The use and misuse of European disinfectant test standards

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The application of disinfectant test standards varies depending on the product's intended area of use, so it is essential that users understand the background to each method/standard before the regulators come calling. Specifically, the airborne disinfection standards are being upgraded. This paper explains the background, illustrates the various 'levels' or 'phases' of some of the common tests, and introduces where the airborne disinfection standards are moving to in the future – to help you be prepared.

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European disinfectant test standards

European (EN) disinfectant test standards are important for manufacturers and users of biocidal products. They identify the level of performance a biocidal product must achieve to make efficacy claims (e.g. the product is 'bactericidal', or 'kills 99.9% of bacteria'). The standards provide users of products with reassurance that a product will achieve what is claimed on its label and will do the job that they want it to do. For example, a user can rest assured that a surface disinfectant that claims to be 'effective against viruses' will kill norovirus on a hospital floor.

Until recently, it has not been a simple task for manufacturers to determine which test standards should be applied to their products to validate the performance claims they make related to their particular intended use areas. A new European standard document EN 14885 provides guidance to manufacturers - in the form of a matrix – as to which disinfectant test methods may be applicable to their products based on the intended use. EN 14485 is known as a living document and is designed to be updated on a regular basis to reflect the development of new standards.

Unfortunately, users of automated airborne bio-decontamination systems (such as Bioquell's) have been at a disadvantage, because no EN standard test methods exist for proving the performance of such systems. Manufacturers have been able to use whatever test methods they deem appropriate to support the efficacy claims they make. Many manufacturers apply test methodologies that are wholly inappropriate such as 'suspension' or 'surface' test methodologies – these do not replicate the real-world application of the biocide via the delivery system (i.e. the gas, vapour, mist, fog or spray generator).

Disinfectant testing: phases and steps

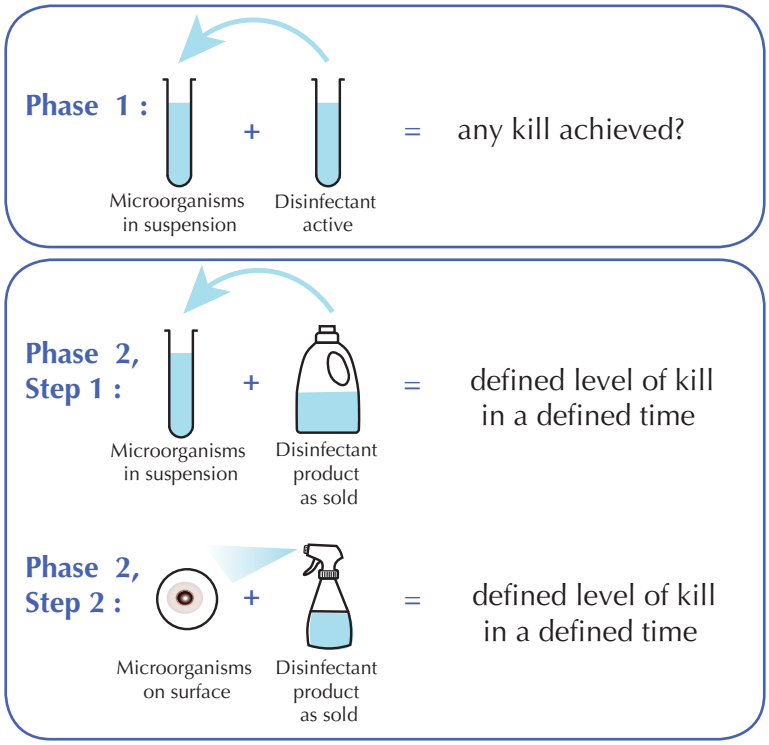
Disinfectant testing is divided into phases and steps.

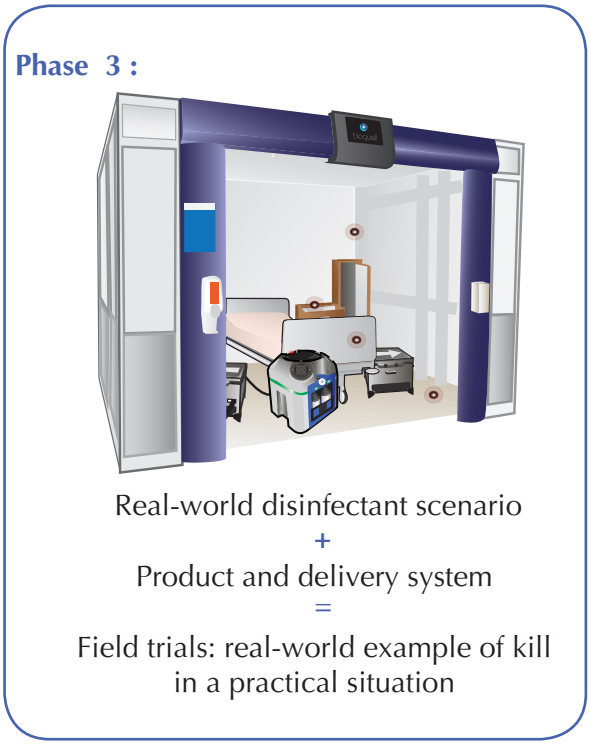
Phase 1 test – these tests are quantitative suspension tests, designed to determine whether the individual active chemicals of the biocide have any general disinfecting activity. In these tests, the chemical is diluted in sterile distilled water and poured into a test tube or vessel in conjunction with a known suspension of bacteria, fungi, etc. depending on the target organism of the disinfecting claim. The chemical is in contact with the suspension for a period of time (such as 5, 15 or 60 minutes), after which the reduction in organisms is ascertained (i.e. a >5 log reduction). EN 1040 (bactericidal) and EN 1275 (fungicidal) are examples of Phase 1 tests. These tests are used during the development of a product and are not acceptable / accepted for regulatory authorisation.

