JEITA 一般社団法人　電子情報技術産業協会
Japan Electronics and Information Technology Industries Association

医療機器の規制に関する国際動向シンポジウム
リスクマネジメント規格の動向

IEC SC62A/JWG1 リスクマネジメント国内委員会主査
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本日の解説内容

- ISO 14971の歴史と対応するJIS
- ISO 24971開発と概要
- IEC/SC62A/JWG1最近の動き
- EN ISO 14971:2012
- Annex ZA(informative)の中身は？
- 最近の情報は？Team NB Position Paper

ISO 14971の歴史	対応するJIS
1994年 TC210が医療機器のリスクマネジメント策定することが決定	
1997年 EN1441リスク分析正式にMDD整合規格	←リスク推定まで
1998年 ISO14971-1 リスクマネジメント 第１部リスク分析の適用	2001年 JIS Q 14971-1 医療機器ーリスクマネジメントー 第1部リスク分析の適用
2000年 ISO14971:2000 医療機器へのリスクマネジメントの適用	2003年 JIS T 14971 医療機器ーリスクマネジメントの医療機器への適用Ed1
2003年 ISO14971 Am1要求事項の理論的根拠	
2007年 ISO14971 Ed.2:2007第２版　発行	2012年 JIS T 14971 医療機器ーリスクマネジメントの医療機器への適用Ed2

ISO24971

ISO 14971：2007改定時には改定による他の規格への影響が多大なため、
ガイダンスの強化をはかった。

2010年のシアトル会議で再度改定に対する各国コメントを審議した結果、
改定は行わず5項目に特化したガイダンスとして、
ISO 24971の開発にとりかかった。

2013年にISO 24971　ISO 14971適用のガイダンスとして発行された。

2013年ラスベガスでのJWG1会議では、
GUDE51、63、73、ISO 14971の現状の問題と今後の改定に関し話し合われた。

ISO24971策定の背景

- ISO 14971はメンテナンスサイクルが近づいた。
- 2010年のシアトル総会でメンテナンスは行わない事を決議した。
- その理由は、数百の規格がこのISO 14971を参照しており、影響が大きい。よって規格の改定は行わず、各国からのコメントで多かった５項目に関してガイダンスを作成する。

ISO24971 ガイダンスの構成

＊赤字：コメントが多かった5項目

1	適用範囲
2	国際製品安全規格とプロセス規格の役割
2.1	概要
2.2	リスクマネジメントにおける国際製品安全規格の利用
2.3	国際プロセス規格とISO 14971
3	リスクの受容可能性の判断基準を決定するための方針の構築
4	製造及び製造後のフィードバック・ループ
4.1	序文
4.2	観察及び伝達
4.3	評価
4.4	実行
5	安全に関する情報と残留リスクの開示の区別
5.1	「安全に関する情報」及び「残留リスクの開示」における違い
5.2	安全に関する情報
5.3	残留リスクの開示
6	全体的な残留リスクの評価
6.1	概要
6.2	全体的な残留リスクの評価に関するインプット及び他の考慮事項

IEC/SC62A/JWG1最近の動き

- 2013年3月　千葉会議（TC210と併設）開催
  ISO 24971　Guidance on the application of ISO 14971の完成
- 2013年12月 ラスベガス会議開催
  GUIDE 51,63,73及びISO 14971Ed2の問題点の相互理解のための会議
- 2014年5月 リュベック会議　問題点の明確化と方向付け、今後の日程決定及びTC210　ノルウエー会議（9月）、TC62プレナリー米国(11月）への報告事項の決定のための会議

IEC/SC62A/JWG1最近の動き（続き）

・ここでGUIDE 51とは何か

Safety aspects — Guidelines for their inclusion in standards

Scope

This Guide provides drafters of standards with guidelines for the inclusion of safety aspects in standards. It is applicable to any safety aspect related to people, property or the environment, or a combination of these (e.g. people only; people and property; people, property and the environment). The term "products and systems" used throughout this Guide includes products, processes, services and systems.

IEC/SC62A/JWG1最近の動き（続き）

・ここでGUIDE 63とは何か

Guide to the development and inclusion of safety aspects in International Standards for medical devices

Scope

This Guide provides additional guidance to standards writers for hoe to include safety aspects in the development of medical device safety standards intended to be used within the risk management framework established in ISO 14971. It expands on the concepts developed in ISO/IEC Guide 51 to include safety- related performance and usability.

