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Report Highlights:

On September 23, 2022, the General Administration of Customs of the People's Republic of China (GACC) published 2022 Special Announcement Number 88 amending the customs clearance declaration requirements for importers or consignees of non-cold chain products to require a declaration on whether "preventive disinfection has been implemented" (according to the "Standards for On-site Disinfection Evaluation During the COVID-19 Epidemic" (WS/T 774-2021). This report provides an unofficial translation of the "Standards for On-site Disinfection Evaluation During the COVID-19 Epidemic."

Summary:

On September 23, 2022, the General Administration of Customs of the People's Republic of China (GACC) published 2022 Special Announcement Number 88 amending the customs clearance declaration requirements for importers or consignees of non-cold chain products (see USDA GAIN report CH2022-0102 for more information and a translation of the Announcement).

Special Announcement Number 88 provides:

A newly added declaration item of "preventive disinfection has been implemented" (according to the "Standards for On-site Disinfection Evaluation During the Novel Corona Virus Epidemic" (WS/T 774-2021): "Preventive disinfection is the disinfection of places and items that may be contaminated by pathogenic microorganisms when there is no clear source of infection)" is a check box, including two options "Yes" and "No," if the domestic consignee of imported goods or its customs declaration agent has carried out "Preventive Disinfection," select "Yes," otherwise select "No."

This report provides an unofficial translation of the "Standards for On-site Disinfection Evaluation During the Novel Corona Virus Epidemic" (WS/T 774-2021), link in Chinese, published by the National Health Commission (NHC) on February 23, 2021. The health industry standard includes 7 seven sections: Scope, Normative Reference, Terms and Definitions, Evaluation Principles, Disinfection Process Evaluation, Disinfection Effect Evaluation and Cautions.

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WS

Health Industry Standards of the People's Republic of China

WS/T 774-2021

Standard of on-site disinfection evaluation during COVID-19 epidemic

Issued on 02-20-2021 Implemented on 02-20-2021

Issued by: the National Health Commission of the People's Republic of China

Table of contents

Foreword

The Standard is drafted in accordance with the rules given in GB/T 1.1-2020.

The Standard is drafted by the National Institute of Environmental Health, China CDC, PLA Center for Disease Control and Prevention, Beijing Center for Disease Prevention and Control, Jiangsu Provincial Center for Disease Control and Prevention, Shanghai Municipal Center for Disease Control and Prevention, Hubei Center for Disease Prevention and Control, Shandong Center for Disease Prevention and Control, Guangdong Provincial Center for Disease Control and Prevention, Wuhan Center for Disease Control and Prevention, and Heilongjiang Provincial Center for Disease Control and Prevention.

The Standard is mainly drafted by: Shen Jin, Duan Hongyang, Wang Lin, Wei Qiuhua, Tong Ying, Zhang Liubo, Zhang Baoying, Xu Yan, Zhu Renyi, Pan Kai, Cui Shuyu, Jiang Yongzhong, Zhong Yuwen, Liang Jiansheng, Lin Ling.

Standard of On-site Disinfection Evaluation During COVID-19 Epidemic

1 Scope

This document provides the principles of on-site disinfection evaluation, disinfection process evaluation, disinfection effect evaluation, and matters needing attention during the COVID-19 epidemic. This document is applicable to the on-site disinfection evaluation related to the COVID-19 epidemic.

2 Normative references

The contents in the following documents constitute the essential clauses of this document through normative references herein. Wherein, in terms of the reference documents with dates, only the version corresponding to the date is applicable to this document; in terms of the reference documents without dates, their latest versions (including all modification lists) are applicable to this document.

GB/T 38502 Test Method for Sterilization Effect of Disinfectants in the Laboratory

WS/T 683 Microbiological Requirements for Disinfection Test

3 Terms and definitions

The following terms and definitions are applicable to this document.

3.1 Preventive disinfection

In case of no clear source of infection, the disinfection of the sites and articles that may be contaminated by pathogenic microorganisms.

3.2 Disinfection of epidemic focus

The disinfection of contaminated environment and articles in the epidemic focus. The epidemic focus is the range that can be reached by the pathogenic microorganisms discharged by the infectious source.

3.3 Terminal disinfection

Thorough disinfection conducted after the infectious source leaves the epidemic focus.

3.4 Concurrent disinfection

In case of clear sources of infection, the timely disinfection of the environment and articles that may be contaminated by causative agents discharged.

