Current Requirements and Methods for VAH-Certification of Chemical Disinfection Procedures

Effective 02 April 2015

Commentary and Interim Measures

With effect from 02 April 2015, the new “requirements and methods for VAH certification of chemical disinfection procedures” have been published. In the process, and with the aim of incorporating European developments and new scientific findings, the former standard methods of the DGHM (Deutsche Gesellschaft für Hygiene und Mikrobiologie [German Society for Hygiene and Microbiology]) for testing chemical disinfection procedures (effective 01 September 2001) have been superseded, along with the catalogue of requirements for including chemical disinfection procedures in the disinfectant list of the DGHM (effective 04 Feb. 2002). For decades, the test methods of the DGHM have been internationally pioneering and have been continually adapted by the VAH in accordance with the state of scientific knowledge. Important aspects have been adopted in the European test methods standardised by the CEN TC 216. In this sense, the specified “requirements and methods for VAH certification in chemical disinfection procedures” should be viewed as contributing to necessary standardisation in Europe. Following stipulation of the test conditions and requirements, it became necessary to define the following transitional measures.

Interim Regulations

I. All disinfection procedures currently certified by the VAH shall retain their validity until expiration of the three-year period.

II. With immediate effect, it is recommended that for applications for the issuance of a certificate, the “requirements and methods for VAH certification of chemical disinfection procedures” (effective 02 April 2015) are taken into consideration and applied.

III. For new additions by 31 Dec. 2015, only complete documentation can be submitted, with expert opinions and test reports in accordance with the “standard methods of the DGHM for testing chemical disinfection procedures” (effective: 2001), and corresponding...
supplementary statements from previous certification notifications by the VAH’s Disinfectant Commission. After 31 Dec. 2015, two expert opinions and test reports should be submitted in accordance with the “requirements and methods for VAH certification of chemical disinfection procedures” (effective 02 April 2015).

IV. For recertification of all already listed disinfection procedures, the application for a 3-year VAH certification can be made with “old expert opinions and test reports” (effective 2001) until 31 Dec. 2015. For procedures that are applied for with “old expert opinions and test reports” after 31 Dec. 2015, the certificate shall be valid for a maximum period until 31 Dec. 2018. This also applies to alterations to already listed procedures.

V. For recertification after 31 Dec. 2015, a three-year certificate duration can only be guaranteed if at least one test report and one expert opinion is submitted in accordance with the “requirements and methods for VAH certification in chemical disinfection procedures” (effective 02 April 2015). This also applies to alterations to already certified procedures. If, as a result of testing according to the “requirements and methods for VAH certification in chemical disinfection procedures” (effective 02 April 2015), other items are applied for, which demonstrate a shorter application time, a lower concentration, a different organic load, a different efficacy spectrum or a different temperature, then two test reports and two expert opinions must be submitted according to the “requirements and methods for VAH certification in chemical disinfection procedures” (effective 02 April 2015).

VI. For recertification after 31 Dec. 2018, at least two test reports and two expert opinions must be submitted in accordance with the “requirements and methods for VAH certification in chemical disinfection procedures” (effective 02 April 2015). This can also be achieved if the test reports are supplemented with the requirements specified under “supplementary statements” and are summarised in the respective expert opinions. This also applies to alterations to already certified procedures.

**Supplementary Statements in the Event of Continuation, or Alteration of Already Listed Procedures**

According to the standard methods of the DGHM dated 2001, the supplementary statements specified below are required in addition to the existing test report, in order to satisfy the “requirements and methods for VAH certification of chemical disinfection procedures” (effective 02 April 2015). All supplementary statements must be summarised in a comprehensive expert assessment. The expert must be aware of the quality management system in place at the laboratories issuing the test reports. It should be stated in the expert opinion, in what form this has been achieved.

1. **Orientational, preliminary neutralisation tests and qualitative suspension tests**

   The orientational preliminary neutralisation tests (Chapter 7) and qualitative suspension tests (Chapter 8) can be taken from earlier test reports, providing they meet the current requirements.
2. **Hygienic hand washing**

The quantitative suspension test must be supplemented with testing for *Candida albicans*. The neutralisation period of 10 seconds should be indicated for the suspension test’s highest product concentration required for efficacy with *Escherichia coli* at the submitted application time.

3. **Hygienic hand disinfection**

The neutralisation period of 10 seconds should be indicated for the suspension test’s highest product concentration required for efficacy with *E.coli* at the submitted application time. The higher statistical evaluation requirements can be confirmed by the summary of test results from the originally submitted field tests on all test subjects, pursuant to the new calculation requirements of Hodges-Lehmann. In return, the number of results may be adapted with a reduction under 3 lg, to the actual number of test subjects evaluated. With 30 evaluated test subjects, there is, for example, an increase of 3 to 4 test subject results with a reduction under 3 lg. This evaluation must be provided by the applicant.

4. **Surgical hand disinfection**

The neutralisation period of 10 seconds should be indicated for the suspension test’s highest product concentration required for efficacy with the most sensitive and most resistant test organism at the submitted application time.

5. **Skin antiseptics**

The neutralisation period of 10 seconds should be indicated for the suspension test’s highest product concentration required for efficacy with the most sensitive and most resistant test organism at the submitted application time.

6a. **Surface disinfection without mechanical action**

For procedures with application times of < 10 minutes, the neutralisation period of 10 seconds should be indicated for the suspension test’s highest product concentration required for efficacy with the most sensitive and most resistant test organism at the submitted application time.

6b. **Surface disinfection with mechanical action**

For procedures with application times of < 15 minutes, the neutralisation period of 10 seconds should be indicated for the suspension test’s highest product concentration required for efficacy with the most sensitive and most resistant test organism at the submitted application time. In order to adopt the same concentration-time-relations in tests under practical conditions, it is sufficient to provide evidence that these values also suffice under the conditions of the “requirements and methods for VAH-certification of chemical disinfection procedures” (effective 02 April 2015). For this purpose, the field test must be performed according to Chapter 14.2.
7a. **Instrument disinfection**
For procedures with application times of < 10 minutes, the neutralisation period of 10 seconds should be indicated for the suspension test’s highest product concentration required for efficacy with the most sensitive and most resistant test organism at the submitted application time.

7b. **Chemical-thermal instrument disinfection**
For chemical-thermal instrument disinfection, expert opinions and test reports must always be submitted in accordance with the “requirements and methods for VAH-certification of chemical disinfection procedures” (effective 02 April 2015).

8. **Chemical disinfection of laundry**
For the chemical disinfection of laundry, expert opinions and test reports must always be submitted in accordance with the “requirements and methods for VAH certification of chemical disinfection procedures” (effective 02 April 2015).

9a. **Chemical-thermal disinfection of laundry at 30 to < 60° C**
In the checklist provided by the VAH, the applicant must demonstrate that the test reports meet the “requirements and methods for VAH-certification of chemical disinfection procedures” (effective 02 April 2015). If necessary, the deviations can be verified by appropriate checks. If unavailable, *Pseudomonas aeruginosa* must be investigated by means of a practical test in accordance with the “requirements and methods for VAH-certification of chemical disinfection procedures” (effective 02 April 2015).

9b. **Chemical-thermal disinfection of laundry at ≥ 60° C to 70° C**
In the checklist provided by the VAH, the applicant must demonstrate that the test reports meet the “requirements and methods for VAH-certification of chemical disinfection procedures” (effective 02 April 2015). If necessary, the deviations can be verified by appropriate checks.

Further details can be requested from the VAH Disinfectant Commission office at:
info@vah-online.de

Reference:
VAH Disinfectants Commission 2015: Interim Measures for VAH-Certification

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