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INTERSTATE COUNCIL FOR STANDARDIZATION, METROLOGY AND CERTIFICATION
(ISC)



ISO
14971 —
2011

(ISO 14971:2007, IDT)



2013

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1.2—2009 «

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Application of risk management to medical devices () .

ISO 14971:2007 Medical devices —

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14971—2009

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a)

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Medical devices
Application of risk management to medical devices

— 2013—01—01

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in vitro,

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(accompanying document):

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(harm):

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(hazard):

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(hazardous situation):

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2.6
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in vitro (IVD) (*in vitro* diagnostic medical device) (IVD

2.15 (residual risk): ,

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2 [2], 3.9, « » « ».

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2.16 (risk): (. [2], 3.2).

2.17 (risk analysis):
(. [2], 3.10).

2.18 (risk assessment): (. [2], 3.12).

2.19 (risk control):

2.20 (risk estimation): ,

2.21 (risk evaluation): , ,

2.22 (risk management): , , ,

2.23 (risk management file): ,

2.24 (safety): (. [2], 3.1).

2.25 (severity):

2.26 (top management): ,

— (5), 3.2.7.

2.27 (use error): ,

(. [6], 2.12).

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2.28 (verification):

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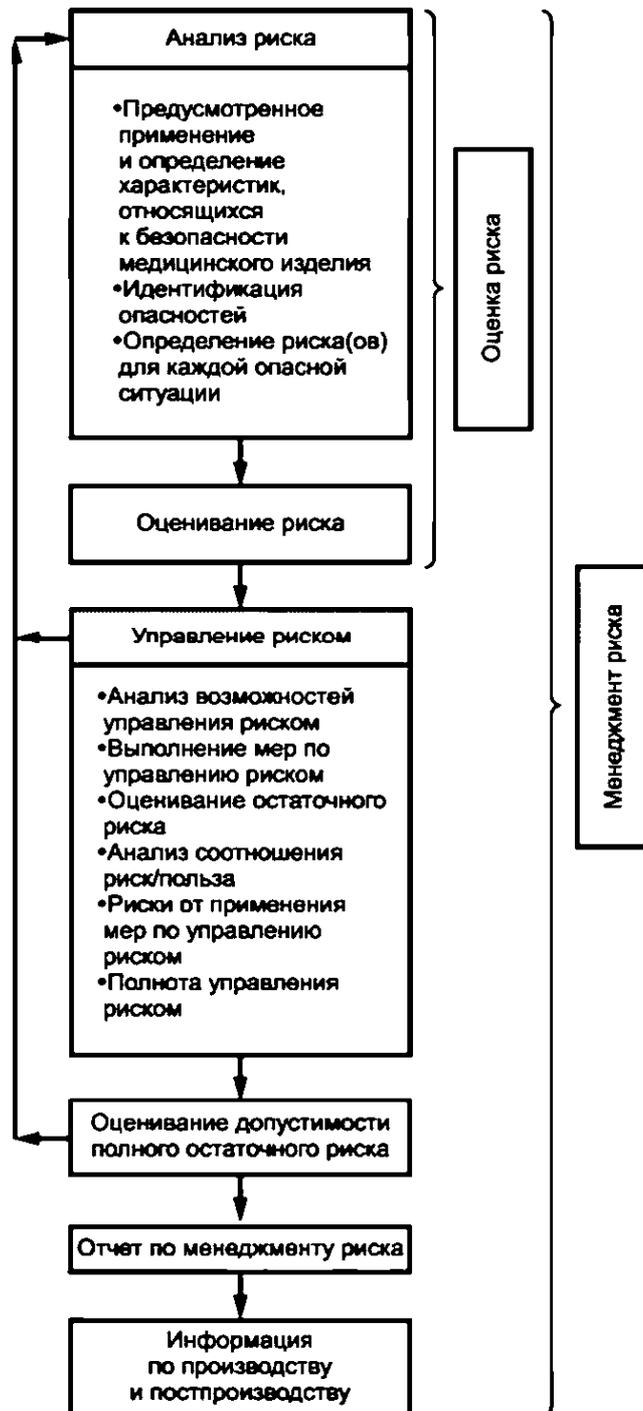
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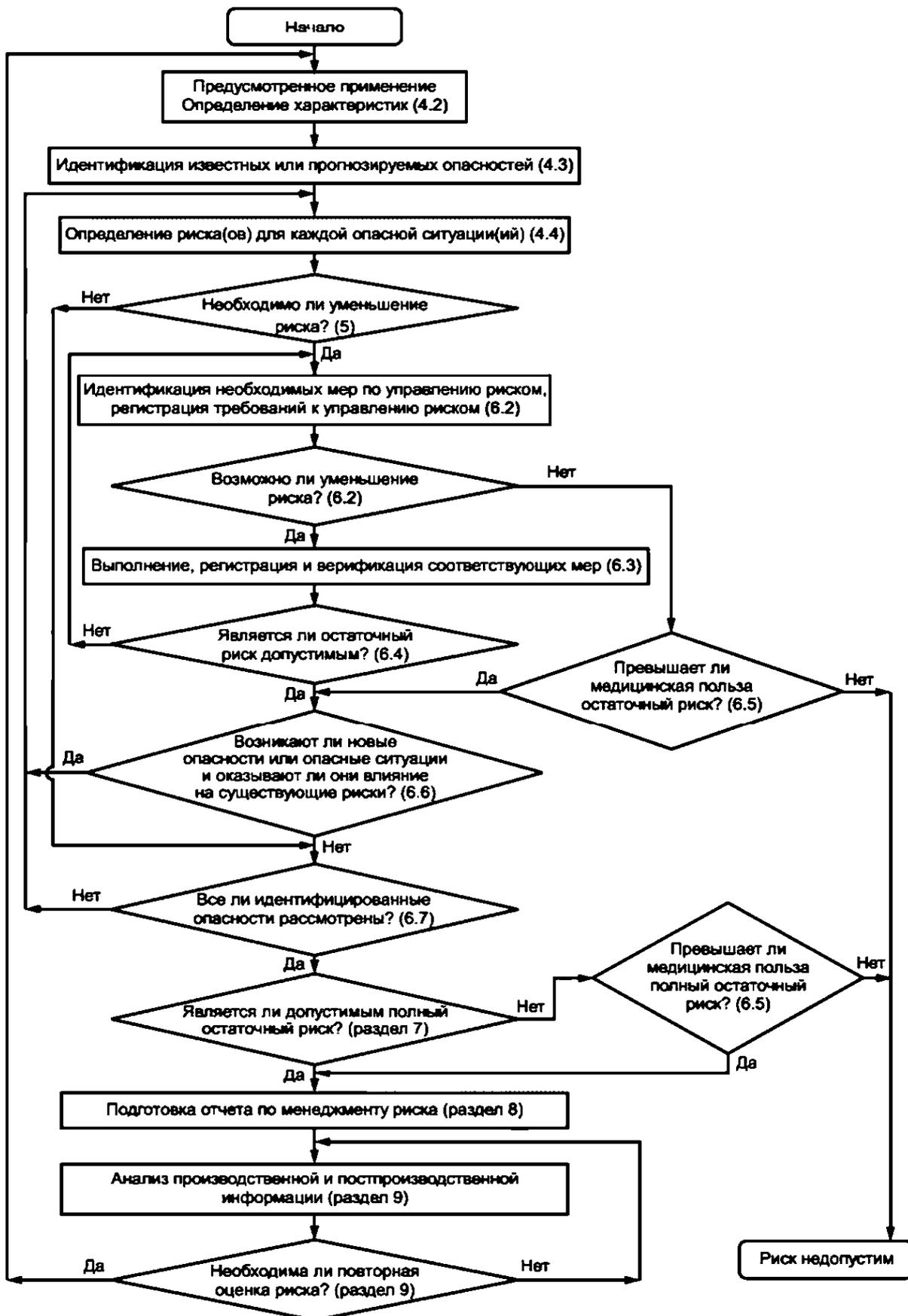
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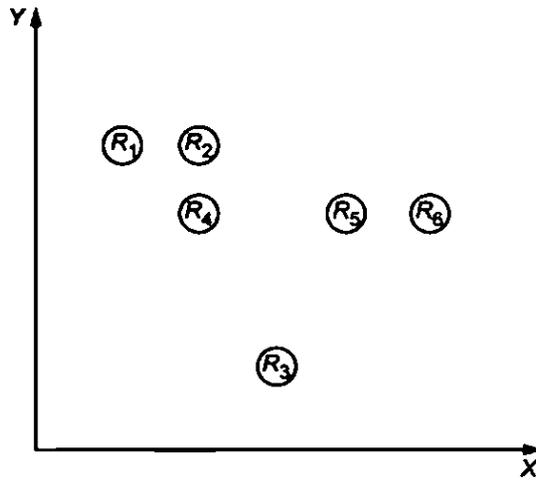
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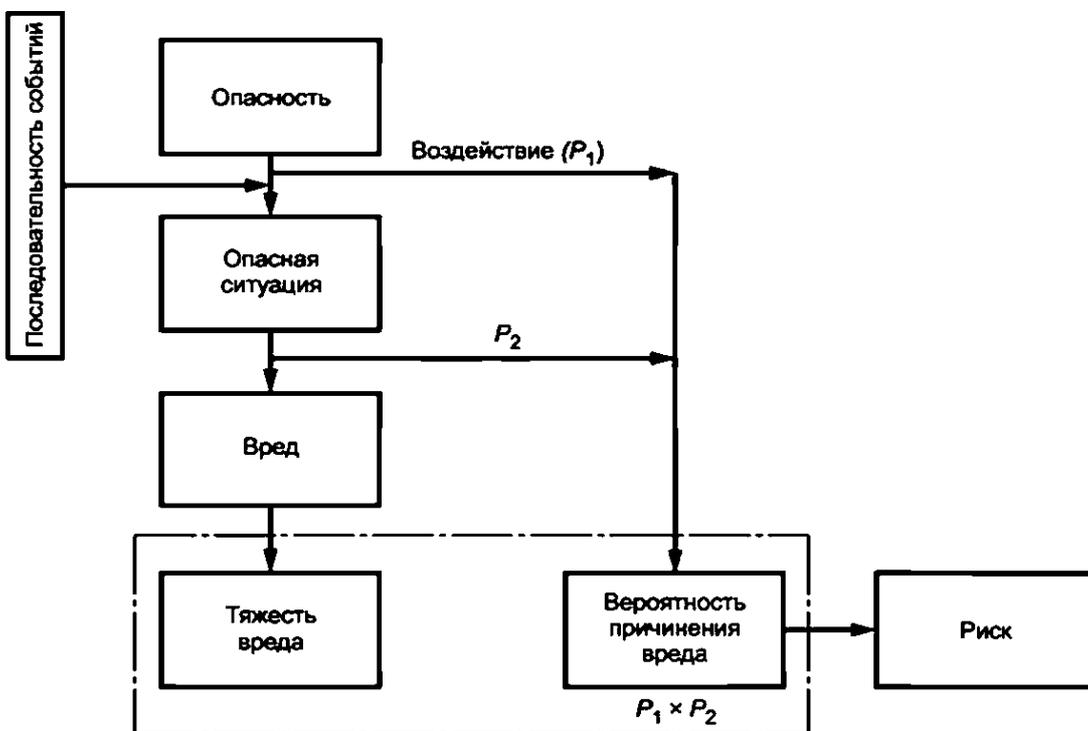
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(Preliminary Hazard Analysis — PHA) —