3.5 Process evaluation

According to the evaluation of each section of on-site disinfection, whether the on-site disinfection work is qualified is evaluated by checking key factors such as the disinfection programs, disinfection products, and disinfection operation.

3.6 Disinfection effect evaluation

According to the evaluation of the on-site disinfection effect, whether the on-site disinfection work is qualified is evaluated through testing the reduction of microorganisms before and after disinfection.

3.7 Cryogenic disinfection

Disinfection of the environment or articles with a temperature below 0°C. Cryogenic disinfection requires the use of disinfection factors that have been proven to be effective at this temperature.

3.8 Responsible entity

During on-site disinfection, the entity or institution that has the main responsibility for the on-site disinfection work.

3.9 Implementing entity

The entity or institution that is responsible for specially implementing disinfection operation by the responsible entity or entrusted by the responsible entity.

3.10 Evaluation entity

The entity or institution entrusted by the responsible entity for disinfection, which is responsible for the specific evaluation of the on-site disinfection process and disinfection effect.

4 Evaluation principles

4.1 The responsible entity for on-site disinfection shall be responsible for determining the implementing entity and evaluation entity and supervising the implementation of on-site disinfection and evaluation. The implementing entity shall be responsible for the implementation of on-site disinfection, and the evaluation entity shall have the corresponding ability of process evaluation and disinfection effect evaluation.

4.2 The on-site disinfection evaluation includes process evaluation and disinfection effect evaluation.

4.3 All on-site disinfection shall be subject to process evaluation, recorded and kept as required.

4.4 The disinfection effect evaluation shall be conducted in case of one of the following six conditions:

a) Preventive disinfection with a wide range and long duration;

b) Terminal disinfection of the epidemic focus with a large social impact;

c) The disinfection implementing entity carries out on-site disinfection for the first time;

d) The on-site cryogenic disinfection is carried out for the first time with cryogenic disinfection technology;

e) Disinfectants and disinfection equipment produced with new materials, new technology and new sterilization principles are used for on-site disinfection for the first time;

f) There is a need on site.

5 Disinfection process evaluation

5.1 Evaluation content

Disinfection process evaluation mainly includes disinfection products, disinfection operation, disinfection work programs, etc.

5.1.1 Disinfection products

The disinfection products used shall be in line with the relevant national health standards and specifications, and the health and safety evaluation shall be qualified. Disinfectant evaluation information includes the disinfectant name, the main active ingredients and their content, validity, preparation method, use scope, use methods, etc. Disinfection equipment evaluation information includes equipment name, main sterilization factors and their intensity, use scope, use methods, etc.

5.1.2 Disinfection operation

It is necessary to evaluate whether the entire disinfection operation is carried out in accordance with the disinfection work program, including but not limited to the disinfection scope, disinfection procedures, disinfectant preparation, disinfection equipment use, personal protection, etc. At the same time, it is necessary to check whether the disinfection records meet the specification, including the disinfection date, disinfection location, disinfection object, concentration and dosage of the disinfectant, action time, disinfection method, etc. Refer to Appendix A for the record.

5.2 Evaluation methods

Evaluation personnel participate in the on-site disinfection process in the whole process to check the on-site disinfection operation and relevant disinfection records.

5.3 Result determination

Disinfection process evaluation shall be in line with the relevant laws and regulations, standards, guidelines or program requirements, in order to determine the qualification of the disinfection process.

6 Disinfection effect evaluation

6.1 Evaluation objects

Disinfection effect evaluation objects include the object surface and air. For the disinfection of the environment and/or articles, the evaluation shall be carried out on the disinfection effect of

the surface of the object; during air disinfection, air disinfection effect evaluation shall be carried out.

6.2 Evaluation index

6.2.1 The on-site disinfection effect on the surface of objects is evaluated based on the killing rate of natural bacteria or indicator microorganisms, and the air on-site disinfection effect is evaluated based on the killing rate of natural bacteria.

6.2.2 The resistance of indicator microorganisms shall be comparable to or higher than that of novel coronaviruses, which shall be easy to culture and meet the requirements of laboratory biosafety and WS/T 683. The resistance of novel coronaviruses to the disinfection factor serves as a basis for selection of indicator microorganisms. During chemical disinfection, staphylococcus aureus (ATCC 6538) and escherichia coli (8099) can be selected; if there are special requirements, poliovirus-I (PV-I) vaccine strain can also be selected as the indicator microorganism. During physical disinfection, the indicator microorganisms that meet the above requirements shall be selected in accordance with the characteristics of disinfection factors.

