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INTERSTATE COUNCIL FOR STANDARDIZATION, METROLOGY AND CERTIFICATION  
(ISC)

# **IEC 62304— 2022**

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**(IEC 62304:2006 + Amd.1:2015, Medical device software —  
Software life cycle processes, IDT)**

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5 IEC 62304:2006 « » ( «Medical device software — Software life cycle processes», IDT), Amd.1:2015. Amd.1:2015

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6 62304—2013\*

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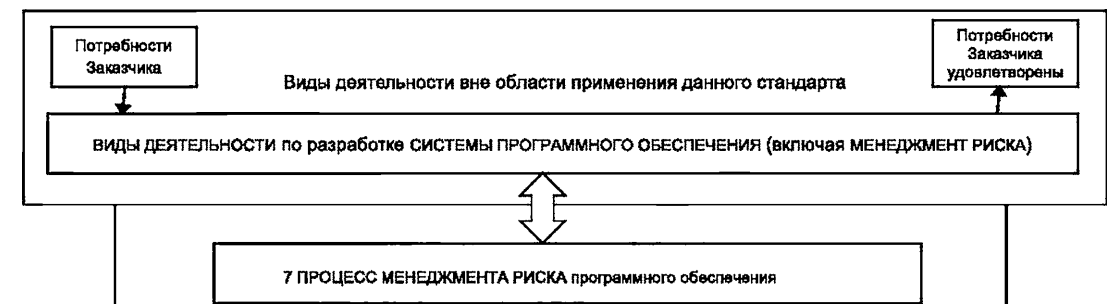
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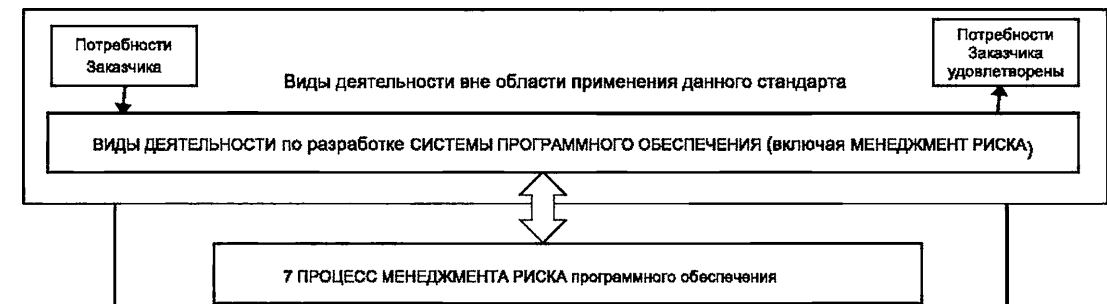


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Medical devices. Software. Life cycle processes

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ISO 14971, Medical devices — Application of risk management to medical devices ( )

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3.1 (ACTIVITY):

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— IEEE 1044:1993, 3.1.

3.3	(ARCHITECTURE):	.
[IEEE 610.12:1990]		
3.4	(CHANGE REQUEST):	-
3.5	(CONFIGURATION ITEM):	,
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3.6	(DELIVERABLE):	(
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3.7	(EVALUATION):	.
[ISO/IEC 12207:2008, 4.12]		
3.8	(HARM):	
[ISO 14971:2007 2.2]		
3.9	(HAZARD):	
[ISO 14971:2007 2.3]		
3.10	(MANUFACTURER):	,
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	[ISO 9000:2005,	3.4.1]		
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	3.15	(REGRESSION TESTING):		-
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	[ISO/IEC 90003:2004,	3.11]		
	3.16	(RISK):		
	[150 14971:2007 2.16]			
	3.17	(RISK ANALYSIS):		
	[150 14971:2007 2.17]			
	3.18	(RISK CONTROL):		
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	3.19	(RISK MANAGEMENT):		-
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	[ISO 14971:2007, 2.12,	— «	» ]	
	3.20	(RISK MANAGEMENT FILE):		
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	3.21	(SAFETY):		
	[ISO 14971:2007 2.24]			
	3.22	(SECURITY):		
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	—	ISO/IEC 12207:2008, 4.39.		
3.23		(SERIOUS INJURY):	,	:
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3.25 (SOFTWARE ITEM):

2 — ISO/IEC 90003:2004, 3.14 ISO/IEC 12207:2008, 4.41.

