

# Traceability and intellectual property

**Peter J. Jenks, FRSC**

The Jenks Partnership

The production of certified reference materials (CRMs) has grown rapidly since the mid-1990s, largely driven by demand created by the accreditation of testing laboratories to ISO/IEC 17025. It is now a multimillion US\$ global business dominated by mixture of public sector Governmental agencies such as NIST and IRMM, public service organisations like United States Pharmacopeia, and the European Pharmacopeia and two businesses, LGC Group Ltd and Merck KgAA. These large suppliers are supported by a myriad of small, specialist commercial producers of secondary CRMs.

The public-sector producers are empowered to issue Primary CRMs. Most, but not all, commercially produced CRMs are secondary CRMs. More on the difference between primary and secondary later.

All CRM production is done by organisations that are either Accredited to ISO/IEC 17034 or work to a quality system based upon this Standard. ISO, the International Standards Organisation is an independent, non-governmental organisation made up of members from the national standards bodies of 161 countries. The Organisation works closely with two other international standards development organisations, the International Electrotechnical Commission (IEC) and International Telecommunication Union (ITU). In 2001, ISO, IEC and ITU together established the World Standards Cooperation (WSC). The WSC also promotes the adoption and implementation of international consensus-based standards worldwide.

ISO also works closely with the World Trade Organisation (WTO), seeking to reduce technical barriers to trade and with United Nations partners including

the UN Economic and Social Council (ECOSOC).

In total, ISO collaborates with over 700 international, regional and national organisations. These organisations take part in the standard development process as well as sharing expertise and best practices.

ISO is funded by the national member organisations, in the UK this is the British Standards Institute (BSI) that pays a subscription towards the operational cost of the Central Secretariat. The subscription paid by each member is in proportion to the country's Gross National Income and trade figures. The sale of published ISO Standards is also a significant source of revenue. But ISO could not function without the support of countless volunteers who are supported by their employer. As an example, this author was part of the Working Group responsible for the creation of ISO/IEC 17034, but all time and travel costs were carried by my employer at the time, Sigma Aldrich Co Ltd.

An ISO/IEC 17025 accredited laboratory is required to validate analytical instruments and methods using CRMs: this is intended to prove that the analytical results produced are "traceable" back to a primary reference: in the case of analytical chemistry this is usually the Mole.

Metrological traceability is defined as a property of a measurement result, whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

For chemical CRMs the traceability is normally ensured by taking a primary CRM, issued by a National Metrology Institute and using this in the calibration chain, or by using a primary method, such as quantitative nuclear magnetic resonance. When a primary CRM is used

the physical artefact is supplied with a comprehensive certificate of analysis (CoA). The data contained in the CoA is essential to the use of the primary CRM by the producer of the secondary CRM.

In an increasingly litigious world, it has been suggested that using a publicly funded CRM to produce secondary CRMs to be sold for commercial gain may be an infringement of the primary producers Intellectual Property (IP). It has been long believed that as primary CRMs are produced with the intention that they will be used to produce secondary CRMs, to be used by the customer, then there is an implicit licence to allow the use of the producers' IP.

But does this still apply when the customer of the primary CRM is a commercial producer that will make a very substantial profit on the sale of the secondary CRMs that are produced, often in a large quantity?

Public sector NMIs are under evermore financial pressure: would it not be reasonable for the NMIs to require the commercial producers to negotiate a formal Licence to use the IP and pay a royalty on the CRMs produced?

There is a precedent for this concept. Back in the 1990s, the US Department of Commerce, under whose authority NIST functions, established the concept of "NIST Traceable Reference Materials, or NTRMs". The NTRM producer was subject to NIST-mandated QA processes and procedures and paid a royalty fee. The process was abandoned with the accreditation of secondary CRM producers to ISO/IEC 17025 + ISO Guide 34, and now ISO/IEC 17034.

This author feels that it would be perfectly reasonable for the large, highly profitable producers of secondary CRMs to pay the NMI for the use of the IP that underpins the commercial product: let me know what you think!