6.2.3 During the on-site disinfection at room temperature, preventive disinfection effect evaluation chooses natural bacteria; air disinfection effect evaluation in the epidemic focus chooses natural bacteria; the evaluation of the disinfection effect on the object surface in the epidemic focus chooses indicator microorganisms. During on-site cryogenic disinfection, the evaluation of the disinfection effect on the object surface chooses indicator microorganisms. See Table 1 for details.

Table 1 Different On-site Disinfection Evaluation Objects and Microorganisms

On-site temperature	Disinfection type	Evaluation objects	Microorganisms
Room temperature	Preventive disinfection	Object surface	Natural bacteria
		Air	
	Disinfection of Epidemic Focus	Object surface	Indicator microorganisms
		Air	Natural bacteria
Low temperature	Preventive disinfection	Object surface	Indicator microorganisms
	Disinfection of Epidemic Focus	Object surface	Indicator microorganisms

6.3 Evaluation methods

6.3.1 Object surface

The key sampling targets are the floors, walls, desktops, bedside tables, toilets, door handles, and buttons. In the places where the disinfection factor is hard to reach, such as drawers, carpets, and wall corners, sampling points or indicator microorganism carriers can be added, with not less than 2 samples for each type of sampling target. In the evaluation based on natural bacteria,

sampling points before and after disinfection shall be set in pairs on the surface of the same object or on the surface of the same type of object. Sampling shall not be conducted twice in the same area. The total number of test samples shall be not less than 30.

For on-site disinfection at room temperature, the sampling and incubation methods shall be based on Appendix B. For on-site cryogenic disinfection, the indicator microorganisms shall be put in the corresponding low temperature environment for at least 30 minutes before disinfection; disinfection can be conducted after the indicator microorganisms are at the same low temperature; the sampling and incubation methods shall be based on Appendix B.

6.3.2 Air

The plate exposure method is used for air disinfection effect evaluation. If the indoor area is≤30 m^2, 3 points are set on the inner, middle, and outer diagonal lines, and the inner and outer points shall be 1 m away from the wall; if the indoor area is >30 m^2, 5 points are set in the 4 corners and the center, and the 4 corners shall be set 1m away from the wall. For the layout of a larger space (indoor area > 60m^2), more sampling points can be added according to the actual needs. The number of layout points is calculated according to Formula (1), with a maximum of 30 points. The sampling and incubation methods shall be based on Appendix B.

$$X = \sqrt{Y} \quad (1)$$

Wherein:

X—The number of points, rounding up to an integer;

Y—Indoor area (m^2).

6.4 Result determination

The average killing rate of natural bacteria on the surface of objects is ≥90%, and the number of samples with the killing rate ≥90% accounts for more than 90%, which can be judged as qualified for disinfection; the average killing rate of indicator microorganisms on the surface of objects is ≥99.9%, and the number of samples with the killing rate ≥99.9% accounts for more than 90%, which can be judged as qualified for disinfection.

The average killing rate of natural bacteria in the air is ≥90%, which can be judged as qualified for disinfection; when the average colony number of natural bacteria in the air is ≤10 CFU/ (vessel · 15 minutes) before disinfection, the killing rate may not be calculated; when the average colony number of natural bacteria in the air is ≤4 CFU/ (vessel · 15 minutes) after disinfection, it can be judged as qualified for disinfection.

7 Cautions

7.1 During on-site disinfection effect evaluation, personal protection is required; legal and effective personal protective equipment shall be selected according to the on-site conditions and relevant standards.

7.2 In view of the difficulty in isolation and culture of novel coronaviruses, it is generally not used to evaluate the disinfection effect. If a live virus is isolated after disinfection, it will be judged as unqualified for disinfection.

7.3 Novel coronavirus nucleic acid is not able to indicate whether it is alive, and nucleic acid detection results shall not be used to evaluate the disinfection effect.

7.4 During the evaluation of disinfection effect in epidemic focus, a layer of sterile pad/paper is used at the bottom of the on-site experimental equipment such as the test rack and alcohol lamp. After sampling, all equipment can be brought back to the laboratory after they are subject to disinfection.

7.5 The test shall be carried out in the bio-safety cabinet to avoid environmental pollution and damage to human health.

Appendix A
(Informative)

Disinfection Process Record

A.1 Preventive disinfection

See A.1 for the preventive disinfection process record.