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3.27 (SOFTWARE SYSTEM):

3.28 (SOFTWARE UNIT):

3.29 software of unknown provenance (acronym): ( ) (SOUP -

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3.30 (SYSTEM):

— ISO/IEC 12207:2008, 4.48.

3.31 (TASK):

3.32 (TRACEABILITY):

[IEEE 610.12:1990]

3.33 (VERIFICATION):

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	[ISO 9000:2005, 3.8.4]	
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3.34	(VERSION):	-
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	2 — ISO/IEC 12207:2008, 4.56.	
3.35	(HAZARDOUS SITUATION):	-
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3.36	[ ] (LEGACY SOFTWARE):	-
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3.37	(RELEASE):	-
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	— ISO/IEC 12207:2008, 4.35.	
3.38	(RESIDUAL RISK):	,
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	1 — ISO/IEC Guide 51:1999, 3.9.	
	2 — ISO/IEC Guide 51:1999, 3.9 « »»,	
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	[ISO 14971:2007, 2.15]	
3.39	(RISK ESTIMATION):	-
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	[ISO 14971:2007, 2.20]	
3.40	(RISK EVALUATION):	,
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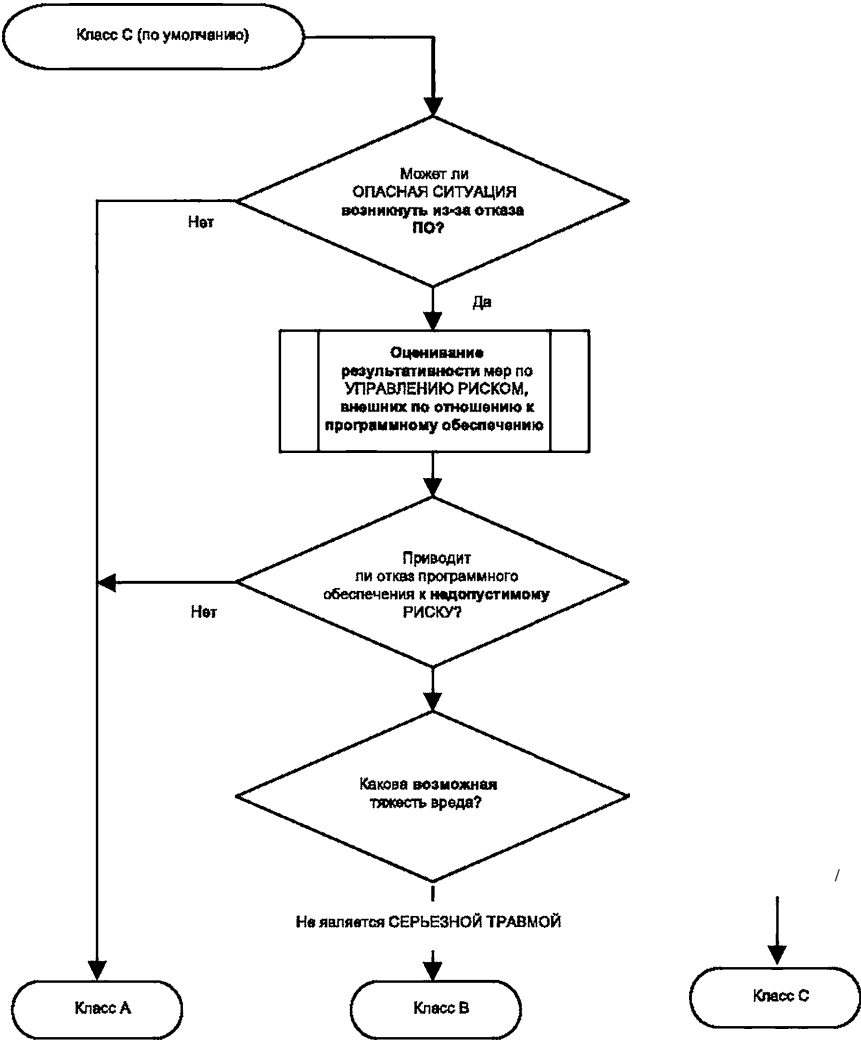
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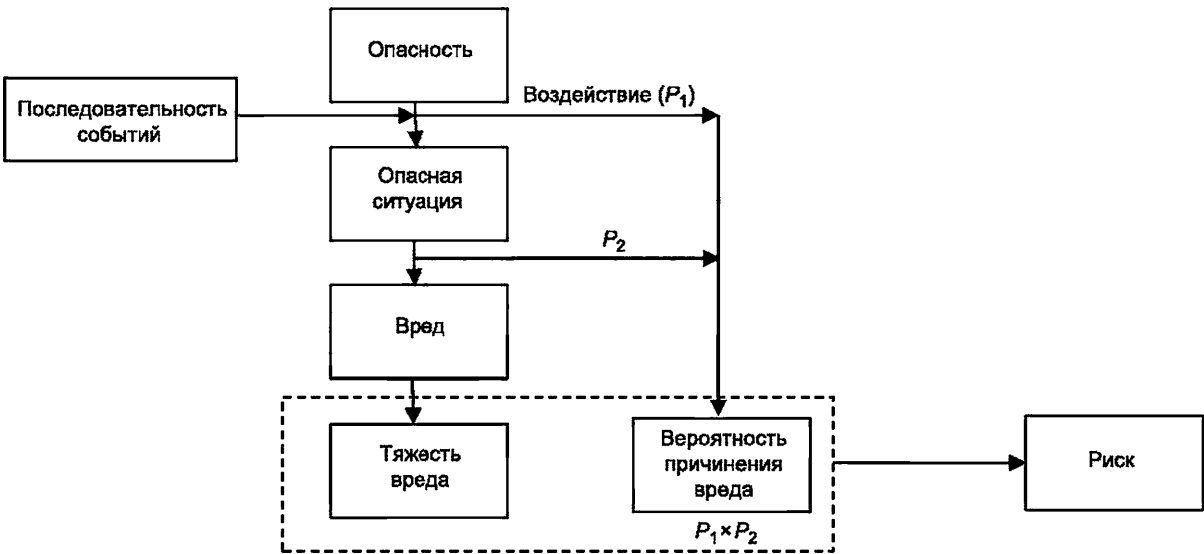
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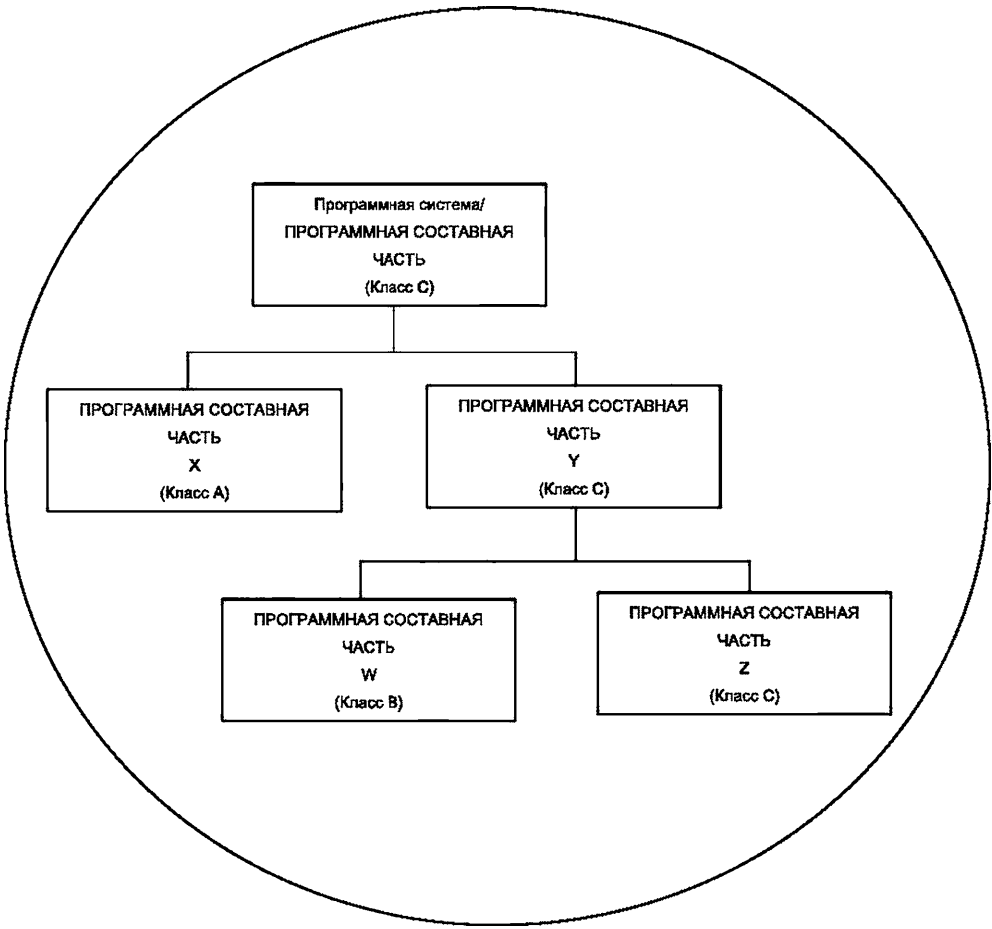


