9623 Guideline for Rubber Closures for Pharmaceutical Packages

This guideline is applicable to the rubber closures used as part of a pharmaceutical product packaging system.

Rubber closures for pharmaceutical packages (hereinafter referred to as rubber closures) could be classified in terms of intended use, base material, overall structure, pretreatment, etc.

In terms of intended use, rubber closures could be classified into rubber closures for packages for injections, inhalation preparations, oral preparations, or other preparations.

In terms of base material, rubber closures could be classified into rubber closures made of (halogenated) butyl rubber, polyisoprene rubber, silicone rubber, ethylene-propylene rubber, other synthetic rubber, etc., and base material by mixing or lamination of different rubbers.

In terms of overall structure, rubber closures could be classified into rubber closures with ordinary, multilayer or filmed structure. According to the film-forming process, filmed rubber closures may be further divided into rubber closures with laminated, coated or deposited film. Film materials generally used include organic fluorine, silicone and other plastic materials.

In terms of pretreatment, rubber closures could be classified into routine, ready-to-sterilize and sterile rubber closures which are also referred to as ready-to-use rubber closures.

1 Terms and Definitions

Rubber Closure: Elastomeric components with different structures and shapes, obtained by crosslinking (vulcanization) of one or various kinds of rubber as base polymer, using necessary additives, such as fillers, curatives, etc., act as closures when combined with other components of container-closure systems.

2 General requirements

2.1 Manufacturing Requirements

During the formulation design, research and development of rubber closures, the regulatory compliance and safety of relevant materials including their compositions shall be confirmed. Raw materials and processing aids that significantly affect the quality of pharmaceutical products would be avoided, the identification and control of toxic or harmful impurities shall be strengthened, and attention should be paid to organic small molecule residues, metal elements or other relevant extractables of rubber closures.

The formulation and manufacturing processes of rubber closures shall be fully validated and effectively controlled in accordance with relevant Good Manufacturing Practice to ensure the quality homogeneity. If barrier materials are used in filmed rubber closures, the quality control of film integrity and thickness should be strengthened.

Rubber closures shall be appropriately cleaned and dried. Selected water for gross rinse and precisely washing shall be of appropriate quality to comply with the requirements for their intended use, and validation of the effectiveness of the cleaning procedures shall be carried out when necessary. If siliconization is performed, dimethicone that meets the requirements for pharmaceutical use should be used, and the control of the amount of silicone oil and the uniformity of siliconization should be strengthened. If sterilization procedures are required, the effectiveness of sterilization shall be validated and its impact on the performance of rubber closures should be fully assessed.

During the processes of manufacturing, packaging, storage and transportation of rubber closures, attention should be paid to the relevant requirements of the quality management of the pharmaceutical products to be packaged. Cleaning, sterilization (when applicable) and packaging procedures of ready-to-sterilize and sterile rubber closures shall be performed in a controlled environment, taking the cleanliness requirements of pharmaceutical products to be packaged into account. For ready-to-sterilize and sterile rubber closures, attention should be paid to the protection ability and the shelf life of the packages used.

2.2 Application Requirements

When necessary, relevant evaluations and tests of Guideline on Biological Evaluation and Test Selection of Pharmaceutical Packaging Materials (Guideline 9629) shall be carried out. Compatibility studies should be conducted when needed, and risk assessments of elemental impurities should be focused on. The performance of processing compatibility in the procedures of packaging pharmaceutical products, the protection ability covering the entire life cycle of the pharmaceutical products, the functionality in the clinical use of pharmaceutical products should be assessed and confirmed.

Attention should be paid to the suitability of shape and dimensions of rubber closures with other components. For filmed rubber closures, the coverage area of the film and the performance of the sealing surface should be concerned to avoid possible adverse effects on the sealability due to partial shedding of the film or the difference in

properties of various materials.

The critical quality attributes of rubber closures shall be defined based on the relevant necessary studies and assessments according to the requirements of risk management throughout the life cycle of pharmaceutical products, and strictly controlled in accordance with enterprise standards or quality agreements to protect the safety, efficacy and quality controllability of the pharmaceutical products.

3 Quality Control

Based on the actual manufacturing and use of rubber closures, the manufacturers and the end users shall define suitable tests for quality control, including but not limited to the relevant provisions of the text and Annex 1 or 2, formulate the enterprise standards or quality agreements, as well as testing rules in line with risk management requirements of manufacturing and use, to meet clinical needs, ensure quality controllability and safe use of pharmaceutical products.

