ICS 13.280
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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 16361-2012

Replacing GB 16361-1996

Specification for patient radiological protection and quality control in nuclear medicine

临床核医学患者防护与质量控制规范

Issued on: June 29, 2012 **Implemented on: October 1, 2012**

**Issued by: Ministry of Health of the People's Republic of China;
Standardization Administration of China**

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Foreword

The standard Chapter 4, Chapter 5 are mandatory, the rest are recommended. This standard was drafted in accordance with GB/T 1.1-2009 given rules. This standard replaces GB 16361-1996 "Clinical Nuclear Medicine Radiological protection standards for the patient." This standard compared with GB 16361-1996, the main technical changes are as follows:

--- Original standard is mainly based on national standards GB 4792-1984 "Radiation Health Protection basic standards"; this standard is based primarily on It has been replaced by a new version of the basic standards 4792-1984 GB of GB 18871-2002 "ionizing radiation protection and safety of radiation sources fundamental Standard "and GB Z179-2006" medical exposure Radiological Protection basic requirements. "

--- International standard original standard is mainly based on ICRP Publication 52 "ProtectionofthePatientinNuclear Medicine, Ann.ICRP17 (4), 1987 "; this standard is mainly based on the IAEA Safety Report No.40" ApplyingRadiationSafetyStandardsinNuclearMedicine, 2005 ", as well as IAEA Safety Report No.63" Releaseof PatientsafterRadionuclideTherapy, 2009 "and the IAEA Technical Report No.454" QualityAssurancefor RadioactivityMeasurementinNuclearMedicine, 2006 ".

--- Standard name from "clinical nuclear medicine patient radiation health protection standards" by "protection of patients in clinical nuclear medicine and quality control System Specifications. "

--- Original standard Chapter 3 ~ Chapter 7 of the content integration, grouped into current standard Chapters 4 and 5, and there are more complementary and modify.

--- Increased in Chapter 6 concerning quality control requirements.

--- By the Appendix 2 to 8, and the corresponding references are given in the appendix. This standard is proposed and administered by the People's Republic of China Ministry of Health. This standard was drafted. Institute of Radiation Medicine, Chinese Academy of Medical Sciences, Sichuan Provincial Center for Disease Control and Prevention. The main drafters. Zhang Liangan, Zhang literary, Jiao Ling, Dingyan Qiu, He Ling, Yang Yi. This standard replaces the standards previously issued as follows:

--- GB 16361-1996. Protection and Quality Control of Nuclear Medicine clinical Specification

1 Scope

GB 16361 covers the branch of medicine in which the radiation source is given to the patient rather than aimed at them: clinical nuclear medicine, diagnostic imaging and radionuclide therapy alike, excluding the implantation of sealed seed sources. Clause 4 sets what a nuclear medicine unit must have before it may practise - the rooms and their shielding under GBZ 120, verified activity meters and quality control instruments, a radiological protection and quality assurance organisation, contingency plans against a mistaken administration - and it reserves the prescribing of a therapeutic radiopharmaceutical to a qualified practitioner who has made the justification assessment case by case. Clause 5 is the longest: justification of each administration, the guidance levels and the smallest activity that will still answer the diagnostic question, and the specific rules for children, for women who are breastfeeding and for pregnant women, including the 100 mGy threshold below which a life-saving treatment need not end the pregnancy. Clause 6 adds the quality control of the equipment and of the procedures. Seven annexes carry the working numbers: the guidance levels for diagnosis (A), how long breastfeeding is to be interrupted (B), how long conception is to be deferred after treatment (C), the dose the patient receives (D, some twenty pages of it), the dose to the people around them (E, normative), and the performance and quality control testing of the activity meter (G). Issued on 29 June 2012, in force since 1 October 2012, replacing GB 16361-1996. This page is published from the official record of the standard and from its published table of contents. The full clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This standard specifies the basic requirements for protection of clinical nuclear medicine patients, patient protection and safety, and quality control requirements. This standard applies to the radionuclides used for diagnosis and treatment of clinical nuclear medicine, but does not include the case of a particle source implantation.

