

# The Westgard Rules

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June 04, 2010

## Is ISO the way to go? Some say, Not So

*[Guest Post by Ian Wilson, Consultant Clinical Microbiologist]*

I read with interest your comments that ISO 15189 may be the way to go. I'd be very surprised if it is!

As a quality manager in a lab accredited by UKAS to ISO 17025 and ISO 15189, I have seen the wastefulness, stress and pathological obsessiveness of these organisations for many years. They elevate inspection of the correct procedures over broader aspects of quality. Study the history and you will see that from its inception it was about creating jobs for inspectors. They are the tail that wags the dog. Bureaucratic technicalities masquerade as quality. The workplace becomes oppressive and quality is not improved. Staff complain, but mostly they are blind to what is going on in the compliance culture. ISOs are OK for technical standards, but management works very badly when run this way.

You can be forgiven for thinking these schemes might be a good idea. Very little criticism gets published. Evidence for their effectiveness is nothing more than the repetition of their own plausible arguments. A mostly European cartel of quality and accreditation organisations effectively offers "protection" to enter the market while legally guarding themselves from competition through single-country arrangements. It continues because of marketplace and legislative coercion rather than evidence of effectiveness.

You may be unaware of Prof John Seddon who has articulated many criticisms of ISO 9000 through his experience of businesses harmed by it. It is easy for scientists to miss what he has been saying because his work is mostly with other industries. I have received very positive feedback on an article [<http://www.acb.org.uk/ACBNews/2010/april%202010v12.pdf> page 18] I wrote with comments that pathology has been done a great service by these radical views being brought to pathologists' attention. You are in a better position than most to think out how Seddon's points apply to the laboratory ISOs and to offer something better. I suggest having a look at the references below:

Seddon J. A brief history of ISO 9000. Where did we go wrong? [cited 2010 Apr 27]. Available from:



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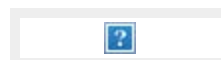
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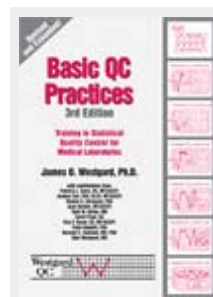
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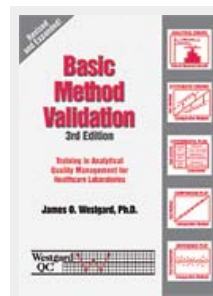
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<http://www.systemsthinking.co.uk/3-1-article.asp>.

Seddon J. Systems Thinking in the Public Sector: The Failure of the Reform Regime.... and a Manifesto for a Better Way. 1st ed. Axminster: Triarchy Press; 2008.

Seddon J. The Case Against ISO 9000. 2nd ed. Dublin: Oak Tree Press; 2000.

Also:

O'Connor PDT. Is scientific management dead? [cited 2010 Apr 27]. Available from: <http://www.pat-oconnor.co.uk/smdead.htm>.

O'Connor, PDT. ISO9000: help or hoax? [cited 2010 Apr 27]. Available from: <http://www.pat-oconnor.co.uk/iso9000.htm>.

New government in the UK is starting to change the mistakes of the last regime:

<http://opinion.publicfinance.co.uk/2010/05/celebrate-the-end-of-caa-by-john-seddon/>

Hopefully inappropriate standards of accreditation forced on us by the EC may also be removed some day. I don't think quality will be done the ISO way in a generation's time.

Eyes need to be opened about the great accreditation deception. The USA still has the opportunity to say no to the international quality cartel and the freedom to do things better.

If accreditation were a drug or treatment, would evidence be found to permit its use?

Why is the expensive intervention of accreditation permitted without evidence of value or efficacy?

Regards,

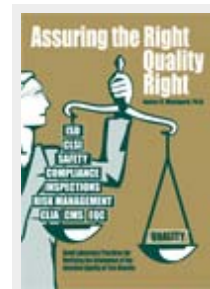
Ian Wilson

Consultant Clinical Microbiologist

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I couldn't agree more!  
Luisane Vieira - Brazil

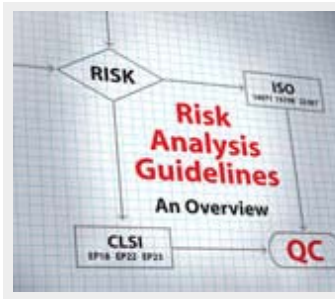
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