3.1 Identification

Applied to identify the base materials and film materials (if any) of rubber closures. To improve the reliability of the characterization of rubber closures, it is advisable to apply various identification methods including the following procedures.

3.1.1 Infrared Spectroscopy. Applied to the base materials of rubber closures. Cut the sample, and examine the cut surface according to Method II of Infrared Spectroscopy of Pharmaceutical Packaging Materials (General Chapter 4002). If rubber materials (with much carbon black) cannot reflect infrared light, perform the test according to Method I-3 of Infrared Spectroscopy of Pharmaceutical Packaging Materials (General Chapter 4002). The infrared spectrum of the base material (including each layer of material) shall comply with the relevant specifications of enterprise standards or quality agreements.

Applied to the film materials of filmed rubber closures. Wipe the film with acetone or other suitable solvents, evaporate to dryness, and examine the wiped part according to Method II of Infrared Spectroscopy of Pharmaceutical Packaging Materials (General Chapter 4002). The infrared spectrum of the film shall comply with the relevant specifications of enterprise standards or quality agreements.

3.1.2 Ash. Applied to the rubber closures containing inorganic fillers. Test according to Determination of Ash in Rubber Closures (General Chapter 4220). If above 10per cent, the percentage content of ash should not exceed ±2.0 percent to which defined in enterprise standards or quality agreements, and the ash content of 10 percent or less

shall comply with the relevant specifications of enterprise standards or quality agreements.

3.1.3 Density. Applied to silicone rubber closures. Heat 2 g of the samples under reflux with 100 mL of water for 2 hours, dry at 80 ℃, and then test according to Determination of Density of Pharmaceutical Packaging Materials (General Chapter 4012). The result shall be 1.05 to 1.25 g/cm^3.

3.2 Physicochemical Tests

Applied to routine assessment of possible leachables from rubber closures. Tests are usually performed for water-soluble substances and specific residues under controlled extraction conditions to reduce the relevant risks of rubber closures actually used. If rubber closures are used for preparations containing non-aqueous solvents, the possible effects should be evaluated, and if necessary, to be controlled by enterprise standard or quality agreements.

3.2.1 Water-soluble Substances

For the rubber closures subjected to steam sterilization, perform the following corresponding tests according to Determination of Extractables for Pharmaceutical Packaging Materials and Containers (General Chapter 4204). If other sterilization procedures are used, such as ethylene oxide sterilization, radiation sterilization, etc., the possible effects of these procedures should be assessed, and if necessary, be controlled by enterprise standard and quality agreements.

When applied to the (halogenated) butyl rubber and polyisoprene rubber closures, take an appropriate amount of uncut samples (with a total surface area close to 200 cm^2) and prepare the test solution (boiling and rinsing procedures are exempted for ready-to-sterilize and sterile rubber closures) and blank solution according to Method II in Table 1 of Determination of Extractables for Pharmaceutical Packaging Materials and Containers (General Chapter 4204).

When applied to the silicone rubber closures, take an appropriate amount of uncut samples (mass close to 25 g) and prepare the test solution and blank solution according to Method XI in Table 1 of Determination of Extractables for Pharmaceutical Packaging Materials and Containers (General Chapter 4204).

3.2.1.1 Clarity and Color. The test solution shall be clear and colorless, otherwise not more opalescent than Reference suspension 2 or not more intensely colored than yellowish green No.5 color standard.

3.2.1.2 Change of pH. The rubber closures for packages for injections or for oral

preparations shall comply with the specifications in Table 1 or Table 2, respectively. If the requirements are met, the test of Acidity or Alkalinity could be exempted, otherwise shall be carried out, and whose results are taken to make the judgment.

3.2.1.3 Acidity or Alkalinity. Not more than 0.3 mL of sodium hydroxide volumetric solution (0.01mol/L) is consumed, or not more than 0.8 mL of hydrochloric acid (0.01mol/L) is consumed.

3.2.1.4 Absorbance. For the maximum absorbance of the test solution at wavelengths between 220 and 360 nm, the rubber closures for packages for injections or for oral preparations shall comply with the specifications in Table 1 or Table 2, respectively.

