

**GHTF.SG4.(99)14**




## **FINAL DOCUMENT**

**Title:** Audit Language Requirements

**Authoring Group:** SG4

**Endorsed by:** The Global Harmonization Task Force

**Date:** June 29, 1999

  
Elizabeth D. Jacobson, Ph.D., GHTF Chair

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide *non-binding* guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

**FINAL DOCUMENT**

**SG4(99)14**

## **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).