approaches to leverage the resources and knowledge of national regulatory authorities reviewing new reactor designs. MDEP full members are regulators from Canada, People's Republic of China, Finland, France, India, Japan, Republic of Korea, Russian Federation, South Africa, Sweden, the United Kingdom and the United States of America. The United Arab Emirates and Turkey are associate members. The OECD Nuclear Energy Agency (NEA) acts as the Technical Secretariat for the MDEP. The International Atomic Energy Agency (IAEA) participates in many of the MDEP activities, including harmonisation efforts.

The Vendor Inspection Cooperation Working Group (VICWG) is one of the issue-specific working groups that the MDEP members are undertaking with one long term goal of the VICWG being to maximize the use of the results obtained from other regulator's efforts in inspecting vendors. To accomplish this goal, it is vital that the regulators learn about each other's procedures, processes, and regulations. To facilitate the learning process the VICWG is coordinating vendor inspections among the involved regulatory authorities with the purpose of enhancing the understanding of each other's vendor inspection procedures. This programme is administered by the NEA. Involvement in specific inspections provides a number of opportunities for member state regulators to witness other regulators' inspection methods, gain useful information on the quality systems and manufacturing arrangements of specific vendors and where appropriate, actively participate in the inspection.

Throughout this document, for brevity, member states' national nuclear safety regulators are referred to as regulators.

**2) 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. It also provides guidance for the sponsoring regulator with regard to its interactions with inspecting, witnessing or participating regulators.

**3) Policy**

These arrangements provide regulators with guidance on how to witness or participate in vendor inspections that have been arranged by the sponsoring regulator.

**4) Definitions**

The following definitions apply to these arrangements and are intended to provide clarity of understanding.

- 4.1 Host regulator- the regulatory body located in the country in which the inspection is taking place regardless of whether or not it is actually conducting the inspection.

- 4.2 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.
- 4.3 Multinational Inspection – an inspection carried out by two or more regulators based on the MDEP Common QA requirements.
- 4.4 Parallel Inspections – inspections that are carried out at the same time on the same vendor by two or more regulators in accordance with their own inspection framework and procedures.
- 4.5 Participate – to act as an inspection team member in line with the inspection procedures, or agreed alternatives, of the sponsoring nuclear regulator.
- 4.6 Sponsoring regulator – the regulatory body that recognises the need for the inspection and formalises this as part of its inspection programme.
- 4.7 Training – the aspect of familiarisation with and understanding of the specific aspects of the sponsoring regulators’ standards, requirements and systems of working to enable effective witnessing or joint participation in the inspection.
- 4.8 Witness – to observe how the inspection is conducted, to take notes, to attend opening, interim and closing meetings but not to take part in, or directly influence the outcome of the inspection.
- 4.9 Witnessed inspection – an activity in which a regulator conducts an inspection according to its own regulatory framework and one or more regulators witnesses it.

## **5) Procedure**

- 5.1 The sponsoring regulator will ascertain from the VICWG integrated inspection schedule the level of interest in witnessing or participating in a specific planned inspection. If there is significant interest the sponsoring regulator will decide, based on need, who will attend and, where necessary, in what capacity. The effectiveness of the inspection should not be compromised by the desire or attempt to involve all the regulatory organisations that have registered an interest.
- 5.2 Organisations invited to witness should be guided by paragraphs 5.8 to 5.12 of this procedure, whilst those participating in joint inspections should be guided by paragraphs 5.13 to 5.20. The sponsoring regulator should inform those selected to witness or participate of the confirmed dates, location and schedule of the inspection together with the name and contact details of the inspection team leader. Due to the timescales of arranging travel and accommodation (especially international) the sponsoring regulator should inform the interested parties as early as possible of their involvement so that arrangements can be made. Unless otherwise agreed with the sponsoring regulator, interested parties should make their own travel and accommodation arrangements.
- 5.3 All due consideration should be given to the need of informing the host regulator (even if a non-MDEP regulator) of the planned inspection, consistent with the sponsoring regulator’s established framework. There may be instances in which it may not be possible to inform the host regulatory body in a timely manner but the sponsoring regulator should keep in mind that informing the host regulatory body may facilitate conduct of the inspection.

- 5.4 Prior to any firm arrangements being made the sponsoring regulator will inform the vendor of the proposed involvement of the interested parties and, where necessary obtain permission for their presence. Where agreement is not given the sponsoring regulator will inform the interested party(ies) and, where provided by the vendor, will explain the reason for the decision.
- 5.5 The sponsoring regulator will determine in its normal consultations with the vendor the language in which the inspection will be conducted. In general it is expected that the language will be either the language spoken by the sponsoring regulator and/or the language spoken by the vendor being inspected. In any case, the sponsoring regulator, in accordance with its normal procedures, will determine the translation resources that it needs to conduct its inspection. The sponsoring regulator will inform other invited regulatory bodies of the arrangements that it has made with regard to the language of the inspection and any translation services. Any other regulatory bodies that need additional translation sources should discuss this with the sponsoring regulator and should NOT pose any unnecessary burden on the vendor.
- 5.6 Care should be taken not to release any sensitive or proprietary information.
- 5.7 The participating countries may use the information gained during the inspection to increase their knowledge of the vendor to inform future inspection activities.

