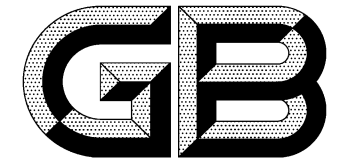


ICS 11.100
C 44



中华人民共和国国家标准

GB 19781—2005/ISO 15190:2003

GB 19781—2005/ISO 15190:2003

医学实验室 安全要求

Medical laboratories—Requirements for safety

(ISO 15190:2003, IDT)

中华人民共和国
国家标准

医学实验室 安全要求

GB 19781—2005/ISO 15190:2003

*

中国标准出版社出版发行
北京复兴门外三里河北街16号
邮政编码:100045

网址 www.bzcb.com

电话:68523946 68517548

中国标准出版社秦皇岛印刷厂印刷
各地新华书店经销

*

开本 880×1230 1/16 印张 2.5 字数 45 千字

2006年4月第一版 2006年4月第一次印刷

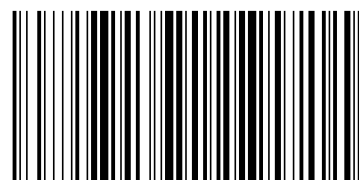
*

书号:155066·1-27144 定价 18.00 元

如有印装差错 由本社发行中心调换

版权专有 侵权必究

举报电话:(010)68533533



GB 19781—2005

2005-06-06 发布

2005-12-01 实施

中华人民共和国国家质量监督检验检疫总局
中国国家标准化管理委员会 发布

tions; *Approved guideline*. 2nd edn. , NCCLS, Wayne, PA 2002

[36] PRUSS A. , GIROULT E. and RUSHBROOK P. , *Safe management of wastes from healthcare activities* , World Health Organization, Geneva, 1999

[37] *Categorisation of Pathogens According to Hazard and Categories of Containment* (ACDP). United Kingdom Dept. of Health, London

[38] *Control of Substances Hazardous to Health and Control of Carcinogenic Substances and Control of Biological Agents. Control of Substances Hazardous to Health Regulations, Approved Code of Practice (ACOP)*. United Kingdom Health and Safety Executive, L 5, HSE Books, London, 1994

[39] *Management and control of viral haemorrhagic fevers* (ACDP). HSE Books, United Kingdom Dept. of Health, London, 1998

[40] *Management of health and safety at work regulations. (ACOP)*, Manual Handling Operations Regulations, Guidance on Regulations. United Kingdom Health and Safety Executive, L 21, HSE Books, London, 1992

[41] *Noise at Work, Noise Guide No. 1: Legal duties of employers to prevent damage to hearing*. United Kingdom Health and Safety Executive, HSE Books, London

[42] *Noise at Work, Noise Guide No. 2: Legal Duties of Designers, Manufacturers, Importers and Suppliers to Prevent Damage to Hearing*. United Kingdom Health and Safety Executive, HSE Books, London

[43] *Personal Protective Equipment at Work*. Guidance on Regulations (ACOP). United Kingdom Health and Safety Executive, L25, HSE Books, London, 1992

[44] *Protection of Persons Against Ionizing Radiation Arising From Any Work Activity; The Ionizing Radiations Regulations*. Approved Code of Practice. United Kingdom Health and Safety Executive, COP 16, HSE Books, London, 1985

[45] *Respiratory Protective Equipment; A Practical Guide for Users*. United Kingdom Health and Safety Executive, HS(G)53, HSE Books, London, 1990

[46] *Work Equipment; Provision and Use of Work Equipment Regulations*. United Kingdom Health and Safety Executive, HSE Books, London, 1992

[47] *Ergonomics at Work Regulations*. United Kingdom Health and Safety Executive, IND(G) 90 L, HSE Books, London, 1990

[48] *Seating at Work*. United Kingdom Health and Safety Executive, HS(G)57, HSE Books, London, 1991

[49] *Workplace Regulations*. Approved Code of Practice, United Kingdom Health and Safety Executive, HSE Books, London, 1992

[50] *Management of Safety at Work Regulations*. Approved Code of Practice. United Kingdom Health and Safety Executive, HSE Books, London

[51] *Display Screen Equipment Work, Display Screen Equipment Regulations*. Guidance on Regulations. United Kingdom Health and Safety Executive, L26, HSE Books, London, 1992

[52] *Safe Working and the Prevention of Infection in Clinical Laboratories*. United Kingdom Health and Safety Executive, C60, HSE Books, London, 1991

[53] *Safe Working and the Prevention of Infection in Clinical Laboratories—Model Rules for Staff and Visitors*. United Kingdom Health and Safety Executive, C41, HSE Books, Lon-

