ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS

FÓRUM NACIONAL DE NORMALIZAÇÃO

CERTIFICADORA DE PRODUTOS E SISTEMAS

Importância da Intervenção das Normas nas Regulamentações

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Painel Setorial Inmetro - Eletromédicos

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Comitê Odonto-Médico-Hospitalar Brasileiro (ABNT/CB-26)

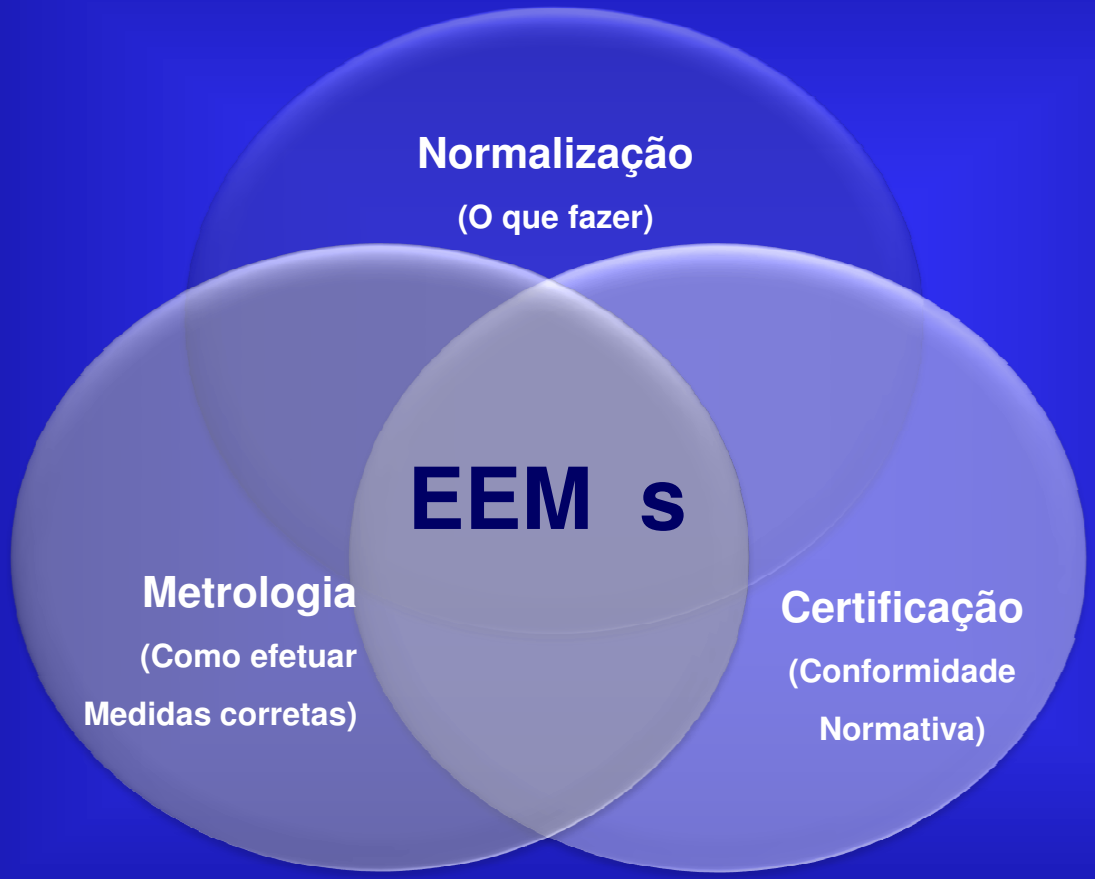
Series Normativas com Estruturação Sistêmica

-Foco na segurança

- Desempenho Essencial

Comitê Odonto-Médico-Hospitalar Brasileiro (ABNT/CB-26)

Segurança, desempenho essencial e gerenciamento de risco.