### **Witnessed Inspections**

- 5.8 For those witnessing the inspection, they should take their own notes and, as appropriate, attend opening, interim and closing meetings and, receive a copy of the final report. They, however, should not take part in, or directly influence the outcome of the inspection. The control, storage and disposal of notes should be as specified by the sponsoring regulator.
- 5.9 Witnessing inspectors, using discretion, may ask questions of the vendor to aid their understanding and can discuss issues with the inspection team at planned meetings. Additional involvement by witnessing inspectors can be agreed at the time of the inspection with the agreement of all parties.
- 5.10 In addition to gaining information about the vendor's organisation and procedures the witnessing inspector should also take note of the sponsoring regulator's inspection processes, with the intention of comparing/sharing inspection practices.
- 5.11 Following the inspection, witnessing inspectors should prepare a record of their involvement (one per regulatory body) and send copies to the sponsoring regulator and the NEA MDEP library. Information relating to inspection processes is of particular interest. Care must be taken not to include in the report information that may be commercially sensitive with respect to the vendor's organisation.
- 5.12 An acknowledgement of the presence of the witnessing inspectors will be made in the sponsoring regulator's inspection report.

### **Joint Inspections**

- 5.13 The sponsoring regulator will inform the vendor of the participation of other regulators and explain

to the vendor the latter's role, inspection scope and the benefits of participation. Should the vendor object to the involvement of a particular regulator(s) the sponsoring regulator will inform the interested party(ies) accordingly.

- 5.14 Regulators participating in inspections should follow the sponsoring regulator's inspection methodology. These arrangements will necessitate prior discussions and planning sessions between the sponsoring regulator and the other participating regulators. The sponsoring regulator will supply the other participating regulators with its inspection arrangements appropriate to the nature and scope of the inspection in sufficient time to allow those involved to study the arrangements.
- 5.15 The inspection programme, duration and scope will be developed by the sponsoring regulator and shared with the other participants accordingly. The sponsoring regulator will indicate the control, storage and disposal requirements for these documents.
- 5.16 Unless otherwise agreed the sponsoring regulator's inspection team leader will manage the team and act as spokesperson for the team.
- 5.17 The participating regulators will carry out their inspection duties in a manner consistent with that of the personnel of the sponsoring regulator. All findings identified by the participating regulator will be agreed by the sponsoring regulator's team leader.
- 5.18 Participating regulators will prepare a record of their involvement in the inspection and forward contributions for the inspection report to the sponsoring regulator's team leader. Participating regulators may be asked to comment on the draft report and will receive a copy of the final inspection report.
- 5.19 The responsibility for subsequent monitoring of the closeout of corrective actions placed on the vendor will rest with the sponsoring regulator. The sponsoring regulator may inform the participating regulators periodically of its monitoring of the vendor's progress to close out the corrective actions.
- 5.20 Participating inspectors should comply with the policies and guidelines of the sponsoring regulatory authority with respect to interactions with the inspected vendor.
- 5.21 Joint inspections may be witnessed by other MDEP VICWG regulators as this would be a very good opportunity for some of the regulators to observe the conduct of a joint inspection.

#### Multinational Inspections

- 5.22 Multinational inspections involve two or more regulators conducting an inspection of a vendor based on the MDEP common QA requirements.
- 5.23 Multinational inspections are a tool to gain vendor performance insights with minimal inspection resources from the participating regulators. Multinational inspections are not intended to be a comprehensive country specific inspection. Multinational inspections should not be considered if a participant's regulatory structure requires strict adherence to a defined country specific inspection

protocol.

- 5.24 One of the regulators will take the lead in organizing the inspection. The lead will make sure the essential pre activities are performed. Based on input from the participating countries the team will prepare an inspection plan based on the scope of supply and the MDEP common QA requirements. The team will also contact the vendor, obtain and distribute pre inspection information and provide logistical information.
- 5.25 During the inspection the participating inspectors will conduct the inspection as outlined in the inspection plan. Inspectors will implement the common QA requirements based on their individual training and practices. Participation by licensees or other non-regulator individuals should be discussed in advance to make sure their activities do not adversely impact the team.
- 5.26 The inspection team leader will coordinate the inspection report and inspection findings. The team leader should prepare one inspection report to describe the scope of the inspection, the observations and findings, the conclusions, and compliance issues. The inspection report will consolidate the input from each of the inspection participants.
- 5.27 Inspection compliance issues should be addressed by the regulator identifying the issue or by an agreed upon regulator if multiple countries share the specific regulatory requirement. Issues should be documented as stand-alone attachments to the report that will be issued by the individual regulator to the vendor. Follow-up to these issues will be conducted by the issuing regulator. Inspection reports and the associated records for compliance issues will be provided to the MDEP library as described in section 6.

### **Training**

- 5.28 The extent of required training, or familiarisation of persons witnessing or participating in joint inspections, should be considered on a case by case basis following appropriate discussions between the sponsoring regulator and the persons witnessing or participating jointly. In all cases, the sponsoring regulator shall make the final decision on the level of training required.
- 5.29 The specific requirements of this protocol and any information confidentiality requirements should be included as part of the training given.

### **6) Records**

The sponsoring regulator will ensure that the formal records of the inspection are retained in accordance with the sponsoring regulator's requirements. It is encouraged that the sponsoring regulator provides the inspection report to the MDEP technical secretariat staff for inclusion in the MDEP library. Those regulators observing or participating will retain whatever records they require as part of their arrangements. It is anticipated that the following will be included in the inspection record of the sponsoring regulator;

- 1) Inspection scope and programme.
- 2) Final inspection report.
- 3) Corrective Actions (proposals, correspondence, etc.) in the case of joint inspections. (NOTE :

Vendor's responses to the sponsoring regulator regarding corrective actions may be considered for inclusion in the NEA MDEP library but, based on the potentially sensitive nature of the documents, may not be appropriate for inclusion in the library. The sponsoring regulator will decide which documents should be placed in the NEA MDEP library.)

Regarding input and feedback from witnessing regulators, it is recommended that witnessing regulators document their observations of the witnessed inspection as a short report, and provide this for inclusion in the MDEP library. This report should have particular emphasis on the process of inspection as compared to that of the witnessing inspector's own organisation. This will assist in the identification of any significant differences in process and approach of the different regulators.