

**AD HOC GROUP OF THE STATES PARTIES  
TO THE CONVENTION ON THE PROHIBITION  
OF THE DEVELOPMENT, PRODUCTION AND  
STOCKPILING OF BACTERIOLOGICAL  
(BIOLOGICAL) AND TOXIN WEAPONS  
AND ON THEIR DESTRUCTION**

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**REPORT OF A NATIONAL TRIAL VISIT TO  
A VACCINE AND SERUM PRODUCTION FACILITY**

*Introduction and pre-visit activities*

1. In order to evaluate the procedures for random visit and to prepare for the effective implementation of the provisions of the Protocol under negotiation, a national trial visit was carried out at the Razi Vaccine and Serum Research Institute on 20 December 1998.
2. Prior to the visit, based on the Rolling Text under negotiation in the twelfth session of the Ad Hoc Group, a declaration format for vaccine production facilities was prepared and filled out by the facility.
3. Due to the characteristics of the facility, the assumed National Authority decided on the composition and expertise required for the visiting team. The visiting team consisted of four persons with the following professional backgrounds:
  - one microbiologist;
  - one pharmacologist;
  - one legal expert;
  - one general manufacturing practice engineer.
4. After designation of the visiting team, the declaration was circulated among the members of the team, to be reviewed before the visit.
5. Twenty-four hours before the visit, the notification of the visit, including the names of members of the team, were issued and forwarded to the facility. At the same time the mandate and notification were submitted to the team for its consideration and review. The mandate was to examine the accuracy of declaration provided by the facility.
6. Upon receiving the notification, the representatives of the assumed national authority met with representatives of the facility. In this meeting, the background of the visit, the mandate, the procedure, the role of the home team and visiting team, managed

access, and the facilities right to protect CPI and the composition of the home team were thoroughly discussed. The home team was composed of the same expertise as the visiting team plus one person as safety officer.

### *Conduct of the visit*

7. At the beginning of the day, the visiting team was transported by bus to the facility, where it was welcomed by the home team. Upon the arrival of the team, as a first step, equipment was inspected by the home team to ensure that the equipment was properly sealed, and confirmed that it was on the approved list of equipment. The team was guided to the meeting room and the briefing was started.
8. During the briefing, the general description of the activities of facility, its organization chart, complex layout and production processes were explained by the representative of the facility. The briefing lasted one hour and a half. During the briefing, a list of documents related to the activities of the facility, including its physical layout were requested by the visiting team.
9. The briefing was followed by questions and answers. Questions were asked by the visiting team in order to prepare the visit plan. Thereafter the leader of the visiting team presented the visit plan to the representative of the facility. According to the visit plan, the team was divided into two subgroups.
10. Following the agreement of the representative of the facility with the visit plan, the home team was also divided into two subgroups and the visit entered into the implementation phase. During the conduct of the visit, vaccine production lines, fermentation, QC Laboratories, BL-3 areas, and key equipment were visited.
11. In a limited number of cases, managed access techniques were practiced by the facility. For instance, the visiting team requested access to some parts of the facility where access was denied for the CPI reason, with the argument that these parts are unrelated to the visit mandate. But as an alternative, the home team made an effort to find other means of satisfying the visiting team to fulfil its mandate.
12. In order to evaluate the measure of auditing, the visiting team requested access to some documentation, which could be justified as being relevant. In some cases such requests were faced with resistance on the side of the facility. The discussions to reaching a conclusion proved to be time-consuming and unproductive.
13. During the visit, the safety and health officer of the facility was present to observe the safety regulations of the facility. In some cases the safety regulations were explained to the team and related equipments were granted to the team.

14. At the end of the visit, the two subgroups of the visiting team and home team joined together and reviewed the preliminary result of the visit and exchanged views. Thereafter a meeting was held in order to resolve the ambiguities and prepare the factual report. In this meeting the home team and representatives of the facility answered the questions raised by the visiting team. This meeting was found very useful to resolve the ambiguities. At the final stage, the preliminary factual findings report was issued which was signed by the leader of the visiting team and initialed by the representative of the home team.

#### *Conclusions and findings*

15. The random visit is considered to be a necessary measure within an effective compliance Protocol. The visiting team, with the cooperation of the visited State Party shall be able to validate the accuracy of the declarations without interruption of the normal work of the facility.
16. Proper recording and classification of the documents in the facility, would be a major factor to enable the visiting team to fulfil its mandate thoroughly within the time devoted to the visit.
17. While the maximum two working days would be sufficient for the visiting team to fulfil its mandate, for many facilities a one day visit seems to be enough.
18. The visit proved that a small visiting team consisting of four members with different expertise who can split into maximum of two subgroups is the sufficient requirement to evaluate the information provided in the declarations.
19. It is necessary to clarify some of the ambiguities of the random visit procedures, such as the section on the report.
20. Anticipating of a debriefing process after the visit seems necessary to resolve any ambiguity before preparation of the report.
21. Preparation of a unified format for draft report to register the factual findings seems necessary. Moreover the final report should be detailed, factual and should provide the necessary ground for objective and concrete conclusion, if necessary.
22. The exercise of the measure of auditing further revealed that auditing is an intrusive measure within the context of a random visit. It might provide some relevant information only if it is exercised in a cooperative manner and not as an obligation.

23. It was concluded that the familiarity of representatives of all declared facilities with the procedures as well as the objective and purpose of the visit would facilitate the conduct of the visit. It would therefore be helpful for the States Parties to brief the facility representatives prior to the entry into force of the Protocol through national, and as appropriate, regional seminars.
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