

Council Directive of 7 June 1988 on the inspection and verification  
of Good Laboratory Practice (GLP) (88/320/EEC) (repealed)

Article 1	.....
Article 2	.....
Article 3	.....
Article 4	.....
Article 5	.....
Article 6	.....
Article 7	.....
Article 8	.....
Article 9	.....
Article 10	.....

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ANNEX

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PART A

REVISED GUIDES FOR COMPLIANCE MONITORING  
PROCEDURES FOR GOOD LABORATORY PRACTICE

Definitions of terms

Components of good laboratory practice compliance monitoring procedures

- Administration
- Confidentiality
- Personnel and training
- (National) GLP compliance programmes
- Follow-up to test facility inspections and study audits
- Appeals procedures

PART B

REVISED GUIDANCE FOR THE CONDUCT OF TEST  
FACILITY INSPECTIONS AND STUDY AUDITS

Introduction

Definitions of terms

Test facility inspections

Inspection procedures

**Status:** EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

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- Pre-inspection
- Starting conference
- Organisation and personnel
- Quality assurance programme
- Facilities
- Care, housing and containment of biological test systems
- Apparatus, materials, reagents and specimens
- Test systems
  - Physical and chemical systems
  - Biological test systems
- Test and reference substances
- Standard operating procedures
- Performance of the study
- Reporting of study results
- Storage and retention of records

Study audits

Completion of inspection or study audit