Reference substances

(a) Chemical

International Chemical Reference Substances (ICRS) are established on the advice of and released by the WHO Expert Committee on Specifications for Pharmaceutical Preparations. They are supplied primarily for use in physical and chemical tests and assays described in the specifications for quality control of pharmaceutical products published in *The International Pharmacopoeia* or proposed in draft monographs.

Directions for use and the analytical data required for the tests specified in *The International Pharmacopoeia* are given in the leaflets enclosed with the substances when distributed. More detailed analytical reports on the substances may be obtained on request from the WHO collaborating host organization for ICRS at the address given below.

ICRS may also be used in tests and assays not described in *The International Pharmacopoeia.* However, responsibility for assessing the suitability of the substances then rests with the user or with the pharmacopoeia commission or other authority that has prescribed their use.

It is generally recommended that the substances be stored protected from light and preferably at a temperature of about +5 °C. When special storage conditions are required, this is stated on the label or in the accompanying leaflet.

The stability of the ICRS kept at the WHO collaborating host organization for ICRS is monitored by regular re-examination and materials that have deteriorated are replaced by new batches when necessary. The numbers for the current batches are issued on the website of the host organization.

Orders for ICRS should be sent to :

• WHO collaborating host organization for International Chemical Reference Substances: European Directorate for the Quality of Medicines & HealthCare, 7 allée Kastner, CS 30026, F-67081 Strasbourg, France; fax: +33 (0)3 88 41 27 71 - for the attention of EDQM Sales Section; email: orders@edqm.eu; website: http://www.edqm.eu

ICRS are supplied only in the standard packages indicated in the list.

(b) Biological

The primary purpose underlying the establishment of International Biological Standards is to provide a means of ensuring uniformity throughout the world in the designation of the activity or specificity of preparations that are used in the prophylaxis, therapy or diagnosis of human diseases, which cannot be expressed directly in terms of chemical and physical quantities. [1]

[1] More information may be found in: *Recommendations for the preparation, characterization and establishment of international and other biological reference standards (Revised 2004).* Annex 2 to the fifty-fifth report of the WHO Expert Committee on Biological Standardization. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 932).

Requests for international biological reference materials should be addressed directly to the following custodian laboratory, together with a brief summary on the intended use. The catalogue of International Biological Reference Preparations current at any particular time is available on the WHO Biologicals website (http://who.int/biologicals).

• International Laboratory for Biological Standards, National Institute for Biological Standards and Control (NIBSC), South Mimms, Potters Bar, Herts EN6 3QH, England; tel:. +44 (0)1707 646399; fax +44 1707 646977.

(c) Radiopharmaceutical

When carrying out tests to identify the radionuclide present in a radiopharmaceutical preparation or when measuring the radioactivity of a radiopharmaceutical preparation, it is necessary to use appropriate reference preparations or standardized solutions.

These preparations and solutions are available from laboratories recognized by the relevant national or regional authority and requests should be addressed directly to the relevant laboratory. Such laboratories include secondary standards radioactivity laboratories (SSRL) defined as follows by the International Atomic Energy Agency (IAEA) in the International Basic Standards (BSS) for Protection against Ionizing Radiation and for the Safety of Radiation sources:[2] "Any qualified entity that has been delegated responsibility for the preparation and calibration of standardized radioactivity samples that has established measurement traceability to a national metrology institute (NMI) that holds primary standards for radioactivity (or the equivalent, as recognized by the Bureau international des poids et mesures (BIPM)."

[2] More information may be found in: *Safety Series,* Vienna, International Atomic Energy Agency. Consult the IAEA website (www.iaea.org) and publications for the current information.