Phase 2, step 1 test – these tests are carried out on the disinfectant product as sold in its container. Again, the disinfectant is added to a suspension of bacteria, often with interfering substances such as hard water, for a period of time (e.g. 5, 15, 30, etc. minutes). The reduction in microbiological organisms is ascertained. Standards contain minimum reduction requirements to enable claims to be made (i.e. to make a bactericidal claim, a reduction of >5-log is required).

Phase 2, step 2 test – these tests are similar to Phase 2, step 1 tests, except that instead of being in suspension, the organisms are applied to a representative surface, often a stainless steel coupon. The disinfectant is applied to the coupon as a liquid or spray (determined by the specific test methodology), or the coupon is submerged in the disinfectant, for a period of time (e.g. 5, 15, 30, etc. minutes). The microbiological reductions are calculated and the pass criteria reviewed to determine whether the required performance has been achieved.

Phase 3 tests – these tests are known as field trials and represent evaluation of the disinfectant in a real-world application. Phase 3 trials are rarely carried out because they are complex, difficult to control and expensive. An example of a Phase 3 trial is the evaluation of the impact of Bioquell's HPV room decontamination technology on the acquisition rates of *Clostridium difficile* in Johns Hopkins Hospital, USA. The study was conducted over a 2 year period and showed in a real-world scenario how the Bioquell technology was effective at reducing rates of *C.diff* acquisition.[1]





The challenge of validating an airborne disinfection system

Phase 1 and Phase 2 step 1 tests cannot be used to validate the performance of disinfection systems that deliver the biocide via the air. The use of air as a vector changes the parameters of the biocide – for example, air contains water (humidity) and thus when a solution is released into the air, it is diluted by the water in the air – it is no longer at the same concentration as in the bottle. Further, to be delivered via the air, the solution is changed into a gas, vapour, mist or fog. The manner in which these chemical states interact with the surface of a microbiological organism is very different to a liquid when the organism is submerged in that liquid. As an example, pouring 35% hydrogen peroxide into a test tube containing organisms will result in very rapid kill of all organisms within that test tube (i.e. tens of seconds depending on the organism). However, application of 35% hydrogen peroxide via an airborne vapour phase distribution will take minutes to achieve the same level of kill – the processes are different.

Don't let the 'EN' numbers lead you astray

A large number of disinfectant manufacturers will test their liquid products as a surface disinfectant without mechanical action and use tests such as EN 13727 (bactericidal activity), EN 13624 (yeasticidal activity), EN 13704 (sporicidal activity) and EN 14476 (virucidal activity) to make label claims. These claims may apply to the liquid product, but they do not apply when that liquid is applied via an airborne distribution system. For example, a manufacturer selling a Quaternary Ammonium Compound (QAC) -based disinfectant, applied via an aerosol misting system, makes a claim that the product will achieve a 6-log reduction of bacteria in one minute. This claim is based on an EN 1276 (Phase 2, step 1) bactericidal activity test conducted on the liquid product. It has no relevance to the aerosol application, but is being used in the supporting literature / advertising. This provides the user with a false understanding of the efficacy of the product for their intended use, which can be dangerous and put users / patients / employees at risk.

"Claims may apply to a liquid product, but they do not apply when that liquid is applied via an airborne distribution system."

European regulators and standards experts are aware of this inappropriate application of the standards and a new EN standard is being developed specifically to test products that apply disinfectants via the air in an automated process. This standard is based on the French standard NF T 72-281 (2014), which itself has been identified in efficacy guidance issued by the European Chemicals Agency (ECHA) as the standard to be used to support efficacy claims for airborne disinfection systems under the European Biocidal Products Regulation (BPR). NF T 72-281 is described as a Phase 2, step 2 semi-field trial, due to the fact that the methodology tests the disinfectant product in combination with the distribution system (vapour, aerosol, mist, fog, etc. generator) in a room scenario. As the 'room' volume is standardised within a range in this test, it is important that results are carefully reviewed alongside the parameters that were given for the volume at the time of the test.

Bioquell's HPV bio-decontamination system has been tested to and passed NF T 72-281 (2014). Users of automated airborne disinfection systems should not accept efficacy claims from manufacturers based on simple suspension or surface tests of the liquid product. Users should request efficacy data showing compliance to NF T 72-281 (2014).

"Bioquell's HPV bio-decontamination system has passed NF T 72-281 (2014)"

Reference

1 Boyce, J.M., Havill, N.L., Otter, J.A., McDonald, L.C., Adams, N.M., Cooper, T., Thompson, A., Wiggs, L., Killgore, G., Tauman, A. and Noble-Wang, J. (2008) Impact of hydrogen peroxide vapor room decontamination on *Clostridium difficile* environmental contamination and transmission in a healthcare setting. *Infect Control Hosp Epidemiol* **29, 723-729**.

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