Australian Standard®

GOOD LABORATORY PRACTICE
Part 1—CHEMICAL ANALYSIS

This Australian standard was prepared by an Ad Hoc Working Group CH/-/2 — OECD Liaison operating under the Chemical Standards Board. It was approved on behalf of the Council of the Standards Association of Australia on 24 July 1985 and published on 4 November 1985.

The following interests are represented on the Chemical Standards Board:

Agricultural & Veterinary Chemicals Assoc. of Aust. Ltd.
Australasian Institute of Mining and Metallurgy
Australian Chemical Industry Council
Australian Gas Association
Bureau of Steel Manufacturers of Australia
Commonwealth Scientific and Industrial Research Organization
Confederation of Australian Industry
Department of Defence
Department of Arts, Heritage and Environment
Department of Science and Technology
National Council of Chemical and Pharmaceutical Industries
Railways of Australia Committee
Royal Australian Chemical Institute
University of Sydney

The following organizations were represented on the Ad Hoc Working Group CH/-/2:

Australian Chemical Industry Council
Australian Government Analytical Laboratory
BHP Central Research Laboratories
Department of Arts, Heritage and Environment
Department of Health
National Association of Testing Authorities
State Chemistry Laboratory, Victoria

This Standard was issued in draft form for comment as DR 84260.

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Part 1—CHEMICAL ANALYSIS

First published 1985

PUBLISHED BY STANDARDS AUSTRALIA
(STANDARDS ASSOCIATION OF AUSTRALIA)
1 THE CRESCENT, HOMEBUSH, NSW 2140

ISBN 0 7262 3954 2

PREFACE

This standard was prepared by an ad hoc working group established by the Chemical Standards Board with the objective of making available a document which would set out general requirements for the technical competence of laboratories engaged in chemical analysis.

The standard should prove useful to large and small organizations wishing to ensure that associated chemical laboratories under their jurisdiction are complying with national and internationally recognized standards of competence and good management.

The standard sets out general requirements for laboratories engaged in chemical analysis. However, in certain cases, regulations may specify additional requirements to be met. For example, the proposed National Chemicals Notification and Assessment Scheme calls for chemicals test data to be generated in accordance with the OECD principles of good laboratory practice. The content of this standard covers the essential elements of the OECD principles of good laboratory practice. It is envisaged that in due course complementary parts to this standard will be developed which would address testing of chemicals for toxicological and ecotoxicological effects.

In the preparation of this standard the following Australian, British, ISO and OECD publications were considered:

SAA MP34— 1978 Guide to the Layout and Preparation of Standard Methods of Chemical Analysis

ISO Guide 25:1982 General Requirements for the Technical Competence of Testing Laboratories

BS 6460 Accreditation of Testing Laboratories

Part 1:1983 Specification of the General Requirements for the Technical Competence of Testing Laboratories

OECD Principles of Good Laboratory Practice

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1 SCOPE. This standard sets out requirements for the technical competence and good management of chemical analysis laboratories. The requirements relate to organization, personnel, facilities and test equipment, safety, quality assurance system, calibration, sample storage, data recording, reporting and regular inspection and assessment of the laboratory.

Application of the standard is intended to ensure that test data generated by the laboratory are of high quality, are scientifically reliable and are in accordance with national and international standards for trade and for safety and health regulations.

The standard can be used by accreditation organizations or other bodies concerned with assessment of the competence of chemical analysis laboratories.

2 REFERENCED DOCUMENTS. The following documents are referred to in this standard:

AS 1057	Quality Assurance and Quality Control—Glossary of Terms
AS 1470	Code of General Principles for Safe Working in Industry
AS 1514	Glossary of Terms Used in Metrology Part 1—General Terms and Definitions
AS 1851	Maintenance of Fire Protection Equipment
AS 2243	Safety in Laboratories Part 8—Fume Cupboards
AS 2252	Biological Safety Cabinets
AS 2415	Calibration System Requirements
AS 2444	Portable Fire Extinguishers— Selection and Location
AS 2508	Safe Storage and Handling Information Cards for Hazardous Materials
AS 2639	Cytotoxic Drug Safety Cabinets—Installation and Use
AS 2647	Biological Safety Cabinets—Installation and Use.
AS 2667	Chemical Testing—Sampling—Glossary of Terms
AS ...	Laboratory Construction*
SAA MP34	Guide to the Layout and Preparation of Standard Methods of Chemical Analysis
ISO Guide 2	General Terms and Their Definitions Concerning Standardization, Certification and Testing Laboratory Accreditation.
ISO Guide 30	Terms and Definitions Used in Connection with Reference Materials
BS 5532	Statistics—Vocabulary and Symbols
OECD	Test Guidelines

3 DEFINITIONS. The terms used throughout this standard are in accordance with AS 1057, AS 2667, AS 1514, BS 5532, ISO Guide 2, ISO Guide 30 and the OECD's 'Principles of Good Laboratory Practice'. For the purpose of this standard, the following definitions apply:

3.1 Good laboratory practice—organizational process, facilities, staff and conditions which ensure that chemical analyses are performed, monitored, recorded and reported in accordance with trade, safety and health requirements.

3.2 Quality assurance system—laboratory self-regulation and checking system which ensures that the laboratory operates and produces analytical results in accordance with this standard.

3.3 Raw data—all original laboratory records and documentation, or verified copies thereof, which are the result of original observations and activities.

3.4 Certified reference material—a commercially available certificated material which is used to validate results and to assess accuracy of analytical methods and procedures.

3.5—Inspection and assessment—an examination of the laboratory to ensure that it is in compliance with all aspects of this standard. The assessor should be suitably qualified and experienced and preferably independent of the laboratory being assessed.

4 LABORATORY ORGANIZATION.

4.1 General. The laboratory shall be organized in such a way that all requirements of this standard can be complied with. In particular, the laboratory should have available suitable staff, facilities and environment for the particular chemical analyses being conducted. All employees should be aware of the extent and limitations of their area of responsibility. Written job descriptions should be available for all staff. Safety regulations should be detailed and in accordance with State/national/international standards and Acts, as appropriate.

4.2 Manager. The laboratory manager (however named) shall have overall responsibility for the laboratory.

4.3 Staff. Laboratory staff should be trained to carry out new and existing procedures. Records should be kept of staff qualifications, experience and training.

* In course of preparation