WHEN CAN VALIDATION *REALLY* BE CALLED VALIDATION!

Steeped in a hierarchy of terminology when the word is being related to medical decontamination products, 'validation' is one of those overused and frequently misused words that now can seem to mean anything from a complex process document that could use the trunk of a small tree to produce a hard copy report, to a speedily completed 'tick-box' on a single A4 sheet of paper.

So which one is suitable for compliance with the HTMs and acceptance from the CQC, RQIA etc. etc.?

The short answer is unfortunately during this current confused state is they both could be! No clear indicators are coming through that the latter 'tick-box' on a single A4 sheet has been judged by the inspectors to be unacceptable, and marked in red pen "see me "!

The dilemma for validation engineers, manufacturers and the dental team is what we all should be doing.

Prompted again at this year's Dental Showcase in Birmingham by the myriad of confused dentists "does the price include validation"? This invariably is followed by a debate again by manufacturers and suppliers; what sort of validation should we or do or do you need? No one wants to throw money away on unnecessary reports on equipment that appear to function normally and appear to do the job asked of it, be it to sterilize, wash & disinfect or ultrasonically clean instruments. Take just one UK guidance document, HTM01-05, the validation pre-amble in all of the equipment sections, states, "Validation is needed for all new equipment and annually thereafter". The relevant tests applicable are listed in table form for all to follow; however, reference could be made to another statement "Manufacturers' guidance on validation should be followed" So one manufacturer may interpret this as the guidance on the methodology for testing, to another manufacturer suggesting a tick-box on a single A4 sheet of paper is their guidance, or another that the frequency of testing must be every 13 weeks is their guidance.

For NHS hospitals & NHS dental community sites, testing and reporting where each piece of equipment is taken out of service for the day, four times per year has always (and still is) the norm. Are they any safer than practices with an annual tick-box on a single A4 sheet of paper? Or are they even part of the tick box-society too? Simply confirming to their peers they have carried out, checked, disposed of, trained, outcome risked assessed, without questioning why or if it is really necessary.

So it may appear to many that anything goes and none of it is really necessary, just an exercise for the bureaucrats or a way for the manufacturer/engineer to exude more money from the dental profession. At my old employer, W&H UK Ltd, they have been validating their equipment for over a decade and this had not been without a

huge investment in time and cost to train and certificate their engineering team and the cost of a kit of specialised testing equipment that ran into more than £10,000 per engineer. All of this equipment then needs to be calibrated, certificated and yes *validated* each year. All validation reports processed were checked and authorised by a competent person and many reviewed by independent or NHS employed AEDs (Authorised Engineers, Decontamination)

So the dilemma of which validation you choose or accept may not currently be answered by any enforcement from the inspection bodies, underwriters of your practice insurers or the complaints body at a GDC tribunal. It was a prerequisite of working fully or partially for the NHS that all decontamination equipment was validated and supported by a correct validation report, I suspect that this should still be the case but may not be 'enforced' universally.

Perhaps then we should just tug at the moral heartstrings. Although arguably a higher risk in procedures performed but lower in the number of patients treated, any hospital or decontamination services be it NHS or private will have all of its decontamination equipment validated using the tried and trusted method where by a small tree is sacrificed to produce a report (don't worry storing data on disc is now more common than printing) that is both meaningful and reassuring. This can be especially poignant if you, a loved one or colleague have or about to use the services of the decontamination department, knowing that the critical parameters are being met to allow the equipment to be used effectively and safely, producing clean and sterile instruments at the point of use.

Currently there seems to be a choice between spending a few pounds or a few hundred pounds, a few minutes equipment downtime to a few hours, a single page tick-sheet to a weighty 30-page report.

I hope someone who oversees and reviews Department of Health guidance documents reads this and gives the definitive and authoritative answer, then notifies the inspection agencies so we can remove the uncertainty and the real feeling of unfairness between dentist A and dentist B of which one is investing in validation or simply wasting time and money.

Meanwhile how to decide which validation is being carried out in your practice? If the next time the engineer brings in what looks like a cross between a seismic monitoring system and a mobile DJ rig, proceeds to takes up residence in the decon area, complete with ample sustenance for the long day ahead, you will realise what type of validation you are getting. This may make you feel smug & contented or slightly miffed & angry depending on your point of view of the definition of 'validation'

Malcolm Card