
Geneva, 19 - 30 September 1994

UNITED KINGDOM BTWC PRACTICE COMPLIANCE
INSPECTION (PCI) PROGRAMME. SUMMARY REPORT

INTRODUCTION

1. The United Kingdom has conducted four practice inspections in the biotechnology, pharmaceutical and vaccine industries. The programme's objectives were:

- a. To test the effectiveness of verifying compliance with the BTWC by means of inspection of biotechnology, research and development, pharmaceutical and vaccine plants, especially those that are large, multipurpose, flexible, compatible with pathogen work and where there are substantial concerns about commercial confidentiality.
- b. To examine the issues that arise for industry, for the government of the State Party receiving the inspection, and for the administration of such verification measures under the BTWC.
- c. To test whether sufficient access within the plant and to documentation could be given to demonstrate compliance with the BTWC, without unacceptable compromise to commercial confidentiality.

MAIN ISSUES

2. There were four issues in the PCIs: access, compliance assessment, commercial confidentiality and logistics.

Access

3. Managed access techniques were important in negotiating access to buildings and to documentation. Some form of physical access is feasible, and in most cases the level of access that can be provided is actually quite extensive. However, there are occasions when plant operators will wish to limit inspectors' physical access on grounds of commercial confidentiality, Good Manufacturing Practice and/or health and safety. The UK believes that in principle specific solutions could probably be developed to deal with most eventualities. Whether the level of access provides all the information required by the inspectors and reassures the company concerned that commercially sensitive information is protected will depend on the individual circumstances.

4. There are no insurmountable obstacles to granting some access to plant documentation during the course of an inspection. Indeed documentation assumes a crucial importance when physical or visual access is denied or otherwise constrained. Access to relevant personnel presented few problems. Imposition on senior managers' time is perhaps the greatest burden imposed by a short notice inspection of a commercial site. Wherever possible the inspectors should be allowed to interview any employee, subject to safeguards.

Compliance Assessment

5. Provided the inspection team is given sufficient access, and the definition of this will vary from site to site, it is possible to determine with confidence that no non-compliant activities are being concealed. The degree of confidence depends on the nature and extent of access provided.

6. Whenever inspectors can establish the internal consistency, technical and commercial plausibility of the evidence and explanations provided across as broad a range of site activities as possible, then the confidence in compliance increases dramatically.

7. Commercial Confidentiality The legitimate need to protect commercial confidentiality presents few insurmountable obstacles to the conduct of an effective inspection. Nevertheless there are occasions when the requirement to safeguard proprietary data clashes with the inspectors' requests for information. However these are infrequent and limited to relatively few areas of critical commercial concern that may be site specific. However, a problem may occur with pieces of information that are not confidential in themselves but when aggregated could give a commercially sensitive overview.

8. As long as the host authorities have prepared themselves beforehand to identify sensitivities and planned managed access approaches, the risk of compromise can be reduced considerably although not eliminated entirely. It is important to make a distinction between the sensitivities of classes of commercial information. The trials showed that in most cases when confidential information could be threatened by disclosure of information, it would be possible to satisfy the particular line of enquiry indirectly without risk to confidentiality.

Logistics

9. General logistical issues such as team size, escorting, briefing, safety, language and general equipment do not impose serious constraints on the conduct of inspections. There are advantages for a real BTWC inspection team in having access to sampling and identification kits specific for a range of candidate BW agents. These would allow relatively real time determination on the presence or absence of an agent of concern. It would also be helpful for host authorities to be prepared to offer any existing laboratory or test facilities to demonstrate the presence

of other microorganisms or biochemicals in samples. On-site analysis avoids the risks to commercial information from removing samples from the site.

CONCLUSIONS

10. In-depth inspections are practicable: auditing, interviewing and visual inspection of key equipment are all essential and mutually reinforcing. Any measure on its own is of little or no value.

11. Provided the sites being inspected make preparations and use managed access, the risks to commercially sensitive information can be reduced. On many occasions the amount of access that can be granted without unduly risking proprietary data can be extensive.

12. The standards of evidence for an effective inspection are high. This is a qualitative problem as unambiguous evidence of non-compliance is difficult to acquire, but indicators of such activity can be identified. Given the potential dual-use nature of biological agents and much related equipment, inspection teams need evidence from all aspects of the site under investigation if they are to form a judgement on its compliance.

13. Availability of portable candidate BW agent identification kits would be of immense value for both inspection teams and home teams; use of host laboratory facilities may also help to prove the presence of other biological agents of biochemicals.

14. The main burden on industry is largely one of diversion of management time to hosting the inspection; there should be no need to disrupt plant operations or enter sterile areas provided alternative means can be found to satisfy inspector concerns.

15. Many of the access problems encountered in the PCI programme were site specific, and the managed access solutions were equally specific. This is probably a general conclusion which might apply to most sites.