This Guide is intended to be read in conjunction with ISO/IEC Guide 51 and ISO 14971.

IEC/SC62A/JWG1最近の動き（続き）

・ここでGUIDE 73とは何か

Risk management — Vocabulary

Scope

This Guide provides the definitions of generic terms related to risk management. This Guide aims to encourage a mutual and consistent understanding, a coherent approach to the description of activities relating to the management of risk, and use of uniform risk management terminology in processes and frameworks

dealing with the management of risk.

IEC/SC62A/JWG1最近の動き（続き）

・問題点

GUIDE 51は一般機器のリスクマネジメントであり、医療機器に対しては完全に合致していない。メディカルが後に出来たため、コメントを出しても相手にされない。Ex. ″tolerable risk″ and ″acceptable risk ″

・GUIDE73も同じく共通フレームワークでの用語であり、メディカルとは微妙に用語が違う。

・GUIDE 63ではこれらを参照しているため影響を受ける。当然ISO 14971も影響を受ける。

IEC/SC62A/JWG1最近の動き（続き）

- **Recommendation to be reported to ISO/TC 210 and IEC/SC 62A.**

Having considered the issues identified during the review of Guide 51, Guide 62 and Guide 73, the JWG is considering recommending a restructuring of Guide 63. The revised Guide 63 would become a blueprint for the eventual revision of ISO 14971. As homework, the members of JWG 1 are asked to look at the current Guide 63 in light of the revision of Guide 51 and prepare proposals for how Guide 63 might be restructured. Based on that work, the JWG will prepare a proposal to be placed on the table at the fall meetings of ISO/TC 210 in Stockholm and IEC/SC 62A in Sao Polo.

EN ISO 14971:2012

- EU地域では2013年1月から強制となった。
- ISO 14971:2007との違いはANNEX Z（ZA,ZB,ZC)
- 要求事項の差はISO 14971：2007とは無い
- MDDを参照している部分が違う

Annex ZA(informative)の中身は？

その構成は

- General
- Risk Control
- Risk Acceptability:
- Clinical data
- Risk Benefit Evaluation:
- Conformity assessment procedures

Annex ZA(informative)の中身は？（続き）

- **General**

This standard provides a process for managing risks associated with medical devices. Because this standard describes an ongoing, lifecycle process applicable in part or in all to the Essential Requirements of Directive 93/42/EEC on medical devices, it is not meaningful to link individual clauses of the standard to specific corresponding Essential Requirements.

Annex ZA(informative)の中身は？（続き）

Compliance with all the requirement clauses in EN ISO 14971 in a rigorous manner will ensure that a process is in place to address general risk management aspects related to medical devices, which are included in the general Essential Requirements 1-6a, and which are the basis of the Essential Requirements 7-13 regarding design and construction. Thus, while all of these Essential Requirements are partly covered, none of them is entirely covered. For particular medical devices and for particular safety aspects, additional specific requirements will need to be complied with in order to fully meet. the Essential Requirements. Relevant harmonized standards may also be used for these purposes.

Annex ZA(informative)の中身は？（続き）

- **Users and third persons**

With respect to users of medical devices and third persons, additional specific requirements from other EU Directives will need to be complied with in order to meet Essential Requirement 1.

- **Risk Control**

European medical devices directives require that, in selecting the most appropriate solutions for the design and construction of the devices, these solutions must conform to safety principles, taking account of the generally acknowledged state of the art, and the manufacturer must apply the following principles in the following order:

Annex ZA(informative)の中身は？（続き）

1. eliminate or reduce risks as far as possible (inherently safe design and construction),

2. where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,

3. inform users of the residual risks due to any shortcomings of the protection measures adopted.

This requirement is emphasized in the Risk Control option analysis section of the standard (Sub clause 6.2 of EN ISO 14971:2009).

Annex ZA(informative)の中身は？（続き）

- **Risk Acceptability:**

EN ISO 14971 requires that the manufacturer must define and document a policy for determining the criteria for risk acceptability. The policy for determining the risk acceptability criteria must meet four requirements (Sub clause 3.2 of EN ISO 14971:2009):

a) ensure that it is based on applicable regulations;

b) ensure that it is based on relevant standards;

c) take into account accepted state of the art; and

d) take into account stakeholder concerns.

