Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15190 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*.

まえがき

ISO (国際標準化機構)は，各国の標準化機関(ISO 会員団体)による世界的な連盟である。国際規格の作成作業は，通常，ISO 専門委員会を通じて実施される。専門委員会が設置された対象内容に関心のある会員団体は，当該の委員会に代表を送る権利を有する。国際的な，政府機関及び非政府機関も ISO と協力して作業を分担する。ISO は電気技術の標準化に関するすべての問題について，国際電気標準会議(IEC)と密接に協力している。

国際規格は，ISO/IEC 専門業務用指針第 2 部に規定されている規則に従って起草される。

専門委員会の主要な職務は，国際規格を作成することである。専門委員会が採択した国際規格案は，投票のため各会員団体に回付される。国際規格として公布されるためには，投票する会員団体の最低 75 パーセントの賛成票が必要となる。

この文書の一部の要素は，特許権の対象となる可能性があることに注意が必要である。ISO では，このような特許権の一部又は全部を特定する責任を負うものではない。

ISO 15190 は，専門委員会 ISO/TC212，*臨床検査及び体外診断検査システム*が作成した。

Introduction

This International Standard specifies requirements to establish and maintain a safe working environment in a medical laboratory. As with all such safety guidelines, there are requirements to ensure that there is a named person ultimately responsible and that all employees take personal responsibility for

— their own safety at work and,

— the safety of others who may be affected by it.

Every task requires risk assessment, with the aim that hazards be eliminated wherever possible. Where this cannot be done, the risk from each hazard is reduced to as low a level as practicable, using the following order of priority:

a) by substitution;

b) by containment; or

c) by the use of personal protective measures and equipment.

Safety is the primary consideration; cost is of secondary importance.

While this International Standard is intended for use throughout the currently recognized disciplines of medical laboratory services, other services and disciplines may find it useful and appropriate. However, medical laboratories handling human pathogens requiring containment levels 3 and 4 will need to meet additional requirements to ensure safety.

While this International Standard is not intended to provide guidance on accreditation, it may be used for such purposes by a government, professional, or other authoritative body.

International, national or regional regulations or guidelines may apply to specific topics covered in this International Standard.

序文

この国際規格は臨床検査室における作業環境の安全を確立し維持するための要求事項を指定する。このような安全性ガイドラインでは，最終責任者が指名されていること及び全ての作業従事者が次の責任を有することを確実にするための要求事項がある。

- 作業上での自己の安全，

- 作業により影響を受ける他の人々の安全。

可能な限り危険性を除去するために全ての作業についてリスク評価を行わなければならない。これが不可能な場合は，それぞれの危険性について下記優先順位に従いリスクを実務的なレベルまで下げなければならない：

a) 代替手段による；

b) (リスクの)封じ込めによる；

c) 個人的防護対策および用具使用による。

安全性を第一義的に考慮するべきであり，コストは第二義的な重要事項である。

本国際規格は，現時点で認知されている臨床検査室サービスや業務全般にわたって使用されるべきことを意図しているが，その他のサービスや業務でも有用でありかつ適切である可能性がある。しかしながら，レベル 3，レベル 4 の病原体を取り扱う臨床検査室では，安全を確保するために新たな追加要求事項が必要になるであろう。

本国際規格は認定のためのガイドラインを提供することを意図したものではないが，政府，専門機関あるいは当局がこの国際規格をそのような目的に使用してもよい。

個々の事項については，国際，国家，あるいは地域の規格もしくはガイドラインを適用してもよい。

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臨床検査患者安全対策

PSAマニュアル

改訂版

平成16年9月

社団法人　日本臨床衛生検査技師会

はじめに

医療事故は度重なる喚起と対策にもかかわらず減るばかりか、毎日のようにマスコミに報道され、この影に隠れている事故を含めると大きな社会問題として捉えざるを得ない状況にあります。

この様な背景の中で、平成１５年１２月２４日に厚生労働大臣が「厚生労働大臣医療事故対策緊急アピール」を発出しました。各自治体を中心とする行政でも、必要に医療機関への立ち入り調査を行い、医療事故防止に向けての取り組みや業務改善を促しているところであります。

当会としても医療安全対策連絡会議構成団体として、通知・連絡の徹底、事業開催への啓発並びに研修会等の開催を行って参りました。

本年度も、ここに医療安全講習会を開催するに当たり、昨年度作成した PSA（Patient Safety Action）マニュアルを大きく改訂し、ここにお届けいたします。

このマニュアルの中では一般的な医療機関を対象にした医療安全管理について簡素にまとめたもので十分な資料とはいえませんが、字数を少なくし、不幸にして事故が発生した場合の取るべき行動をシェーマにして示しました。これを参考に自施設に合ったものに書き改めていただければ幸いであります。同時にチエックリストや安全マニュアルは絶えず改善し、全職員に徹底することが重要であることはいうまでもありません。検査技師の知識、技術、経験、体験が語り継がれ、情報を共有し、注意を喚起することによって検査室全員が医療安全へ対して同じコンセンサスを持ち、チーム医療を担う一員として専門的立場から医療安全に寄与することを期待します。

日本臨床衛生検査技師会　医療安全対策委員会

安全な医療を提供するための 10 の要点

（１）根づかせよう安全文化　みんなの努力と活かすシステム

（２）安全高める患者の参加　対話が深める互いの理解

（３）共有しよう　私の経験　活用しよう　あなたの教訓

（４）規則と手順　決めて　守って　見直して

（５）部門の壁を乗り越えて　意見かわせる　職場をつくろう

（６）先の危険を考えて　要点おさえて　しっかり確認

（７）自分自身の健康管理　医療人の第一歩

（８）事故予防　技術と工夫も取り入れて

（９）患者と薬を再確認　用法・用量　気をつけて

（１０）整えよう療養環境　つくりあげよう作業環境

（厚生労働省）

ＰＳＡマニュアル目次