(Fault Tree Analysis — FTA) —

(Failure Mode and Effect Analysis — FMEA)
(Failure Mode, Effects and Criticality Analysis — FMECA)

(Hazard and Operability Study — HAZOP)
(Hazard Analysis on Critical Control Points — HACCP) —

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- a)
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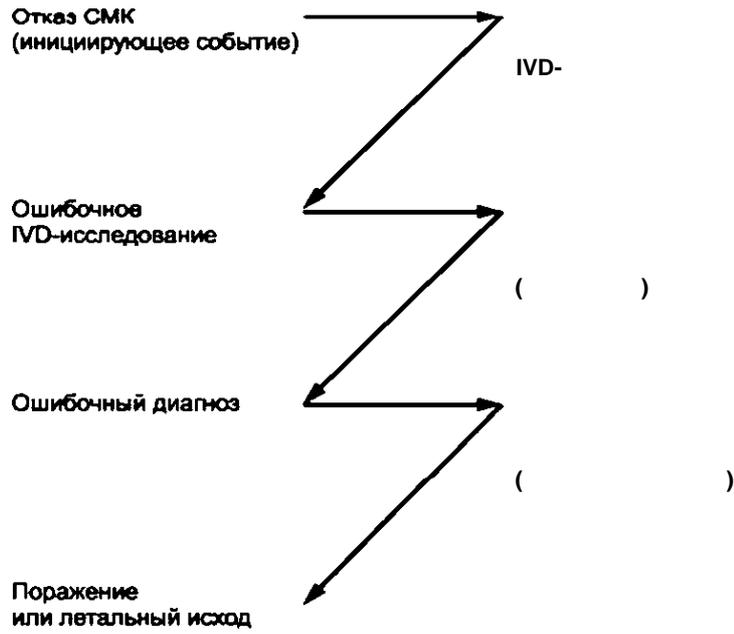
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(Fault Tree Analysis — FTA).

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(External Quality Assessment Schemes

— EQAS),

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- [1] IEC 60601-1:2005 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
(1.) -
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(1-8.) -
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(1.) -

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() 2. -
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()
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(*in vitro*.) -
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(*in vitro*.) -
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(*in vitro*.) -
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(*in vitro*) *in vitro*. -
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(*in vitro*.) *in vitro* -
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