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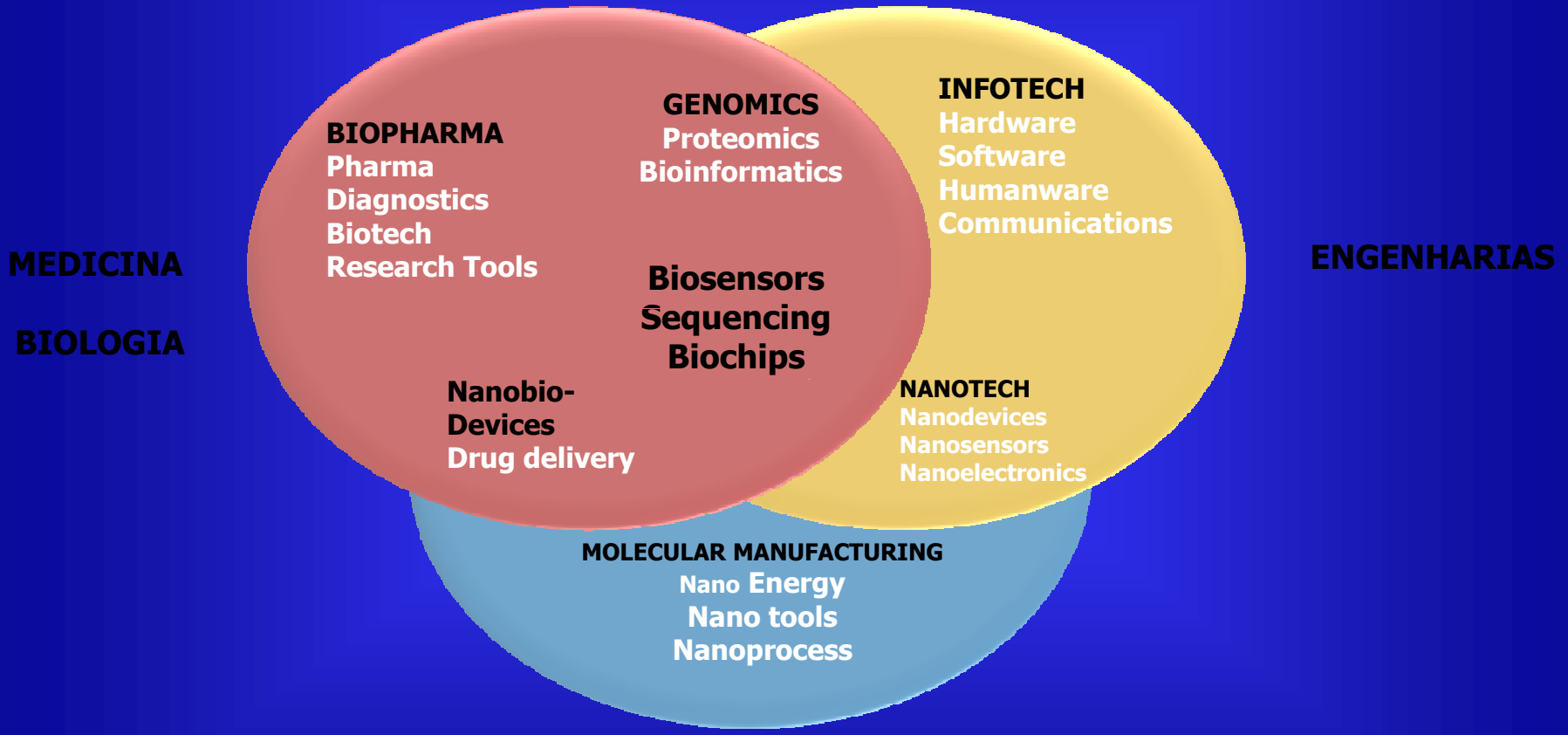
TECNOLOGIAS PRESENTES NO COMPLEXO DA SAÚDE



FATORES PRINCIPAIS QUE INTERFEREM NO DESEMPENHO E NÍVEL DE SEGURANÇA DOS EEM´s NO USO PRETENDIDO

Comitê Odonto-Médico-Hospitalar Brasileiro (ABNT/CB-26)

Normas colaterais
60601-2-6 Usabilidade
60601-2-8 Alarmes

-Especificação de Requisitos Gerais

NBR IEC 60601-1 ed. 2 – 2005
EEM´s e SEEM´s

Referencias normativas
-38 IEC´s
-IEC 60878 Simb. Graf.
-IEC 61558 Segurança de Trafos de Pot. e Fontes de Al.

-20 ISO´s
- NBR IEC 14971 seg. ed. 2009

EEM´s
Série de normas de requisitos particulares para Segurança Básica e Desempenho Essencial:
NBR IEC
60601-1-12 Ventiladores Pulm.
60601-2-19 Incubadoras Infantis

-Modifica
-Substitui
-Suprime

2 * Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ATTENTION: Additional collateral standards of the IEC 60601 series, which are issued subsequent to publication of this standard, become normative at the date of their publication and shall be considered as being included among the normative references below. See 1.3.

