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Australian Standard 1079, Part 1—1981

PACKAGING OF ITEMS (STERILE) FOR PATIENT CARE

Part 1—GUIDE TO SELECTION OF PACKAGING MATERIALS FOR GOODS UNDERGOING STERILIZATION

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THE FOLLOWING SCIENTIFIC, INDUSTRIAL AND GOVERNMENTAL ORGANIZATIONS and departments were officially represented on the committee entrusted with the preparation of this standard:

Australian Dental Standards Laboratory

Australian Institute of Packaging

Australian and New Zealand Pulp and Paper Industry Technical Association

Confederation of Australian Industry

Department of Defence

Department of Health, A.C.T.

Deapartment of Health, Queensland

Government Stores Department, New South Wales

Health Commission of Victoria

National Council of Chemical and Pharmaceutical Industries

National Health and Medical Research Council

Packaging Council of Australia

Plastics Institute of Australia Incorporated

South Australian Health Commission

Sterilizing Research and Advisory Council of Australia

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Packaging of items (sterile) for patient care

AS 1079.1—1993
Selection of packaging materials for goods undergoing sterilization
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AUSTRALIAN STANDARD

PACKAGING OF ITEMS (STERILE) FOR PATIENT CARE

Part 1
GUIDE TO SELECTION OF PACKAGING MATERIALS FOR GOODS UNDERGOING STERILIZATION

AS 1079, Part 1—1981

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PREFACE

This standard was prepared by the Association's Committee on Packaging of Sterile Goods under the direction of the Packaging Standards Board to supersede AS 1079—1971, The Sterilization of Packaged Goods (Metric Units).

To avoid any misinterpretation, this standard has been revised in such a way that any process conditions quoted are given only as examples of the sterilization conditions to which packaging materials may be subjected. They must be recognized only as among the criteria to be considered in determining the suitability of a potential packaging material for a particular sterilization process under specific circumstances.

This standard in final form will consist of four parts as follows:

Part 1—Guide to selection of packaging materials for goods undergoing sterilization.

Part 2—Paper and paper packages for sterile goods (now AS 1662, under revision).

Part 3—Paper bags for sterile goods (now AS 1662, under revision).

Part 4—Plastics (including laminates) containers for sterile goods (now AS 1164, under revision).

This standard may require reference to AS 2400, SAA Packaging Code, Part 1—Glossary of Packaging Terms.

Attention is also drawn to the following standards:

AS 1301	Methods of Test for Pulp and Paper
AS 1410	Pre-vacuum Pressure Steam Sterilizers (with Mechanical Air Removal)
AS 1714	Ethylene Oxide Sterilizers
AS 1862	Aeration Cabinets (for use with Ethylene Oxide Sterilizers)
AS 2182	Portable Electrically Heated Steam Sterilizers (Downward Displacement Pressure Steam Type)
AS 2192	Horizontal Sterilizers (Downward Displacement Pressure Steam Type)
AS	Dry Heat Sterilizers (Hot Air Type)*

*In course of preparation.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
PACKAGING OF ITEMS (STERILE) FOR PATIENT CARE

PART 1—GUIDE TO SELECTION OF PACKAGING MATERIALS FOR GOODS UNDERGOING STERILIZATION

1 SCOPE. This standard outlines the principal requirements of materials used for the packaging of goods undergoing sterilization.

Packaging materials for pharmaceuticals are not included.

NOTE: *THIS STANDARD IS NOT A CODE OF STERILIZATION PRACTICE.* The process parameters included for saturated steam under pressure, ethylene oxide, dry heat or ionizing radiation are given only as examples of the sterilization conditions to which packaging materials may be subjected.

2 DEFINITIONS. For the purpose of this standard, the definitions of AS 2400 and the following definitions apply:

Load—that quantity of packed product intended to be sterilized at the one time in one sterilizing unit.

Packaging materials—those materials and components used in construction of the intended microbiological barrier.

Parameter—(in relation to sterilization) any condition which is given a quantitative value, e.g. temperature or time.

Sterilization—the process of destruction of all forms of microorganisms.

Sterilization cycle—the period of time made up of the 'pre-sterilization period', the 'effective sterilization period' and the 'post-sterilization period'.

Pre-sterilization period—that time taken for the least accessible part of the load to reach the effective sterilization conditions.

Effective sterilization period—that period of time during which the least accessible part of the load is subjected to the conditions laid down for the sterilization of that load.

Post-sterilization period—that period of time, from the end of the effective sterilization period to the removal of the load from the sterilization unit.

3 PACKAGING MATERIAL REQUIREMENTS. The principal requirements of the packaging material for use in the chosen method of sterilization are as follows:

(a) The ability of the packaging material to be formed, closed and sealed.

(b) The ability of the packaging material to allow the enclosed goods to be sterilized.

(c) The compatibility of the packaging material with the contents under the proposed process conditions.

(d) The physical ability of the packaging material to withstand the conditions of the selected sterilization cycle without either adverse effect on the performance of the package or deleterious effect on the goods being sterilized.

(e) The ability of the packaging material to act as a microbiological barrier adequate to maintain the sterility of the sterilized product throughout the nominated shelf life.

NOTE: Sterilizers and auxiliary equipment for hospital use are described in the standards listed in the Preface.

4 REQUIREMENTS OF PACKAGES.

4.1 General. The sealed package shall—

(a) permit the sterilization of the contents;

(b) protect the contents prior to, during and after sterilization and subsequent normal handling, transport and storage;

(c) maintain the sterility of the contents throughout the nominated shelf life, unless damaged or opened; and

(d) allow the packaged goods to be removed from the pack aseptically.

4.2 Requirements Specific to Selected Sterilization Processes.

4.2.1 *General.* Requirements specific to four common sterilization processes are described in Clauses 4.2.2, 4.2.3, 4.2.4 and 4.2.5.

4.2.2 *Saturated steam under pressure.* The essential physical requirements of the packaging materials chosen for sterilization by saturated steam under pressure are as follows:

(a) The ability of the material to allow the transfer of heat and passage of air and steam in and out of the package during the sterilization cycle.

(b) The ability of the package to withstand the hot and moist conditions existing at various times during the sterilization cycle while maintaining both physical integrity and microbiological properties.

(c) The ability of the material to withstand temperatures between 121° C and 136° C for periods up to 60 min.

(d) The ability of the packaging material to withstand sudden increases or decreases of pressure occurring when pre-vacuum sterilizers are used.

NOTE: The permeability of some packaging materials may change during the process and may retard the egress of steam or condensate from the package.

4.2.3 *Ethylene oxide.* The essential physical requirements of the packaging materials chosen for sterilization by ethylene oxide are as follows:

(a) The ability of the package to allow the transfer of heat and passage of air, water vapour,

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