3.2.1.5Reducing substances. The rubber closures for packages for injections or for oral preparations shall comply with the specifications in Table 1 or Table 2, respectively.

3.2.1.6Residue on evaporation. The rubber closures for packages for injections or for oral preparations shall comply with the specifications in Table 1 or Table 2, respectively.

3.2.1.7Conductivity. The rubber closures for packages for injections shall comply with the specifications in Table 1.

Table 1

Packaging System/Assembly	Rubber Closures	Limits				
		Change of pH	Absorbance	Reducing substances (ml)	Residue on evaporation (mg)	Conductivity (μS/cm)
Packaging System for Injections	Stopper	1.0	0.1	3.0	2.0	10.0
Packaging System for Sterile Powders for Injection	Stopper	2.0	0.2	7.0	4.0	20.0
Prefilled Syringes and Pen-injectors	Plunger	1.0	0.1	3.0	2.0	20.0
	Tip cap	2.0	0.2	3.0	2.0	20.0
	Needle shield (Multilayer)	3.0	0.3	7.0	4.0	40.0
	Septum	2.0	0.2	3.0	2.0	20.0
Combination Caps of Plastic Infusion Containers	Cap Liner	3.0	0.3	3.0	4.0	40.0

Table 2

Packaging System	Rubber Closures	Limits			
		Change of pH	Absorbance	Reducing substances (ml)	Residue on evaporation (mg)
Packaging System for Oral Preparations	Silicone rubber closures	1.0	0.1	1.0	2.0
	(Halogenated) butyl rubber, polyisoprene rubber closures	3.0	0.3	7.0	4.0

3.2.1.8 Ammonia. Applied to rubber closures using or generating compounds containing amine groups. Not more than 0.0002%.

3.2.1.9 Metal Ions. When applicable, taking into account of the possible hazardous elements and formulation elements in the rubber closures, perform the test according to Determination of Element Impurities in Drug Packaging Materials (General Chapter 4214). The results shall comply with the relevant specifications of enterprise standards or quality agreements.

3.2.2 Specific Residue

The type and the content of the residues mainly depend on the formulation and process of rubber closures. The following test of Volatile sulfides shall be carried out for (halogenated) butyl rubber and polyisoprene rubber closures, the following tests of Phenylated compounds, Substances soluble in hexane, Volatile matter, Mineral oils and Residual peroxides should be carried out for silicon rubber closures according to the Determination of Specific Residues in Silicon Rubber Closures (General Chapter 4223).

3.2.2.1 Volatile sulfides. Applied to rubber closures using sulfur or sulfur-containing compounds. Test according to Determination of Volatile Sulfides in Rubber Closures (General Chapter 4219). Any black stain caused by test samples is not more intense than that of the reference (not more than 1.0μg/cm2, calculated as sulfur).

3.2.2.2 Phenylated compounds. The maximum absorbance is not greater than 0.4.

3.2.2.3 Substances soluble in hexane. The residue weighs not more than 15 mg.

3.2.2.4 Volatile matter. Maximum 2.0 per cent.

3.2.2.5 Mineral oils. Fluorescence shall not appear, and if appears, it is not greater than that of the reference solution.

3.2.2.6 Residual peroxides. Applied to silicone rubber closures prepared using peroxides. The difference between the titration volumes of test sample and the blank is not greater than 2.0 mL (equals to 0.08 per cent, calculated as dichlorobenzoyl peroxide).

Annex 1 Rubber Closures for Packages for Injections

This annex is applicable to the rubber closures used as part of injection packaging systems.

In addition to the classification in the text, rubber closures for packages for injections could also be classified according to their intended uses and shapes, degree of contact with preparations, and the manner of clinical use.

In terms of the intended uses and shapes, rubber closures for packages for injections may be classified into rubber stoppers for glass bottles for infusions and glass vials for

injections, rubber closures for plastic packaging systems and components for infusions, rubber closures for prefilled syringes and for pen-injectors, etc. Rubber closures for plastic packaging systems and components for infusions may be classified into cap liners for combination caps of plastic packaging systems, rubber stoppers and liners for administration ports of plastic infusion bags, and rubber stoppers for plastic infusion bottles, etc. Rubber closures for prefilled syringes may be classified into plunger stoppers and caps, including needle shields and tip caps. Rubber closures for pen-injectors may be classified into plunger stoppers and septums, which are generally used in combination with aluminum caps.