目 次

前言	V
引言	VI
1 范围	1
2 规范性引用文件	1
3 术语及定义	1
3.1 气溶胶	1
3.2 防腐	1
3.3 防腐剂	1
3.4 生物因子	1
3.5 清洁(净化)	1
3.6 传染控制计划	1
3.7 去污染	1
3.8 消毒剂	1
3.9 消毒	2
3.10 工效学	2
3.11 排风罩(烟罩)	2
3.12 危险	2
3.13 危险废物	2
3.14 材料安全数据单	2
3.15 微生物安全柜(生物安全柜)	2
3.16 微生物	2
3.17 噪声	2
3.18 个人防护装备	2
3.19 放射性核素	2
3.20 风险	2
3.21 安全罩	2
3.22 溅漏处理工具包	3
3.23 挡溅板	3
3.24 灭菌	3
3.25 技术区	3
3.26 组织	3
4 风险分级	3
5 管理要求	3
5.1 管理责任	3
5.2 员工健康管理	3
6 安全设计	4
6.1 预先考虑	4
6.2 通用设计要求	4

6.3 物理环境	4
6.3.1 照明	4
6.3.2 温度	4
6.3.3 通风	4
6.3.4 噪声	4
6.3.5 工效学因素	4
6.3.6 从事活病原体工作的设计	5
6.3.7 门标	5
6.3.8 实验室安防	5
7 员工、程序、文件、检查和记录	5
7.1 实验室安全负责人	5
7.2 程序	5
7.3 安全计划的审核及检查	5
7.3.1 安全计划的审核	5
7.3.2 安全检查	6
7.4 安全手册	6
7.5 记录	6
7.5.1 总则	6
7.5.2 职业性疾病、伤害和不利事件记录	6
7.5.3 风险评估记录	6
7.5.4 危险废物记录	7
8 危险标识	7
9 事件、伤害、事故和职业性疾病的报告	7
10 培训	7
11 个人责任	7
11.1 食品、饮料及类似物品	7
11.2 化妆品、头发、胡须和饰品	7
11.3 免疫状态	8
11.4 个人物品	8
11.5 喜庆装饰	8
12 服装和个人防护装备(PPE)	8
12.1 实验室防护服	8
12.2 实验室外的防护服	8
12.3 面部及身体保护	8
12.4 手套	8
12.5 鞋	9
12.6 呼吸防护	9
12.7 洗手	9
12.8 培训	9
12.9 设备	9
12.10 洗眼台	9
12.11 紧急喷淋装置	10
13 良好内务行为	10

	<i>and laboratory use—Part 2-043; Particular requirements for dry heat sterilizers using either hot air or hot inert gas for the treatment of medical materials, and for laboratory processes</i>
[20]	IEC 61010-2-045, <i>Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 2-045; Particular requirements for washer disinfectors used in medical, pharmaceutical, veterinary and laboratory fields</i>
[21]	IEC 61010-2-051, <i>Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 2-051; Particular requirements for laboratory equipment for mixing and stirring</i>
[22]	IEC 61010-2-061, <i>Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 2-061; Particular requirements for laboratory atomic spectrometers with thermal atomization and ionization</i>
[23]	IEC 61010-2-101, <i>Safety requirements for electrical equipment for measurement, control and laboratory use—Part 2-101; Particular requirements for in vitro diagnostic (IVD) medical equipment</i>
[24]	IEC/TR3 61010-3, <i>Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 3; Protocol for the preparation of conformity verification reports for the IEC 61010 series</i>
[25]	IEC/TR3 61010-3-1, <i>Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 3-1; Conformity verification report for IEC 61010-1</i>
[26]	IEC/TR 61010-3-010, <i>Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 3-010; Conformity verification report for IEC 61010-2-010, Particular requirements for laboratory equipment for the heating of materials</i>
[27]	IEC/TR 61010-3-020, <i>Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 3-020; Conformity verification report for IEC 61010-2-020, Particular requirements for laboratory centrifuges</i>
[28]	IEC/TR 61010-3-051, <i>Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 3-051; Conformity verification report for IEC 61010-2-051, Particular requirements for laboratory equipment for mixing and stirring</i>
[29]	IEC/TR 61010-3-061, <i>Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 3-061; Conformity verification report for IEC 61010-2-061, Particular requirements for laboratory atomic spectrometers with thermal atomization and ionization</i>
[30]	<i>IUPAC-IPCS Chemical Safety Matters</i> , International Union of Pure and Applied Chemistry, 1992
[31]	ISO/IEC Guide 63, <i>Guide to the development and inclusion of safety aspects in International Standards for medical devices</i>
[32]	ISO/IEC Guide 51, <i>Safety aspects—Guidelines for their inclusion in standards</i>
[33]	NCCLS GP5-A, <i>Clinical laboratory waste management; Approved guideline</i> . NCCLS, Wayne, PA 1993
[34]	NCCLS GP17-A, <i>Clinical laboratory safety; Approved guideline</i> . NCCLS, Wayne, PA 1996
[35]	NCCLS M29-A2, <i>Protection of laboratory workers from occupationally acquired infec-</i>