NOTE Informative references are listed in the Bibliography on page 743.

IEC 60065:2001, *Audio, video and similar electronic apparatus – Safety requirements*

IEC 60068-2-2:1974, *Environmental testing – Part 2: Tests. Tests B: Dry heat*
Amendment 1 (1993)
Amendment 2 (1994)

IEC 60079-0, *Electrical apparatus for explosive gas atmospheres – Part 0: General requirements*

IEC 60079-2, *Electrical apparatus for explosive gas atmospheres – Part 2: Pressurized enclosures "p"*

IEC 60079-5, *Electrical apparatus for explosive gas atmospheres – Part 5: Powder filling "q"*

IEC 60079-6, *Electrical apparatus for explosive gas atmospheres – Part 6: Oil-immersion "o"*

IEC 60083, *Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC*

1.3 * Collateral standards

In the IEC 60601 series, collateral standards specify general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE applicable to:

- a subgroup of ME EQUIPMENT (e.g. radiological equipment);
- a specific characteristic of all ME EQUIPMENT not fully addressed in this standard.

Applicable collateral standards become normative at the date of their publication and shall apply together with this standard.

NOTE 1 When evaluating compliance with IEC 60601-1, it is permissible to independently assess compliance with the collateral standards.

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ISO 5349-1, *Mechanical vibration – Measurement and evaluation of human exposure to hand-transmitted vibration – Part 1: General requirements*

ISO 7000-DB:2004 [15)], *Graphical symbols for use on equipment – Collection of symbols*

ISO 7010:2003, *Graphical symbols – Safety colours and safety signs – Safety signs used in workplaces and public areas*

ISO 9614-1, *Acoustics – Determination of sound power levels of noise sources using sound intensity – Measurement at discrete points*

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 11134, *Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization*

ISO 11135, *Medical devices – Validation and routine control of ethylene oxide sterilization*

ISO 11137, *Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization*

ISO 13852, *Safety of machinery – Safety distances to prevent danger zones being reached by the upper limbs*

ISO 14971:2000, *Medical devices – Application of risk management to medical devices*

ISO 15223, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied*

ISO 23529, *Rubber – General procedures for preparing and conditioning test pieces for physical test methods*

3.55

MANUFACTURER

natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, **assembling an** ME SYSTEM, **or adapting** ME EQUIPMENT **or an** ME SYSTEM, **regardless of whether these operations are performed by that person or on that person's behalf by a third party**

NOTE 1 ISO 13485 [30] defines "labelling" as written, printed or graphic matter

– affixed to a medical device or any of its containers or wrappers, or

– accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents. In this standard, that material is described as markings and ACCOMPANYING DOCUMENTS.

NOTE 2 "Adapting" includes making substantial modifications to ME EQUIPMENT **or an** ME SYSTEM **already in use.**

NOTE 3 In some jurisdictions, the RESPONSIBLE ORGANIZATION **can be considered a** MANUFACTURER **when involved in the activities described.**

NOTE 4 Adapted from ISO 14971:2000, definition 2.6.

CONTENTS

3.3 Qualification of personnel

Text of ISO 14971:2007

3.3 Qualification of personnel

Persons performing RISK MANAGEMENT tasks shall have the knowledge and experience appropriate to the tasks assigned to them. These shall include, where appropriate, knowledge and experience of the particular MEDICAL DEVICE (or similar MEDICAL DEVICES) and its use, the technologies involved or RISK MANAGEMENT techniques. Appropriate qualification RECORDS shall be maintained.

NOTE RISK MANAGEMENT tasks can be performed by representatives of several functions, each contributing their specialist knowledge.

Compliance is checked by inspection of the appropriate RECORDS.

3.3.1 General

Team members involved in the development and maintenance of the SOFTWARE SYSTEM should have the knowledge and experience appropriate to the TASKS assigned to them. It is fundamental that the person assigned to TASKS has the required knowledge of RISK MANAGEMENT. The involvement of a multidisciplinary team, including clinical experts, software engineers, SYSTEM designers, experts on usability/human factors engineering, and domain experts, and the degree and type of their interaction with the software engineering and test staff should also be considered with respect to RISK MANAGEMENT.