According to the degree of being in contact with preparations, the rubber closures may be classified into rubber closures in persistent contact, in transient contact and in indirect contact with preparations in terms of the direct contact time, or classified into rubber closures for packages for aqueous injections and for sterile powders for injection (including freeze-dried preparations for injection) in terms of the contact state.

In terms of the manner of clinical use, the rubber closures may be classified into rubber closures to be pierced and not to be pierced. Rubber closures to be pierced may be further classified into rubber closures singly pierced by infusion sets for intravenous administration (hereinafter referred to as rubber closures pierced by infusion sets), and singly or multiply pierced by hypodermic needles for product dissolution or transfer (hereinafter referred to as rubber closures singly or multiply pierced by hypodermic needles).

Rubber closures for packages for injections shall comply with the relevant provisions in the text and the following requirements.

1 Overall Requirements

For ready-to-sterilize and sterile rubber closures for packages for injections, validation of the processes of depyrogenation and sterilization (when applicable) shall be conducted.

For the rubber closures for freeze-dried preparations, attention should be paid to the structure design, such as the position and size of the positioning element, which should not adversely affect the sealing performance of the rubber closures. Attention should be

paid to residual moisture of the rubber closures, on which the possible effects of the formulations and processes should be evaluated when necessary. Appropriate techniques could be used to assess the water content and the effectiveness of the drying process conditions, and water content of rubber closures shall be effectively controlled before use following the stability requirements of the pharmaceutical products.

For the design of rubber closures for prefilled syringes and for pen-injectors, the different functional requirements of manual or automatic use should be taken into account.

The packaging materials in direct contact with rubber closures shall comply with the relevant requirements of pharmaceutical packages. The packages for sterile rubber closures should be resistance to the sterilization processes applied, cause no adverse influence on the effects of sterilization, and meet the requirements of quality management and needs of pharmaceutical production. The sealed packages shall be of enough integrity, and the primary and secondary packaging as a whole should meet the requirements for protection performance during the transportation and storage. The rubber closures should be stored in the dry, clean and well-ventilated indoor environment.

2 Physicochemical Tests

2.1 Water content. Applied to sterile rubber closures for packages for freeze-dried preparations for injection. When necessary, perform the test according to Method II of Determination of Water for Rubber Closures (General Chapter 4221), and the results shall comply with the relevant specifications of enterprise standards or quality agreements.

2.2 Silicone oil content on the surface. Applied to rubber closures for packages for injections which are in direct contact with pharmaceutical products whose quality could be affected by the silicone oil. When necessary, perform the test according to Determination of Silicone Oil on the Surface of Rubber Closures (General Chapter 4222), and the results shall comply with the relevant specifications of enterprise standards or quality agreements.

3 Clinical Use Performance Tests

If rubber closures would be penetrated by hypodermic needles and infusion sets simultaneously in clinical use, corresponding tests of rubber closures pierced by infusion

sets and pierced by hypodermic needles are carried out respectively when necessary, and all results shall comply with the relevant requirements.

3.1 Rubber Stoppers for Glass Bottles for Infusions and Glass Vials for Injections

The following tests are carried out for rubber stoppers for glass bottles for infusions and glass vials for injections. For rubber stoppers for packages for freeze-dried preparations, the following tests are carried out after the samples were pretreated under freezing conditions specified in enterprise standards or quality agreements.

3.1.1 Fragmentation. Applied to the rubber stoppers pierced by infusion sets. Perform the test according to Method I of Test for Fragmentation of Closures and Seals for Parenteral Preparations (General Chapter 4016). The number of observed particles is not more than 20.

Applied to the rubber stoppers pierced by hypodermic needles. Perform the test according to Method II of Test for Fragmentation of Closures and Seals for Parenteral Preparations (General Chapter 4016). The number of observed particles is not more than 5.

3.1.2 Penetration force. Applied to the rubber stoppers pierced by infusion sets. Perform the test according to Method I of Test for Penetrability of Closures and Seals for Parenteral Preparations (General Chapter 4015). The average of all test samples is not more than 75 N and all test samples does not exceed 80 N, and no rubber stopper is pushed into the bottle during the piercing.

