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SUPPLEMENT No. 1

Audit language requirements

1. Introduction

In preparing this guidance, the study group was not aware of any regulations, which required written translation of quality system documentation into a specific national language. However if this should be required it is recommended that this be limited to the very top level of documents. The use of widely accepted international commercial languages should be allowed.

Note: the very top-level documentation would normally be the quality manual excluding standard procedures, work instructions and other similar documents.

2. Definitions

Audit language

The language(s) routinely used for the communication or exchange of information between auditee’s personnel and auditors.

3. Guidance

The audit team must have available:

   (i) as a minimum, one member able to read and understand the quality system documentation and interview the auditee’s personnel;

   or

   (ii) an audit interpreter, arranged and agreed in advance.

4. Language requirements for auditees

Auditees are expected to prepare their quality documentation in the company’s operational language(s).