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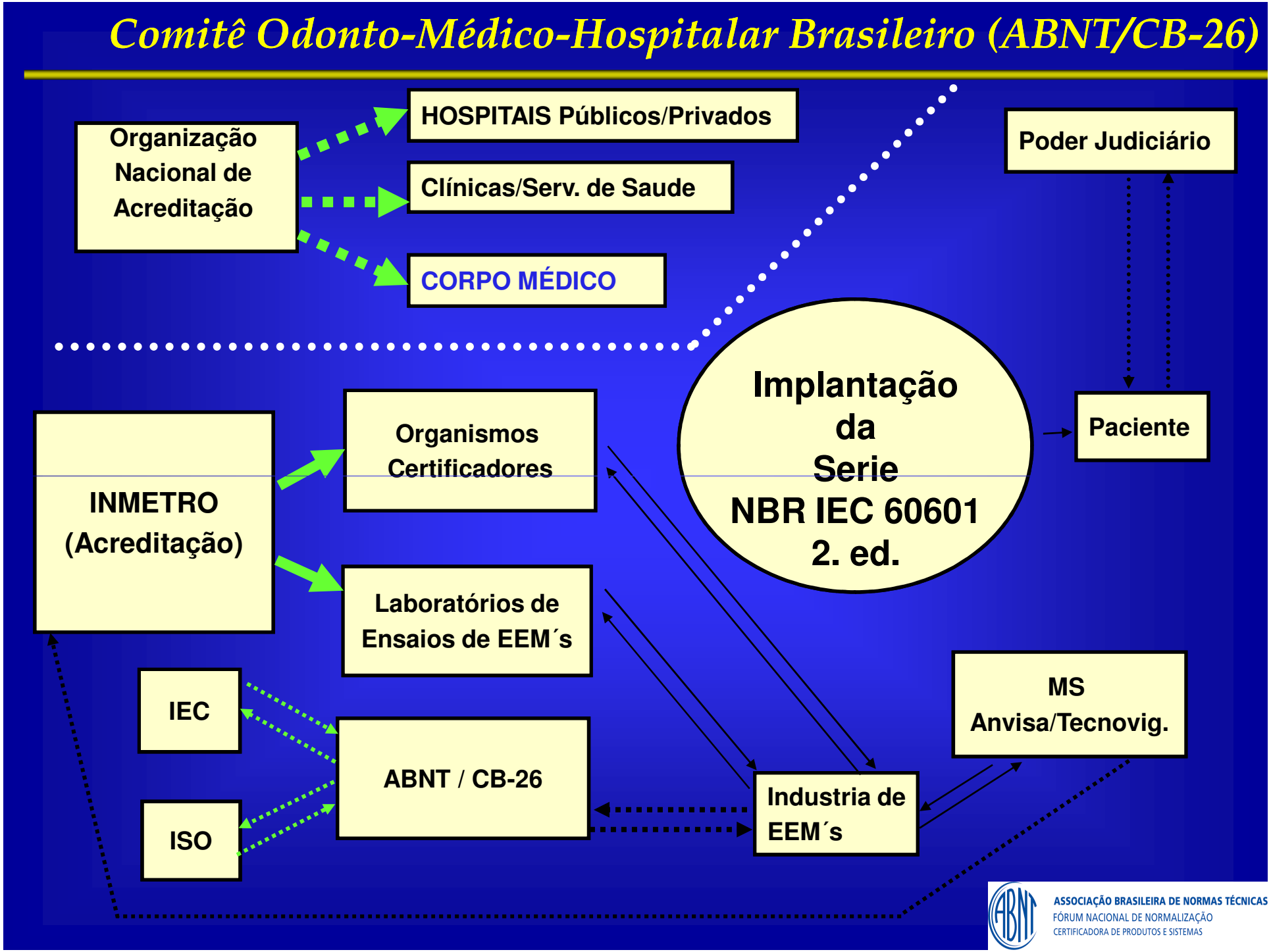

Porque os EEm´s podem causar efeitos adversos

- Equipamentos projetados sem a consulta as normativas.

- Uso de componentes não homologados.

- Homologação de componentes em conformidade com normas inadequadas para aplicação em EEM´s.
(Falhas em transformadores, componentes, fontes chaveadas .....).

- Arquivo de gerenciamento de risco incompleto ou sem a profundidade demandada pelo EEm quanto ao uso pretendido.

- Alterações no processo geram alteração de produto.

- Tempo insuficiente no ciclo de desenvolvimento para análise do EEm no uso pretendido.

Obrigado

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