Dear Sir,

We appreciate the comments of Kastrop and Weima, who point out a new ISO standard 15189 for clinical laboratories. It is quite possible that this new standard may be of value to clinical laboratories. However, ISO 9001 is the basic standard for ISO-certification and is a requirement before other standards are implemented such as EN 17025 and 15189.

IVF centres are far more complex and integrated than the typical clinical laboratory. More specifically, IVF is a clinical enterprise that involves physicians, nurses and others whose tasks go far beyond a clinical laboratory. In fact, it is the integration of the clinical team with the laboratory that requires the most attention to ensure that the highest quality service will prevail.

In many IVF centres today, the laboratory is far more sophisticated in quality management matters than their clinical counterparts—protocols and systems are usually in place. But it is the clinical arm of the centre that often suffers from lack of stringent protocols and methods to measure outcomes.

We welcome any international standard that focuses on quality matters for the entire IVF process. Currently, there are IVF Centres with ISO 9001 and 17025 certification. Also, several European countries are beginning to recognize the value of a quality management system; Germany will mandate a quality management system for all health care providers in 2005.

We appreciate Kastrop and Weima’s comments that ISO 15189 may offer new and improved standards for clinical laboratories and we anxiously await to see if and how this may apply to the entire clinical and laboratory enterprise. But most importantly, ISO 9001 forms the basis for a quality management system internationally. Other standards may be sought afterwards by those that may be interested in taking their quality systems further. We also recognize that ISO implementation can be costly, and careful attention should be made to not set too many standards as a requirement.

We believe that ISO 9001 serves as an excellent world-wide standard. We encourage all IVF centres to consider implementing a quality management system. Experience has shown that, when conscientiously and properly implemented, ISO 9001 can improve employee and patient satisfaction and overall quality.