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What is ISO Certification, and What Does It Mean?

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I have been asked the following question many times over the years by HTM's, and a host of other technical and clinical professionals; "*what exactly does ISO certification mean and how important a consideration is it when I am thinking about potentially doing business with a 3rd Party ultrasound service company*". This is always a great question as there can sometimes be a fog around what it actually does mean. Before we move forward let's take a step back and look at ISO. ISO is a TLA (three letter acronym) that stands for; International Organization for Standardization. So the first question is; "*why isn't the acronym IOS?*" The Organization, founded in 1947, explains it this way; "*Because 'International Organization for Standardization' would have different acronyms in different languages (IOS in English, OIN in French for* Organisation internationale de normalisation*), our founders decided to give it the short form ISO. ISO is derived from the Greek word isos, meaning equal. So whatever the country, whatever the language, we are always ISO*."

Ok, so far so good. So you ask "*what do they do*"? A fine question indeed. Well for one thing they have published almost 20,000 International Standards related to both manufacturing and technologies! Those efforts are the result of the work accomplished by almost 4,000 technical bodies charged with standards development. At Acertara we have been involved in a few of those Technical Committees over the years related to diagnostic ultrasound through our membership with MITA (Medical Imaging Technology Alliance, http://www.medicalimaging.org/about-mita/members/, the medical arm of the National Electrical Manufacturers Association or NEMA).

One very common question we receive relates to how ISO Standards and certification relates to the United States Food and Drug Administration's (US FDA) Quality Systems Regulations, or QSR. Well, the short answer is; obtaining ISO certification is voluntary, but if you are offering for sale in the United States a regulated medical device or some types of service then registering as a medical device facility with the FDA is both required and enforced by law. For example, if you fail an annual re-certification audit with an ISO auditor you may not be renewed, but if you fail an audit with an FDA inspector, your business may get shut down.

"*Are there various ISO classifications and if so what do they mean to me?*" There are in fact a couple of classifications worth noting for those involved in the medical device field. The first one is known as ISO 9001:2008, the second relevant classification is ISO 13485:2003, and lastly ISO 17025:2005. Looking at each one we find the following:

ISO 9001:2008 – established the criteria for an overall quality management system (QMS). It can be used by any organization, large or small, regardless of its field of activity (e.g., from an Auto-body shop to a Zoo). While this standard does audit many essential aspects of a business operation it is not in itself enough for medical devices (a regulated industry). For example, a company that is only ISO 9001:2008 certified cannot truthfully claim or **even imply** they are ISO certified to repair ultrasound probes or ultrasound systems. This

type of a claim (Scope) requires successfully passing one more standard with specific requirements, known historically as the MDD, or medical device directive involving ISO 13485:2003.

ISO 13485:2003 - ISO 13485:2003 specifies those particular requirements for a QMS where an organization must demonstrate through objective evidence its ability to provide **medical devices and related services** that consistently meet both customer **and** regulatory requirements applicable to medical devices and related services. For example a Company that wishes to claim, and advertise, probe repair in its ISO scope must have passed a detailed ISO 13485:2003 audit where the auditor is focused on those elements of the quality system and relevant regulatory requirements (e.g., IEC 60601-2-37) related to probe manufacturing and repair. All requirements of ISO 13485:2003 are specific to organizations providing medical devices, regardless of the type or size of the organization.

The last ISO standard we will address in this short paper is ISO 17025:2005 which is an Accreditation, not simply a Certification as with ISO 9001:2008. Certification means that you have a QMS system in place that addresses the various elements in the ISO 9001:2008 standard, it does not address the Company's competence to carry out those elements. Competency to perform any given task is audited in the 17025 standard as defined below, and allows the lab to be accredited to its Scope.

ISO 17025:2005 - ISO/IEC 17025:2005 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods. At Acertara our ultrasound Acoustic Power Laboratory (API) is accredited to this standard for both regulatory testing of ultrasound systems and probes as well as for calibration; for example we are the only company in the world accredited to calibrate the probe testing device known as FirstCall.

So what are the "*take-aways*" from this brief look at the three ISO standards? Well, ISO 9001:2008 is a good QMS certification for any company to have, but it is not enough to satisfy the particular customer and regulatory requirements of the Medical Device Directive, or ISO 13485:2003. Therefore a company that is only certified to ISO 9001:2008 **cannot truthfully claim or infer** that they are "certified" to perform, for example, probe repair, or ultrasound, MRI, or CT system repair. We also addressed how ISO certification compares with FDA registration; specifically that ISO certification is voluntary, while a company that is subject to FDA requirements must be a registered entity; it is the law and not voluntary. So if a company touts they are a registered FDA facility what they are actually saying is they are conforming to the law; it is not an endorsement by the FDA of the facility's competency. Lastly, ISO 17025:2008 is about demonstrating, through various means, the technical competency of the company's staff to perform the work within the scope of the standard. This is perhaps the most difficult standard to obtain in that it requires significant testing, sampling, and inter-lab comparisons to ensure proper and accurate data are being consistently generated by the Laboratory under audit. At Acertara Acoustic Laboratories our technical and subject-matter competencies in the API and calibration lab Venn's by design into all other areas of our ultrasound business including advanced probe repair.