Table A.1 Preventive Disinfection Process Record

No.:

Disinfection location:								
Environment temperature of disinfection:								
Disinfection area/number of pieces:								
Disinfection products/equipment name:								
Main active ingredients/sterilization factors and their content (intensity):								
Valid date (opening date):								
Preparation method:								
Freshly prepared for use (Y/N):								
Brief description of the disinfection procedure:								
Hand disinfectant for the disinfection personnel (opening date):								
Protective equipment for disinfection personnel:								
Preparation date	Disinfection date	Starting and ending time of disinfection	Disinfection object	Concentration or intensity	Action time	Disinfection method	Total usage amount	Disinfection area (m^2)/space (m^3)/quantity
Disinfection implementing entity:								
Disinfection implementing personnel:								
Recorded by:					Date and time of recording:			

A.2 Terminal disinfection

See A.2 for the terminal disinfection process record.

Table A.2 Terminal Disinfection Process Record

No.:

<table>
<tr><td colspan="4">Disinfection notification entity:</td><td colspan="3">Disinfection location:</td></tr>
<tr><td colspan="4">Contact person:</td><td colspan="3">Contact telephone number:</td></tr>
<tr><td colspan="4">Name of infectious disease:</td><td colspan="3">Date of diagnosis:</td></tr>
<tr><td colspan="4">Disinfection notification date:</td><td colspan="3">Disinfection completion date:</td></tr>
<tr><td colspan="4">Starting time of disinfection:</td><td colspan="3">Completion time of disinfection:</td></tr>
<tr><td colspan="4">Environment temperature of disinfection:</td><td colspan="3">Disinfection area/number of pieces:</td></tr>
<tr><td colspan="7">Name of disinfectant/equipment:</td></tr>
<tr><td colspan="7">Main active ingredients/sterilization factors and their content (intensity):</td></tr>
<tr><td colspan="7">Valid date:</td></tr>
<tr><td colspan="7">Preparation method:</td></tr>
<tr><td colspan="7">Freshly prepared for use (Y/N):</td></tr>
<tr><td colspan="7">Brief description of the disinfection procedure:</td></tr>
<tr><td colspan="7">Hand disinfectant for the disinfection personnel (opening date):</td></tr>
<tr><td colspan="7">Protective equipment for disinfection personnel:</td></tr>
<tr><td>Preparation date</td><td>Disinfection object</td><td>Concentration or intensity</td><td>Action time</td><td>Disinfection method</td><td>Total usage amount</td><td>Disinfection area (m^2)/space (m^3)/quantity</td></tr>
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<tr><td colspan="7">Disinfection implementing entity:</td></tr>
<tr><td colspan="7">Disinfection implementing personnel:</td></tr>
<tr><td colspan="3">Recorded by:</td><td colspan="4">Date and time of recording:</td></tr>
</table>

A.3 Concurrent disinfection

See A.3 for the concurrent disinfection process record.

Table A.3 Concurrent Disinfection Process Record

No.:

Disinfection location:							
Name of infectious disease:							
Date of diagnosis:							
Name of disinfectant/equipment:							
Main active ingredients/sterilization factors and their content (intensity):							
Valid date:							
Preparation method:							
Freshly prepared for use (Y/N):							
Brief description of the disinfection procedure:							
Hand disinfectant for the disinfection personnel (opening date):							
Protective equipment for disinfection personnel:							
Preparation date	Date and time of disinfection	Disinfection object	Concentration or intensity	Action time	Disinfection method	Total usage amount	Disinfection area (m^2)/space (m^3)/quantity
Disinfection implementing entity:							
Disinfection implementing personnel:							
Recorded by:			Date and time of recording:				

Appendix B

(Normative)

Evaluation Methods for On-site Disinfection Effect

B.1 Basic requirements

B.1.1 During the evaluation based on natural bacteria, the sampling of disinfection objects is conducted before and after disinfection.

B.1.2 After chemical disinfection, the sampling solution shall be the corresponding neutralizer (which is proved to be effective by neutralization qualification test).

B.1.3 Samples shall be tested as soon as possible after sampling, and the inspection time at room temperature shall not be more than 4h; if the sample is stored at 0℃ - 4℃, the inspection time shall not be more than 24h.

B.1.4 During disinfection effect evaluation, the disinfection effect evaluation shall be recorded, including the sample name, source, quantity, number, inspection index, sampling date, sampling personnel, inspection results, signatures of inspectors and auditors, etc.