Applied to the rubber stoppers pierced by hypodermic needles. Perform the test according to Method II of Test for Penetrability of Closures and Seals for Parenteral Preparations (General Chapter 4015), and the penetration force for all test samples does not exceed 10 N.

3.1.3 Spike retention and sealability Capacity. Applied to the rubber stoppers pierced by infusion sets. Take 10 samples pretreated according to Method I of Test for Penetrability of Closures and Seals for Parenteral Preparations (General Chapter 4015), and 10 matched bottles for injections filled to the nominal volume with water, then crimp the matched aluminum caps or aluminum-plastic caps. Use the metal spikes described in Method I of Test for Penetrability of Closures and Seals for Parenteral Preparations

(General Chapter 4015) to vertically pierce the marked area until complete penetration is achieved. Position the bottles with the bottom end up and attach a mass of 0.5 kg to each spike. Spikes shall be retained in the closures for 4h and no liquid leakage shall be observed at the puncture sites of the stoppers.

3.1.4 Self-sealing Capacity. Applied to rubber stoppers multiply pierced by hypodermic needles, and need to be performed only after being fitted with other assembly components. Take 10 samples pretreated according to Method II of Test for Penetrability of Closures and Seals for Parenteral Preparations (General Chapter 4015).Take 10 matched vials for injections filled to the nominal volume with water, then fit the above rubber stoppers and secure with the matched fasteners. Use injection needles defined in Method II of Test for Penetrability of Closures and Seals for Parenteral Preparations (General Chapter 4015)to vertically pierce the different puncture sites of each stopper3 times, changing a new needle after every 10 punctures. Immerse the above test samples bottom end up in 0.1% methylene blue solution in a container with a vacuum pump, reduce the pressure by 27kPa and hold for 30 min, then restore to atmospheric pressure and hold for another30 min. Take the test samples out, rinse the outsides of the vials with water. Any trace of methylene blue solution is observed in none of the containers. For rubber stoppers specified the test of self-sealing capacity, the test of Sealability of Closures for Containers is generally not required further.

3.1.5 Sealability of closures for containers. Applied to the rubber stoppers singly pierced by hypodermic needles, and need to be performed only after being fitted with other assembly components. Take 10 samples pretreated according to Method II of Test for Penetrability of Closures and Seals for Parenteral Preparations (General Chapter 4015). Take 10 matched vials for injections filled to the nominal volume with water, then fit the above rubber stoppers and secure with the matched fasteners. Immerse the above test samples bottom end up in 0.1% methylene blue solution in a container with a vacuum pump, reduce the pressure by 27kPa and hold for 30 min, then restore to atmospheric pressure and hold for another 30 min. Take the test samples out, rinse the outsides of the vials with water. Any trace of methylene blue solution is observed in none of the vials. If direct observation is impossible, the solution may be taken out by a

suitable method and inspected visually. The solution does not appear blue.

3.2 Rubber Closures for Plastic Packaging Systems and Components for Infusions

The following tests are carried out for cap liners for combination caps of plastic packaging systems. For other rubber closures for plastic packaging systems and components for infusions, taking account of the characteristics of packaging systems and the manners of clinical use, the relevant clinical use performance tests specified in enterprise standards or quality agreements shall be complied with.

3.2.1 Fragmentation. Perform the test according to Method III of Test for Fragmentation of Closures and Seals for Parenteral Preparations (General Chapter 4016) (The plastic packaging systems for infusions may act as the supporting device. Fit the cap liners to matched plastic infusion containers separately, fill the containers to the nominal volume with water, seal and sterilize according to the pretreatment conditions.). The number of observed particles shall be not more than 20.

3.2.2 Penetration force. Perform the test according to Method III of Test for Penetrability of Closures and Seals for Parenteral Preparations (General Chapter 4015) (The plastic packaging systems for infusions may act as the supporting device. Fit the cap liners to matched plastic infusion containers separately, fill the containers to the nominal volume with water, seal and sterilize according to the pretreatment conditions.). The average of all test samples are not more than 75 N and all test samples do not exceed 80 N.

3.2.3 Spike retention and sealability. Need to be performed only after the rubber closures are fitted with other assembly components. Fit 10 cap liners to matched plastic infusion containers separately, fill the containers to the nominal volume with water and seal. Use the plastic spike described in Method III of Test for Penetrability of Closures and Seals for Parenteral Preparations (General Chapter 4015) to vertically pierce the marked area until complete penetration is achieved. Position the containers with the bottom end up and attach a mass of 0.3 kg to each spike. Spikes shall be retained in the closures for 4h and no liquid leakage shall be observed at the puncture sites of the closures.