Annex ZA(informative)の中身は？（続き）

Thus, if EN ISO 14971:2009 is used to claim compliance with the European medical device directives, the manufacturer's policy, and hence the acceptability criteria based on that policy, must meet the Essential Requirements (ERs) of the relevant directives. In this context, it is especially important to apply the safety principles as described in the section above on risk control.

Annex ZA(informative)の中身は？（続き）

- **Clinical data**

The risk management process described in EN ISO 14971 could establish the need for collection of clinical or other experimental data for risk-benefit evaluation purposes. It does not describe how this has to be carried out. Relevant harmonized standards may be used for this purpose.

Annex ZA(informative)の中身は？（続き）

- Risk Benefit Evaluation:

Essential requirements in the European medical device directives require a risk-benefit analysis for any risks. EN ISO 14971 explicitly requires a risk benefit analysis if any residual risks are not judged acceptable using the acceptability criteria (Sub clause 6.5 of EN ISO 14971:2009). For risks judged acceptable using the acceptability criteria, a risk benefit analysis is implicitly performed since it is one of the basic elements in determining the acceptability criteria. EN ISO 14971 also requires that all residual risks combined are weighed against the medical benefit (Clause 7 of EN ISO 14971:2009).

Annex ZA(informative)の中身は？（続き）

- **Conformity assessment procedures**

EN ISO 14971 can also be used to support the following parts of conformity assessment procedures in the European medical devices directives:

- an adequate description of results of the risk analysis (included in the risk management file, see sub clause 3.5 of EN ISO 14971:2009),

Annex ZA(informative)の中身は？（続き）

- an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action (see clause 9 of EN ISO 14971:2009). NOTE: Other and more detailed requirements may be applicable to this aspect.

最近の情報は？Team　NB Position Paper

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EN ISO 14971:2012	

最近の情報は？（続き）

- **What is the difference between EN ISO 14971:2012, EN ISO 14971:2009 and ISO 14971:2007?**

There has been **no change to the Normative Text** of the standard; the Normative Text contains the requirements and is the **same in all three versions**. Only the **Annex Zs of EN ISO 14971 have changed in the 2012 version**. The new Annex Zs describe where the EN ISO 14971 standard does and does not meet the requirements of the European Directives. The Annex Zs describe these differences as Content Deviations for each Directive.

What does this mean for future Notified Body Quality System or Technical Documentation Audits and Design Dossier Reviews?

最近の情報は？（続き）

The role of the Notified Body is to assess compliance to the Directives, focusing on risk management and whether clinical benefits outweigh risk to patients and users. Manufacturers should have read the new harmonized standard and can then choose to use the harmonized standard to help meet the requirements of the Directives. The latest harmonized version has clarified the gaps.

Notified Body Assessors and Technical Specialists will be asking questions in upcoming audits and reviews that ensure that manufacturers who place devices on the market in Europe are aware of the gaps between the requirements of the standard and those of the Directives, and that manufacturers have undertaken (or are undertaking) any actions needed to address these.

最近の情報は？（続き）

- **Key questions will include:**

1. Are all design solutions conform with the safety principles given in the essential requirements and EN ISO 14971? (inherent safe design > protection measures > information)

2. Have manufacturers shown that risks have been reduced as much as possible?

3. Have manufacturers conducted a risk benefit analysis for all risks?

最近の情報は？（続き）

4. As publication of residual risks in the information given to the user does not reduce the risk, but publication of residual risks and warnings used as risk control measure may be beneficial, have residual risks been correctly placed on IFUs or provided in training, and have manufacturers evaluated whether those warnings are effective (refer to IEC 62366).

最近の情報は？（続き）

The wording in the Directives has not changed and some manufacturers will have procedures and risk management files that already comply. Others may have corrective actions to take. Please be ready at your next Notified Body QMS or Technical File Assessment to share evidence to show that EN ISO 14971:2012 Annex Z has been considered in your compliance to the Essential Requirements for newer devices and to share your plans for evaluating and addressing the impact of EN ISO 14971:2012 Annex Z on older and legacy devices that will continue to have CE Marking applied.

まとめ

- ISO 14971Ed2は２回目メンテナンスサイクルに入った。大幅な変更は無いと予測されるがGUIDE51,73によるGUIDE63に対する変更の影響がISO 14971にも懸念される。
- EN ISO 14971:2012は2013年１月より強制になった。製品への影響を評価する必要がある。NBとの見解の整合が必要。

END

ご清聴ありがとうございました。