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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 28044-2011

General guide to the detection of the biological effects of nanomaterials by transmission electron microscopy

纳米材料生物效应的透射电子显微镜检测方法通则

Issued on: October 31, 2011 **Implemented on: February 1, 2012**

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Standardization Administration of the PRC

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. This standard by the National Standardization Technical Committee of nano technology (SAC/TC297) and focal points. This standard is drafted by: Second Military Medical University, Shanghai Medical College of Fudan University. The main drafters of this standard. Yang Yong Ji, Chang Yu, Zhang Tianbao. Biological effects of nanomaterials TEM General Detection

1 Scope

China's national general guide to examining the biological effects of nanomaterials by transmission electron microscopy. It specifies the techniques and the requirements for the preparation and examination of biological specimens containing nanomaterials, and it applies to the ultrastructural analysis of the biological effects of nanomaterials by TEM. The question the method answers is where the particles went. A nanomaterial administered to a cell or to an animal distributes somewhere, and what it does depends entirely on where it ends up: outside the cell, adsorbed on the membrane, inside an endosome, free in the cytoplasm, in the mitochondria or in the nucleus. Those are different biological outcomes, and no bulk measurement distinguishes them. Transmission electron microscopy does, because it resolves both the particle and the cell structure around it in the same image - and at these dimensions it is very nearly the only technique that does. What makes the examination difficult is that almost every stage of specimen preparation can produce the answer rather than reveal it. Fixation, dehydration, resin embedding and sectioning all move material; a particle can be dragged through a section by the knife; staining introduces heavy metal deposits that look like particles; and the operator is looking for a small dense object in a field full of small dense objects. So the standard fixes the preparation, the sectioning, the staining and the examination conditions, and it requires the identity of what is seen to be confirmed rather than assumed - by elemental analysis in the microscope, following the quantitative procedures of GB/T 18873 for thin biological specimens. Issued on 31 October 2011 and in force since 1 February 2012.

This standard specifies the transmission electron microscope techniques and specifications nanomaterials biological samples. This standard applies to biological effects of

nanomaterials TEM analysis of the ultrastructural analysis.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB/T 18873-2008 thin biological specimens transmission electron microscope -X-ray spectrum quantitative analysis General

GB/T 19619-2004 nanomaterials term ISO /

IEC 17025.2005 testing and calibration laboratory accreditation criteria (Generalrequirementsforthecompetenceof testingandcalibrationlaboratories)

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Nanomaterial nanomaterial Material structure in three-dimensional space has at least one dimension in the nanometer scale, or by the nano-structure unit and with extraordinary properties material.

3.2 Biological effects biologicaleffect Physiological function of the interaction of nanomaterials with life processes produced biochemical changes in the function and morphology.

3.3 Biological effects detected biologicaleffecttest Using experimental techniques biology, chemistry, toxicology and other medical fields to test measurements.

3.4 Support film supportfilm Using collodion or polyvinyl formal (Formvar) had a thickness of about 12nm film.

3.5 Nanomaterials thin specimens thinnanomaterialsample Nanomaterials thin sample refers to support film infusion solution containing nano-materials and after drying oven at 60 °C thin specimens.

3.6 Thin biological specimens thinbiologicalsample Refers to the use of thin biological specimens cut microtome thickness of 40nm ~ 100nm thin sample containing a biological tissue or cells.