

**INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

SN/T 4801-2017

**Requirements and assessment procedures of qualified
suppliers for import and export animal quarantine reagent**

进出境动物检疫试剂合格供应商的基本要求与评定程序

(English Translation)

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard is proposed and managed by the National Certification and Accreditation Administration.

This standard was drafted. Beijing Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China, Liaoning Entry-Exit Inspection and Quarantine Bureau, Beijing Veterinary Drug Supervision Institute, China Academy of Inspection and Quarantine, Jiangsu Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China.

1 Scope

This standard specifies the basic requirements and assessment procedures for qualified suppliers of animal quarantine testing reagents for entry and exit.

This standard applies to the assessment of qualified suppliers of animal quarantine testing reagents for entry and exit.

2 Evaluation of the basic conditions that the laboratory should have

2.1

The laboratory shall establish a qualified supplier evaluation procedure for the testing reagents that have an impact on the quality of the testing work.

2.2

The laboratory shall have the technical ability to verify the quality of the test reagents (including professional technicians and corresponding equipment).

2.3

The laboratory should be aware of the transport and storage conditions of the test reagents used.

2.4

The laboratory shall establish an evaluation index for the qualified supplier of the evaluation test reagent.

2.5

The laboratory should be aware that the supplier is the manufacturer of the test reagent or the sales agent for the test reagent.

2.6

There is a person responsible for the quality of the test reagents.

3.1 Qualification

3.1.1

The agent must have the qualification for administrative approval of legally operating animal testing reagents, such as business license, organization code certificate, Tax registration certificates, etc., all of these documents should be within the validity period.

3.1.2

The agent must have a product agency authorization letter from the manufacturer and is within the validity period.

3.2 Agent's reserve and transportation conditions

3.2.1

The agent of the bioassay reagent should have a fixed business place that is compatible with the bioassay reagents it operates, and can provide housing rent.

Proof of contract or title certificate.

3.2.2

Cold chain equipment and related supplies that meet the storage and transportation conditions, and matched with the supply, can provide relevant supporting documents.

3.2.3

Control measures such as anti-freeze, sun protection, moisture-proof, leak-proof, insect-proof and rodent-proof are necessary, and relevant procedures and certification materials are provided.

3.2.4

There are emergency equipment (backup power supply) and preventive measures to prevent water cuts, power cuts, etc., and provide relevant emergency plans.

3.2.5

Storage and transportation equipment such as warehouses and refrigerators, freezers, etc. have real-time monitoring of temperature and humidity, and should have corresponding monitoring equipment and be verified.

Keep relevant records for future reference.

3.2.6

There are a series of disinfection and anti-pollution measures, and provide program files and necessary equipment certification materials and equipment list.

3.2.7

Warehousing and transportation equipment shall be subject to metrological certification, and relevant equipment verification/calibration certificates shall be provided and within the validity period.

3.3 Professional technical service capabilities

3.3.1

The agent shall have more than one veterinarian or biological professional technician, who can provide a list of personnel, a degree certificate, a labor contract, Proof documents such as social security contributions.

3.3.2

Technicians can provide the necessary technical guidance for the storage and transportation of biological reagents, and can provide technical solutions to customer questions.