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

GB/T 16126-2025

Replacing GB/T 16126-1995

Specification for quality assurance of human biomonitoring

人体生物监测质量保证规范

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. This document replaces GB/T 16126-1995 "Quality Assurance Specification for Biological Monitoring". Compared with GB/T 16126-1995, except for structural adjustments... Aside from integration and editorial changes, the main technical changes are as follows:

---Added 14 terms and definitions. human biosurveillance, field investigation, bias, biobank, biosafety, limit of detection, quantification Limits, precision, accuracy, calibration curves, standard samples/reference materials, certified reference materials, quality control samples Products and sample blanks (see Chapter 3);

---Two terms and definitions have been deleted. biomonitoring and living environment (see Chapter 3 of the.1995 edition);

---One term and definition has been changed. Quality Assurance (see Chapter 3, Chapter 3

of the.1995 edition);

---Added content on ethics and human genetic resource review (see Chapter 4);

---Added on-site investigation content such as questionnaires and physical examinations (see

---The criteria for determining the monitoring targets have been changed (see 5.1, 4.1 of the.1995 edition);

---The sample size and sampling method for the monitored population have been removed (see sections

4.3 of the.1995 edition);

---Added content on sampling biosafety, sample blank, sample receiving, sample aliquoting, and sample storage (see 5.4.4, 5.4.8, etc.) 5.4.12,

5.4.13 and 5.4.15);

---Changes have been made to the procedures for collecting blood, urine, breast milk, and hair samples (see 5.4.9.1, 5.4.9.2, 5.4.9.3, and 5.4.9.4,.1995 edition). 4.7.3.1, 4.7.3.2,

1 Scope

GB/T 16126-2025 is the Chinese national standard on specification for quality assurance of human biomonitoring, in the field of environment and health protection, safety. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 29 August 2025 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 March 2026. Classification: ICS 13.040.30, CCS C 51. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This document specifies the quality assurance and quality control procedures for field investigations, laboratory testing, data management, and application in human biomonitoring. Technical requirements and operating procedures. This document serves as guidance for monitoring human exposure levels to environmental chemicals in production and living environments.

2 Normative references

The contents of the following documents, through normative references within the text,

constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 6682 Specifications and test methods for water used in analytical laboratories

GB/T 8170 Rules for rounding off numerical values and the representation and determination of limiting values

GB 19489 General Requirements for Laboratory Biosafety

GB/T 27417 Guidelines for Conformity Assessment of Chemical Analysis Methods

GB/T 27476.5 Laboratory Safety - Part

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Human biomonitoring Regularly (scheduledly) monitor the levels of chemical substances and their metabolites in human biological samples, or the harmless biological effects they cause. Levels are used to assess the extent to which humans are exposed to chemicals and their potential health effects.

3.2 field survey The process by which trained investigators systematically collect information from a target population using on-site or remote survey methods.

Note. Survey methods include centralized surveys, door-to-door surveys, intercept surveys, observation methods, telephone surveys, mailed questionnaires, email surveys, and online surveys.

3.3 bias Systematic errors arising from each stage of the research, from design and implementation to data processing and analysis, as well as biases in the interpretation and inference of results. Sexual factors can lead to biased discrepancies between research findings and reality.

5 Chemical Factors

GB/T 32465 Requirements for Validation and Internal Quality Control of Chemical Analysis Methods

GB/T 37864 General requirements for the quality and competence of biobanks

GB/T 38576 Collection and Processing of Human Blood Samples

GB/T 38735 Collection and processing of human urine samples GBZ /T 295 General Rules for Biomonitoring Methods for Occupational Populations