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 18871-2002 ionizing radiation protection and safety of radiation sources basic standards GB Z120 Nuclear Medicine Radiological protection standards GB Z179 basic requirements for medical exposure Radiological Protection

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Radiopharmaceuticals radiopharmaceutical For the purpose of diagnosis and treatment may be applied to the human body any compound containing radionuclides. In addition to the radioactive properties, chemical and biological On consideration, radioactive drugs and other drugs.

3.2 Radionuclide purity radionuclidicpurity Specific radioactivity short-lived radionuclides and daughters accounted for radioactivity total activity score.

3.3 Radiochemical purity radiochemicalpurity Radionuclides in the desired chemical form of the mass fraction.

Note. If you can not reach the radiochemical purity requirements may lead to target specific radiopharmaceutical tissue deterioration, resulting in radiation on non-target organs.

3.4 Chemical purity chemicalpurity Regardless of the presence of radioactive or not, according to the desired chemical form of the mass fraction. In general, radiopharmaceuticals, there are only of Learn toxicity or physiological process radiopharmaceutical impurities proposed chemical purity requirements.

3.5 Radioactivity specificradioactivity Radiopharmaceutical unit mass contained radionuclide activity and activity concentration of bound and free form.

3.6 Radionuclide generators radionuclidegenerator The device can be isolated from the decay of its long half-life radionuclide-containing preparations (known as the parent) of the short half-life nuclides (called daughters) generated by the vulgar Called "cow."

4.1 Clinical nuclear medicine diagnosis and treatment units

4.1.1 clinical nuclear medicine diagnosis and treatment unit (hereinafter referred to as nuclear medicine units) should follow the "radiation medical management regulations" for clinical Practicing nuclear medicine diagnosis and treatment conditions (hereinafter referred to as clinics) provided personnel and equipment, and other related requirements, and GB 18871- 2002 GB Z179 and other related technical standards.

4.1.2 should be equipped to adapt its services and the performance of qualified nuclear

medicine diagnostic equipment (including related auxiliary equipment), and protection of patients Quality control testing equipment, personal protective equipment.

4.1.3 in accordance with relevant regulations, regularly test equipment for verification or calibration, to obtain competent and effective verification or calibration certificate. When it is detected Instrument after major repairs, you should re-test or calibration.

4.1.4 should be set to adapt its services and meet the protection requirements of GB Z120 laboratory examination room, injection rooms, treatment ward And waiting areas and other workplaces and their corresponding protection facilities.

4.1.5 It should be noted configured to adapt its services and reasonable structure of various professionals, including enforcement of the Nuclear Medicine have qualified Industry, physicians and clinical nuclear medicine technician, etc., and they are active in patient protection and safety and quality control knowledge, training and assessment.

4.1.6 There shall be established radiological protection and quality assurance management organizations, various medical technicians in their work should strictly follow the protection and safety to Demand and quality control requirements, and undertake corresponding responsibilities.

4.1.7 should develop the Nuclear Medicine Clinic quality assurance program, including strengthening the establishment of a sound management system, including the protection of patients, from the management system Ensure the correct implementation of the Nuclear Medicine Clinic of the degree and quality control procedures.

4.1.8 should be possible for the implementation of treatment failures or mistakes, development of contingency plans, and training and emergency drills will likely The consequences of failure or error is minimized.

4.2 Requirements for clinical nuclear medicine practitioners and associated personnel

4.2.1 only with a qualified medical practitioner to the patient prescribing radiation therapy and should be administered to the patient by virtue of prescription treatment Therapeutic radiopharmaceuticals.

4.2.2 The practitioner should be the legitimacy to judge case by case, only to meet the requirements of the legitimacy of radiopharmaceuticals to issue medical prescriptions.

4.2.3 practitioners and related personnel should be strictly controlled indications, should clinical nuclear medicine diagnosis and treatment when administered to a patient sensitive radiopharmaceuticals strict control.

4.2.4 Before the implementation of the Nuclear Medicine Clinic, practitioners and stakeholders have a responsibility to possible risks to patients orally or in writing inform Or their families.

5 patient protection and safety requirements