3.3 Rubber Closures for Prefilled Syringes

Only after rubber closures for prefilled syringes are subassembled or assembled with other assembly components，corresponding tests need to be performed, and the results shall comply with the relevant specifications of Prefilled Syringes (Guideline 9626 Annex 1).

3.4 Rubber Closures for Pen-injectors

Only after rubber closures for cartridge systems for pen-injectors are subassembled or assembled with other assembly components，corresponding tests need to be performed, and the results shall comply with the relevant specifications of Cartridge Systems for Pen-Injectors (Guideline 9626 Annex 2).

4 Other Tests

4.1 Particulate matter. Applied to ready-to-sterilize and sterile rubber closures, and tested when necessary. Perform the test according to Determination of Particulate Matter for Pharmaceutical Packaging Materials and Containers (General Chapter 4206), and the results shall comply with the specifications in the following table.

packaging System/Assembly	Rubber Closures	Limit (particles/mL)	
		10 μm and above	25 μm and above
Packaging System for Injections	Stopper	30	3
Packaging System for Sterile Powders for Injection	Stopper	60	6

4.2 Bioburden. When necessary, perform the test of bioburden according to Guideline on Microbiological Testing of Pharmaceutical Packaging Materials (Guideline 9627), and the results shall comply with the relevant specifications of enterprise standards or quality agreements. For rubber stoppers for packages for injections specified the test of sterility, the test of bioburden is generally not required further.

4.3 Sterility. Applied to sterile rubber closures. When necessary, perform the test of sterility according to Guideline on Microbiological Testing of Pharmaceutical Packaging Materials (Guideline 9627), and the results shall comply with the specifications.

4.4 Bacterial endotoxins or pyrogens. Applied to ready-to-sterilize and sterile rubber closures. When necessary, perform the test of bacterial endotoxins according to Guidelines for the Application of Bacterial Endotoxin Test (Guideline 9251), and the results shall comply with the relevant specifications directed in the specific monograph of

pharmaceutical products. If the pharmaceutical product and its relevant specifications cannot be defined, the results of bacterial endotoxins shall be less than 0.25 EU/mL, or take an appropriate amount of the test solution to perform the test of pyrogens according to Test for Pyrogens (General Chapter1142), and the results shall comply with the specifications.

Annex 2Rubber Closures for Packages for Oral Preparations

This annex is applicable to the rubber closures used as part of packaging systems for oral preparations.

The packaging materials in direct contact with rubber closures shall comply with the relevant requirements of pharmaceutical packages. The sealed packages shall be of enough integrity, and the primary and secondary packaging as a whole should meet the requirements for protection performance during the transportation and storage. The rubber closures should be stored in the dry, clean and well-ventilated indoor environment.

Rubber closures for packages for oral preparations shall comply with the relevant provisions in the text and the following requirements.

1OverallRequirements

For the design of rubber closures for packages for oral preparations, the possible effects of the formulations and processes on the sense of smell and taste should be taken into account.

2 Sealability of Closures for Containers

Applied to rubber closures to be secured with fasteners, and need to be performed only after rubber closures being fitted with other assembly components. Place 10 rubber closures in a beaker, add water and boil for 5 min. Take out and dry the rubber closures at 70 ℃ for 1 hour for later use. Fill each of 10 matched containers for oral preparations to the nominal volume with water, then fit the above rubber closures and secure with the matched fasteners. Immerse the above test samples bottom end up in 0.1% methylene blue solution in a container with a vacuum pump, reduce the pressure by 27kPa and hold for 30 min, then restore to atmospheric pressure and hold for another 30 min. Take the test samples out, rinse the outsides of the containers with water. Any trace of methylene blue solution is observed in none of the containers. If direct observation is impossible, the

solution may be taken out by a suitable method and inspected visually. The solution doesn't appear blue.

3 Microbial limit

Applied to ready-to-sterilize rubber closures. When necessary, perform the corresponding tests according to Guideline on Microbiological Testing of Pharmaceutical Packaging Materials (Guideline 9627). The results should comply with the relevant requirements of enterprise standards or quality agreements.

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