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LETTER TO THE EDITOR

Quality management and accreditation of research tissue banks

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Herpel et al [1] are to be congratulated on achieving accreditation of their tissue bank against ISO 17020:2004 *General criteria for the operation of various types of bodies performing inspection.* However, the appropriateness of the use of this standard can be questioned. This standard is used widely to accredit *inspection bodies* in the engineering, food and asbestos sectors in the UK and in the electrical, gas and pulverisation engineering, food and radiotherapy sectors in France. It is difficult to see the parallels between research tissue banks and inspection bodies. The authors' use of ISO 17020:2004 to accredit some aspects of a research tissue bank's activities, whilst excluding the clinical data associated with the samples, collection and processing of blood and blood derivatives and any testing carried out on these samples, illustrates the difficulty in finding an accreditation standard suitable for human tissue banks set up to support research.

As Herpel et al [1] stated, ISO 9001:2008 is a suitable standard for the certification of the quality management system of all tissue banks' activities, but it does not give assurance of the quality of the technical aspects of a tissue bank's work, the accuracy of any results it produces or the professional competence of its staff. A more specific accreditation would be required to provide assurance to donors, funders, researchers and patients of a tissue bank's technical competence, as well as providing a benchmark for competitors.

There are several publications dealing with the best practices for research tissue banks, as quoted by Herpel et al [1], but these give guidance only, and none are suitable for use as an accreditation standard in their current formats. As a result, in 2007, Betsou and colleagues examined these guidelines and alternative standards for certification and accreditation (ISO 9001:2008 [2], ISO 17025:2005 [3], ISO Guide 34 [4]) and compiled them into a format compatible with an ISO accreditation standard for laboratory testing activities [5]. This proposed new standard has not been taken up by any accreditation bodies yet, and so has not progressed significantly beyond its initial publication.

The only existing national biobank-specific standard is the French standard, NF S 96-900 *Quality of biological resource centres (BRC)–Management system of a BRC and quality of biological resources form human or micro-organism origin,* published in July 2008. Its design was based on ISO9001:2008, and includes some specific technical requirements. It is applicable to the wide activities of research tissue banks and is suitable as a certification, but not as an accreditation standard. Certification against either ISO9001:2008 or NF S 96-900 is requested of research tissue banks by the French research infrastructures funding organisation (IBISA), and so far, 47 organisations have been certified, of which the majority are research tissue banks.

The French standard has not been used outside of France, but its application in France shows that a *specific* standard design for research tissue banks is useful and applicable. A project to develop a European or even better an International (ISO) standard for *accreditation* of research tissue banks is long overdue.

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