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## Dentistry — Mercury and alloys for dental amalgam

*Art dentaire — Mercure et alliages pour amalgame dentaire*



Reference number  
ISO 24234:2004(E)

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 24234 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This International Standard cancels and replaces ISO 1559:1995, ISO 1559:1995/Cor.1:1997 and ISO 1560:1985.

A number of technical revisions have been made as improvements or as a consequence of combining the International Standards that have been replaced.

- The scope of this International Standard applies to alloys for dental amalgam and dental mercury, whether provided individually or together.
- The clause permitting a deviation in the composition of alloys for amalgam has been removed.
- Guidance on biocompatibility assessment has been introduced.
- A limit on the presence of large alloy particles has been introduced.
- The requirement for loss of mercury from predosed capsules has been removed, since it is a requirement in ISO 13897.
- The values for the requirements on creep, dimensional change and compressive strength at 1 h have been revised.
- The criterion for compliance with the compressive strength requirements has been revised.
- Provisions for packaging and marking have been revised.
- Markings required for mercury safety warnings and precautions have been revised to conform to ISO requirements and the United Nations *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS). They are no longer dependent upon national or regional requirements.
- Procedures for corrosion testing have been added as normative annexes.

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## Introduction

Dental amalgam alloy and mercury are the essential and only components of dental amalgam restorative material. This International Standard combines the requirements and the test methods for the alloy with those for the mercury in a single standard, of which this is the first edition. Formerly, these were contained in two separate standards.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that, in assessing possible biological hazards, reference be made to ISO 10993-1 and ISO 7405.

To enhance the safety of dentists and support staff, it would have been preferred to limit the scope solely to the use of predosed capsules of alloy and mercury. It is, however, recognised and accepted that both amalgam alloy and mercury are supplied in bulk form in some parts of the world where, for economic reasons, this is necessary for the provision of dental treatment. Therefore requirements for these products are included in this International Standard. Safety precautions relating to marking, labelling and packaging have been strengthened in this revision.

Inclusion of a requirement for corrosion resistance was considered, using the procedures for corrosion testing given in ISO/TS 17576. However it was decided that the data available were insufficient to justify a corrosion requirement in this International Standard, and as a consequence the test methods alone are given, as normative annexes. A requirement for the corrosion resistance will be set and incorporated at the earliest possible date.