

## BCR® Reference Materials by IRMM

### Introduction

Certified reference materials (CRM) constitute an essential tool in achieving comparability and traceability of measurements. CRMs enable the optimization of industrial processes, the protection of public health and the environment, the promotion of international trade and the implementation and standardization of European legislation. They play an important role in

- Ensuring comparability of results of trade partners (on a voluntary basis)
- Proper application of written standards and implementation of national legislation or European directives
- Implementation of quality control schemes, laboratory accreditation and mutual recognition of laboratory results
- Reaching the state of the art in industrial technologies where measurements are critical
- Performing measurements which require a common calibrant or reference point.

There is an increasing number of CRM producers, and a demonstration of their scientific and technical competence and the reliability of their products is now a basic requirement for ensuring the quality of reference materials.



The demand for new CRMs of higher quality is increasing as a consequence of the increased precision of measuring equipment, and the requirement for more accurate and reliable data in the scientific and technological disciplines.

### Rules/Definitions

The ISO (International Organization for Standardization) has set up several rules to assure a suitable comparable quality of reference materials (ISO Guide 30 – 35). Among them the ISO Guide 30 serves as a guide to terms and definitions used in connection with reference and certified reference materials.

#### Reference Material (RM) –

material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

#### Certified Reference Material (CRM) –

reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

## Contents:

- **Why use Certified Reference Materials?**
- **Rules/Definitions**
- **The Product Programme**
- **The Distribution Pathway**



The following table shows a short summary of the contents of these guides:

ISO Guide No.	Content
30 (1992)	Terms and definitions used in connection with reference materials
31 (1996)	Contents of certificates of reference materials
32 (1997)	Calibration of chemical analysis and use of certified reference materials
33 (1989)	Use of certified reference materials (under revision)
34 (1996)	Quality system guidelines reference material producers
35 (1989)	Certification of reference materials – General and statistical principles (under revision)

In Europe, the Bureau Communautaire de Référence (BCR<sup>®</sup>), a department of the European Commission, has published Guidelines for the Production and Certification of Reference Materials which summarize the principles to be applied in certification of BCR<sup>®</sup> reference materials, the precautions to be taken to ensure the quality of the reference materials, and the information which should be provided to their users.

### IRMM/BCR<sup>®</sup> Reference Materials

The IRMM (Institute for Reference Materials and Measurements) founded in 1957 with a total staff count of ~200 persons and situated in Belgium, is one of the eight institutes of the Joint Research Center, the European Commission's scientific and technical research laboratory. IRMM serves the policies of the European Union by delivering scientific/technical products and services for the European Commission's Directorate Generals (DGs), international organizations, Member States and their institutions, and industry.

Since 1995 the IRMM has shared the responsibility for the production and certification of BCR<sup>®</sup> CRMs. BCR<sup>®</sup> reference materials are produced and certified in accordance with internationally accepted rules laid down in the various guides by BCR<sup>®</sup>, the ISO and the WHO (World Health Organization). These products are produced either on IRMM's own initiative (e.g. to replace exhausted stocks of BCR<sup>®</sup> reference materials) or on requests from research, public or industrial organizations and/or partners.

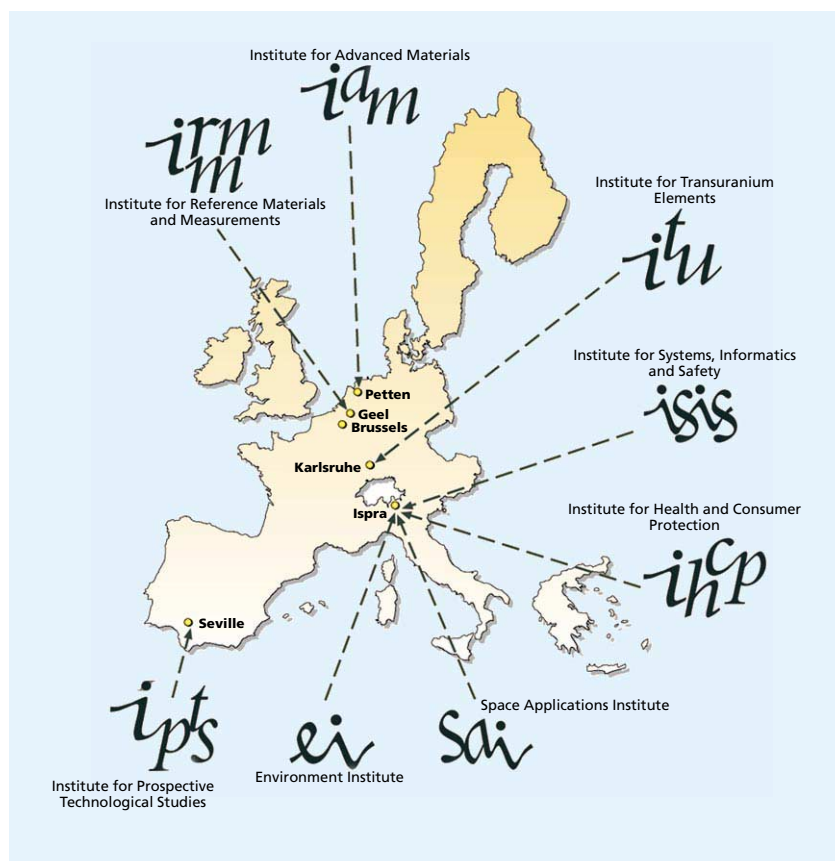
The major steps in the certification process include:

- A feasibility study
- Preparation of the candidate reference material
- Homogeneity testing of the candidate reference material
- Stability testing of the candidate reference material
- Certification measurements employing in general 6 – 15 laboratories.

The results of each BCR<sup>®</sup> certification exercise are evaluated at a technical discussion meeting in which all certifying laboratories participate. The project coordinator then prepares a draft certification report and a draft certificate following the instructions for the certification of BCR<sup>®</sup> reference materials.

The European Commission coordinates the actual certification procedure which involves submission of the certification documents to an independent group of experts. These experts perform, on the basis of these documents, a technical audit to confirm the validity of the certificate. This expert group is referred to as the Scientific Evaluation Group for the Certification of Reference Materials. On the basis of their advice, the European Commission may decide to certify the reference material, which is then made available world-wide through authorized distributors, such as the Fluka Chemie GmbH. The IRMM has a complement of unique facilities for the production of biological and environmental reference materials as well as storage

Figure 1:  
The institutes of the Joint Research Center



facilities with temperatures ranging from +18 °C to –70 °C. Moreover, reference samples as required for stability monitoring are stored at temperatures down to –196 °C to prevent any thermal and/or microbial degradation.

The unique multi-functional and flexible production laboratories contain clean chambers, cryogrinding, freeze drying, high purity milling and ultrafine classification and levitation melting machines. These facilities are presently being extended to the production of potentially infectious materials and/or materials where cross contamination through ambient air is critical (e.g. reference materials for DNA analysis). The modern analytical laboratory is equipped with various spectroscopic methods, neutron activation analysis, gas and liquid chromatography, PCR and immunochemical techniques used for in-process control and certification analyses.

### Product Programme

Reference materials can be divided into two categories:

- Pure substances or solutions for the calibration of instruments e.g. standard solutions, mixtures for pesticide analysis, isotopic standards
- Matrix reference materials for the validation of analysis procedures, e.g. heavy metal traces in milk powder, sediments, and sludge; pesticide traces in vegetables and fish.

The BCR® products belong to the last group, except for the environment certified reference materials, which consists of pure compounds and calibration solutions. The whole programme contains ~400 products belonging to various segments such as

- Environment – polycyclic aromatic compounds, nitro-polycyclic and oxygenated aromatic hydrocarbons, polychlorinated biphenyls (for purity), soils, sludge, sediments, biological material, water, waste
- Occupational hygiene – filter media, charged tubes with Tenax or charcoal
- Water and food microbiology – milk powder
- Food and agriculture – dairy products, alcohol, GMO standards, meat, cereals, vegetables, oils, fat, fish, mussels, animal feed, seeds
- Clinical chemistry – plasma, serum, body liquids, blood
- Physical properties – heat transmission, particle size, surface area, properties of films and surfaces, linewidth measurements, color measurements, mechanical properties
- Industrial raw materials and products – ores, fuels, gas, oil, metals, semiconductors, plastics, glass, ceramics, fertilizers

Each certified reference material is provided with a comprehensive certificate of analysis stating the certified values along with the associated measurement uncertainty for each certified value. In addition to the certificate the certification report is delivered with each product which provides details on the production, characterization and certification of the material.



Figure 2:  
The site of the IRMM institute  
in Geel, Belgium

When using certified reference materials it should be remembered that all analytical results have inherent uncertainties due to both random and systematic effects. It is therefore unlikely that the results obtained by a method when measuring a CRM will be exactly the same as the certified value of the CRM. What is important is that the results obtained are within an acceptable tolerance limit for the end-use requirement of the method. In addition, CRMs need to be selected and used correctly for optimum instrumental performance to be achieved.

For example:

- the possible effects of structure, sample preparation and physico-chemical interference need to be considered;
- calibration should be based on similar materials.

### Distribution of IRMM/BCR® Reference Materials

Since May 2000 Fluka Chemie GmbH has become an authorized distributor of all IRMM reference materials. By ordering through Fluka you benefit from:

- a fast and reliable delivery service
- attractive prices in your local currency
- our competent technical service

BCR® is a registered  
trademark of IRMM

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