ISO 15190:2003(E)

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
- 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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- [21] IEC 61010-2-051, Safety requirements for electrical equipment for measurement, control, and laboratory use Part 2-051: Particular requirements for laboratory equipment for mixing and stirring
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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の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。同時にチェ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。

日本臨床衛生檢查技師会 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

はじめに

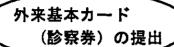
安全な医療を提供するための10の要点

I. 安全対策.

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患者誤認対策 1. 採血室

※患者確認に使用する証明ツールは患者から離さない (診察券や外来基本カード等)



- ●所定位置に提出できるよう明示する
- ●採血の順番を確認できる工夫をする



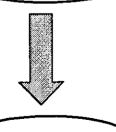
外来基本カードの受付 (採血管準備)



採血室への 患者呼び入れ



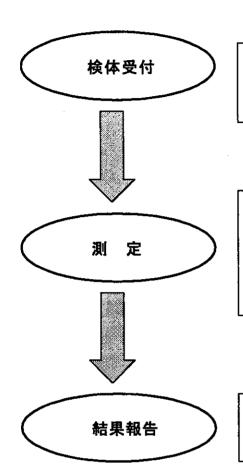
採血



採血終了

- ●採血の依頼は2科以上ないか確認する
- 2 科以上ある場合検査内容が重複していないか確認する
- ●採血管を外来基本カードの提出順に並べてあるか確認 する
- ●大きな声で語尾まではっきりとフルネームで呼ぶ (プライバシーを重視する場合、番号で呼ぶなど考慮)
- ●コミニュケーションの困難な患者は家族等の協力を得て確 認する
- ●患者が持っている診察券等を用い患者確認をする 氏名(患者自身にも名乗ってもらう、 生年月日(必要に応じ患者に申告してもらう)
- ●採血管ラベルの名前が患者と一致しているか確認する (患者にも確認してもらう)
- ●採血管の本数を確認する
- ●外来基本カード等と患者が一致するか最終確認し、外 ・ 来基本カード患者に返却する
- ※可能な範囲で、人的確認と機器による確認を併用する

患者誤認対策 2. 検体検査



※確認作業は2名以上で行うことが望ましい

- ●採血容器名と依頼伝票名の確認をする
- ●受付番号を間違わないようにする (バーコードシールなど貼付する際は必ず番号確認)
- ●検体種別は誰が見てもわかるようにする
- ●データチェックをする (前回値・項目間・時系列・再検等) 本人の検体か疑わしい場合は依頼先に問合わせる →採血状況など確認し検体再提出を依頼する
- ●手入力結果報告は注意する
- ●印刷ミス、印字ずれなどのチェックも行う

患者誤認対策3. 生理機能検査