B.2 Object surface disinfection effect evaluation

B.2.1 Natural bacteria

Before disinfection, put a 5 cm×5 cm sterilization specification plate on the surface of the object, smear horizontally and vertically with a cotton swab soaked with sterile 0.03 mol/L phosphate buffer solution or normal saline sampling solution on the sterilization specification plate for 5 times back and forth, then rotate the cotton swab, continuously take samples on several specification plate areas, cut off the part of hand contacting, and put the cotton swab into a test tube containing 10 mL of sampling solution; after the active time of disinfection is reached, take samples on the surface of the object paired with the former according to the above method, and put the cotton swab into a test tube containing 10 mL of corresponding neutralizer. When the surface of the object subject to sampling is < 100 cm^2, all the surfaces are taken; when the surface of the object subject to sampling is ≥100 cm^2, 100 cm^2 is taken. The areas subject to the two samplings shall be consistent.

B.2.2 Indicator microorganisms

The experimental bacteria pieces are prepared according to GB/T 38502 (tryptone soya broth culture medium is used as the organic interference during the evaluation of on-site cryogenic disinfection effect), so that the number of bacteria recovered from each bacteria piece is 1×10^6 CFU/ piece - 5×10^6 CFU/piece. Generally, a cloth piece (1 cm×1 cm) is selected as the carrier of bacterial infection. When disinfection methods such as aerosol or spray with an ultra-low volume are used, carriers with adsorption capacity such as cloth pieces and filter paper shall not be used. A metal piece (Φ1.2 cm) or glass piece (1 cm×1 cm) can be selected.

Before disinfection, according to the point arrangement requirements, place the bacteria pieces on the on-site. After the active time of disinfection is reached, use sterile tweezers to move the bacteria pieces into a test tube containing 5.0 mL of corresponding neutralizer, and then shake it in your palm for 80 times or mix them with a blender, and neutralize them for 10 minutes. At the same time, a positive control group shall be set. During on-site cryogenic disinfection, the positive control group and the experimental group are put into the corresponding low temperature environment, and after the same low temperature is reached, they are put into the diluent for counting.

B.2.3 Detection method

Shake the sampling tube on the blender for 20s or shake it hard for 80 times, absorb 1.0 mL of the sample to be tested and inoculate it into the sterile plate, inoculate 2 plates in parallel for each sample, add 15 mL - 18 mL of the dissolved culture medium (corresponding culture medium) at 45℃ - 48℃, pour it while well shaking, wait for the agar to solidify, incubate at 36℃ ± 1℃ for 48h (the special indicator microorganisms are incubated according to the corresponding requirements), count the number of colonies, and calculate the killing rate.

B.2.4 Result calculation

The killing rate is calculated as per Formula (B.1):

$$X = \frac{A-B}{A} \times 100\% \quad \text{(B. 1)}$$

Wherein:

X—The killing rate (%);

A—The number of bacteria before disinfection or the number of bacteria recovered from the positive control group (CFU/sample);

B—The number of bacteria after disinfection or the number of bacteria recovered from the experimental group (CFU/ sample).

B.3 Air disinfection effect evaluation

B.3.1 Sampling method

Sampling before disinfection: According to the sampling requirements, place a common nutrient agar plate (Φ90 mm) at each sampling point, and the sampling height is 0.8 m - 1.5 m above the ground. During sampling, put the sterile pad/paper at the arranged points, place the plate on the pad/paper, open the plate cover, buckle it beside the plate, cover the plate cover after exposure for 15 minutes, disinfect the outer surface of the plate, and send it for inspection in time. The pad/paper shall be treated as medical waste. Each plate shall be marked.

Sampling after disinfection: After air disinfection reaches the specified time, put another group of common nutrient agar plate with the corresponding neutralizer on the same position of sampling before disinfection. The placing method and exposure time are the same as those of

sampling before disinfection. At the same time, 2 identical plates without sampling are taken as negative controls.

B.3.2 Detection method

Put the plate in a constant temperature box at 36℃±1℃ for 48h, and count the number of colonies.

B.3.3 Result calculation

The average killing rate of natural bacteria is calculated as per Formula (B.2):

$$X = \frac{A-B}{A} \times 100\% \quad \text{(B. 2)}$$

Wherein:

X- The average killing rate of natural bacteria (%);

A- Average number of colonies per vessel CFU/ (vessel • exposure time) before disinfection;

B- Average number of colonies per vessel CFU/ (vessel • exposure time) after disinfection.

END UNOFFICIAL TRANSLATION

Attachments:

No Attachments.