

**THE USE OF LABORATORY ACCREDITATION WITH
REFERENCE TO GLP COMPLIANCE MONITORING:
POSITION OF THE OECD PANEL ON GOOD LABORATORY PRACTICE**

**(as endorsed by the 22nd Joint Meeting of the Chemicals Group and Management Committee
of the Special Programme on the Control of Chemicals on 16th November, 1994)**

OECD Member countries in 1989 agreed in a Council Decision-Recommendation¹ that where "testing of chemicals for purposes of assessment related to the protection of health and the environment is being carried out pursuant to principles of good laboratory practice that are consistent with the OECD Principles of Good Laboratory Practice as set out in Annex 2 of the Council Decision C(81)30(final) (hereafter called "GLP Principles") they shall:

- i) establish national procedures for monitoring compliance with GLP Principles, based on laboratory inspections and study audits;
- ii) designate an authority or authorities to discharge the functions required by the procedures for monitoring compliance; and
- iii) require that the management of test facilities issue a declaration, where applicable, that a study was carried out in accordance with GLP Principles and pursuant to any other provisions established by national legislation or administrative procedures dealing with good laboratory practice."

The primary task of the national GLP compliance monitoring authority is to verify the validity of such declarations made by laboratory management. GLP compliance monitoring not only examines the procedures and practices used by a test facility to carry out safety studies on chemicals or chemical products, (e.g., industrial chemicals; pharmaceuticals; veterinary drugs; pesticides; food and feed additives; and cosmetics) but also evaluates performance, i.e., the integrity of the data and the reconstructibility of the study. The types of safety studies which are monitored by GLP compliance monitoring authorities include physical-chemical tests; toxicity studies; mutagenicity studies; environmental toxicity studies on aquatic and terrestrial organisms; studies on behaviour of chemicals in water, soil and air and on bioaccumulation; residue studies; studies on effects in mesocosms and natural ecosystems; analytical and clinical chemistry tests. The driving force for GLP compliance monitoring is the requirement to assure regulatory authorities that data they receive in safety studies can be relied upon when making assessments of hazards or risks to man, animals and/or the environment.

Laboratory accreditation addresses and underwrites the technical competence of a laboratory to carry out specified determinations on a continuing basis to defined standards. A laboratory accredited for such determinations (e.g., physical-chemical and analytical procedures) according to ISO/IEC Guide 25² or equivalent standards can be considered to have satisfied many of the GLP requirements. However, certain fundamental requirements of the GLP Principles are not covered by laboratory accreditation according to ISO/IEC Guide 25² or equivalent standards, i.e., the use of study plans and the Study Director as a concept.

¹ Council Decision-Recommendation on Compliance with Principles of Good Laboratory Practice C(89)87(Final).

² revised and renamed ISO/IEC 17025 in 2001

Other requirements, while called for laboratory accreditation, are much more stringent under GLP; these are related to recording and reporting of data; management of data retained in archives to allow complete reconstruction of a study; and a programme of independent quality assurance including internal audits of every study. Therefore, data generated solely under ISO/IEC Guide 25² or equivalent standards are unlikely to be accepted by regulatory authorities for purposes of assessment of chemicals related to protection of health and the environment.