# Guidance for Preparing Product Technical Requirements for Medical Devices

### NMPA Announcement No. 8 of 2022 | Unofficial English Reference Translation

**Translation status:** Independently prepared English reference translation of the Chinese NMPA guidance issued on 8 February 2022. This document is **not** an official NMPA English publication or a legally authoritative text. Consult the Chinese original and qualified regulatory counsel for submissions.

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## NMPA Notice (Announcement No. 8 of 2022)

To improve the consistency and scientific rigor of technical reviews of medical devices, and to guide registrants and filing entities in preparing product technical requirements, the National Medical Products Administration (NMPA) has revised and issued the Guidance for Preparing Product Technical Requirements for Medical Devices. This work follows the Regulations on the Supervision and Administration of Medical Devices, the Provisions for Medical Device Registration and Filing, and the Provisions for Registration and Filing of In Vitro Diagnostic Reagents.

**Issued by:** National Medical Products Administration (NMPA) | **Date:** 8 February 2022

## Annex: Guidance for Preparing Product Technical Requirements for Medical Devices

This guidance sets out general requirements for the structure and content of product technical requirements (PTRs), with the aim of making medical-device technical assessments more consistent and scientifically grounded.

## I. Scope

This guidance applies to medical devices submitted for registration or filing, including in vitro diagnostic (IVD) reagents.

It establishes general formatting and content expectations; it does not prescribe technical specifications for individual products. Examples are illustrative. Regulators and applicants should adapt the guidance to the circumstances of each device.

## II. General Requirements

• **Legal compliance.** PTRs must meet applicable Chinese laws and regulations.

• **Consistent terminology.** Use established, widely understood terms. Clearly define any special terms in Section 4, “Terminology.” Terms taken directly from recognized standards or guidance need not be repeated. Do not redefine an established term in a way that changes its original meaning.

• **Aligned numbering.** As a rule, the numbering of test-method provisions should correspond to the numbering of the applicable performance indicators.

• **Standardized presentation.** Text, numbers, formulas, measurement units, symbols, tables, and figures should follow applicable standardization conventions.

• **Standards references.** When citing national or industry standards, identify both the standard number and its publication year.

## III. Main Content of the PTR

PTRs normally include the product name; models and specifications, with a description of their grouping where necessary; performance indicators; test methods; terminology where relevant; and appendices where relevant.

### 1. Product name

State the product name in Chinese. It must match the name used in the registration or filing application.

### 2. Models, specifications and grouping

Clearly identify the device models and specifications. If one registration unit covers multiple models or specifications, explain their differences and grouping. Diagrams or tables are recommended; lengthy descriptions may be included in an appendix.

For devices containing software, specify the software release version and the naming rules for the complete software version.

### 3. Performance indicators

Performance indicators are characteristics of the finished device that can be objectively evaluated and that relate to function or safety.

Information that has no material bearing on safety or effectiveness need not become a performance indicator. For example, the diameter or length of certain drainage catheters may be descriptive, provided these values do not determine their critical safety or functional performance. Drawings generally do not need to appear as performance indicators.

However, device dimensions must be specified when they materially influence safety or effectiveness, such as the length and outer diameter of a vascular stent or dimensional tolerances of an orthopedic implant.

Derive performance indicators from relevant national and industry standards, the device design, and the intended use. Comply with applicable mandatory standards. If a mandatory standard is not applicable because of the product’s structure, intended use, or mode of use, provide a rationale and supporting evidence.

State concrete, testable requirements. Avoid replacing them with phrases such as “see attached documents” or “according to the supply contract.”

### 4. Test methods

Select test methods that can demonstrate conformity with each performance indicator. Prefer established methods in applicable standards. Where needed, validate methods to establish repeatability and practical operability.

Methods should normally explain the test procedure and how results are expressed or calculated. Where relevant, add the test principle; specimen preparation and storage; instruments; and any conditions essential to reproducing the result.

For IVD reagents, identify the reference materials or standards used, specimen preparation, number of test runs, and calculation approach.

### 5. Appendices

For Class III IVD reagents, include the main raw materials and manufacturing-process requirements in an appendix.

For other medical devices, appendices may describe characteristics such as sterile or nonsterile supply state, shelf life, principal raw materials, manufacturing processes, major safety features, key technical specifications, critical components, and magnetic-resonance compatibility, where relevant.

### 6. PTR identification number

The PTR identification number corresponds to the product registration certificate number or filing number. It may be left blank in a draft submitted for registration or filing.

## IV. Requirements for Performance Indicators

Performance indicators are objectively assessable functional and safety properties of the finished product. Such indicators are normally quantifiable or objectively describable, and a defined test method should allow a directly verifiable result.

Examples of performance indicators include:

• **Hemodialyzers:** clearance of target substances, measured through the amount remaining after treatment.

• **Intravascular catheters:** absence of leakage under stated operating conditions, demonstrated through an objective leakage test.

• **Infusion pumps:** infusion flow rate and corresponding accuracy, verified using specified methods.

• **Diagnostic ultrasound imaging equipment:** image resolution, assessed using a scientifically suitable test method.

### Items generally not recommended as PTR performance indicators

**A. Research and evaluation activities.** These are normally addressed in design, development, validation, or other technical evidence rather than expressed as finished-device performance indicators. Examples include:

• Shelf-life studies and aging assessments for passive or active medical devices;

• Sterilization-validation studies, fatigue testing, in vitro degradation research, human-factors validation, reliability studies, and magnetic-resonance-compatibility research;

• Biocompatibility assessments (including material-mediated pyrogenicity), which may draw on multiple biological tests, chemical analysis, toxicological evidence, historical data, or comparable marketed products;

• Environmental adaptability assessments for medical electrical equipment, including specified storage, transport, and operating conditions; and

• Other evaluations, such as viral inactivation effectiveness or immunogenicity.

**B. Items concerning non-finished materials or intermediates.** PTRs describe the performance of finished devices. As a rule, raw-material and semi-finished-product characteristics, such as certain mechanical or chemical properties, should not appear as finished-device PTR performance indicators.

## V. Format Requirements

The original guidance supplies a format for PTR submissions. Its main structure is translated below. The Chinese original specifies SimSun (“Song”) font sizes and permits Times New Roman for Western characters.

**Product Technical Requirements Number:** [registration or filing number]

**Product Name:** [Chinese name consistent with the registration/filing application]

**1. Product Model/Specification and Grouping Description** (if applicable)

1.1 …  1.1.1 …

**2. Performance Indicators**

2.1 …  2.1.1 …

**3. Test Methods**

3.1 …  3.1.1 …

**4. Terminology** (if applicable)

4.1 …  4.2 …

**Page break — Appendix A** (if applicable)

A1 …  A1.1 …

**Formatting notes from the NMPA guidance:** Do not add unauthorized content to a submitted PTR, such as a cover, registrant name or logo, or signature block. Page numbering may show the current and total pages, for example “1/9.”

## Primary Regulatory Sources

**Original NMPA announcement (Chinese):** NMPA Announcement No. 8 of 2022.

**Official NMPA announcement summary (English):** NMPA Notice on Issuing the Guidance.

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