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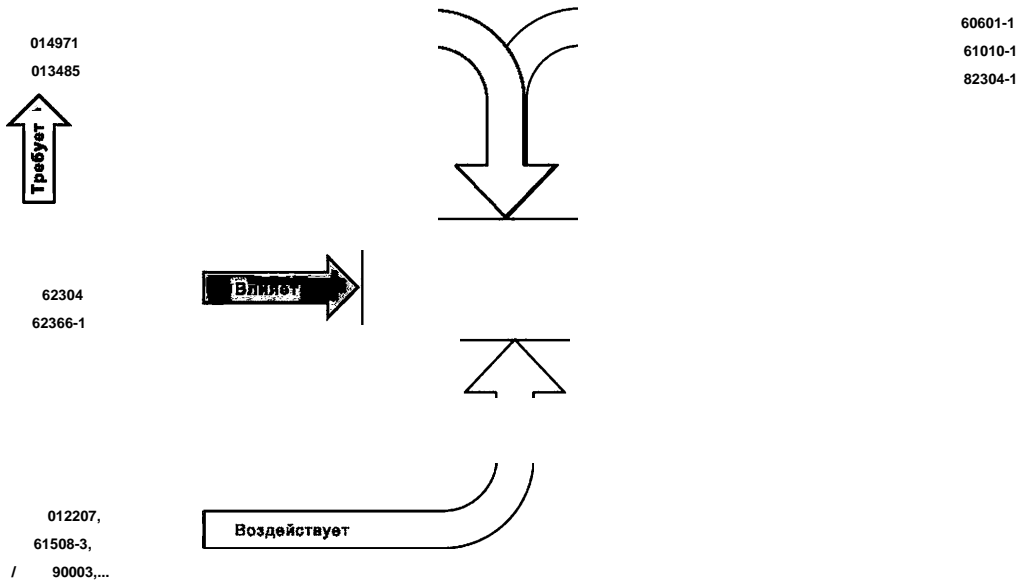
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.6), IEC 61508-3 [4] ( . .7) ISO/IEC 90003 [15], -  
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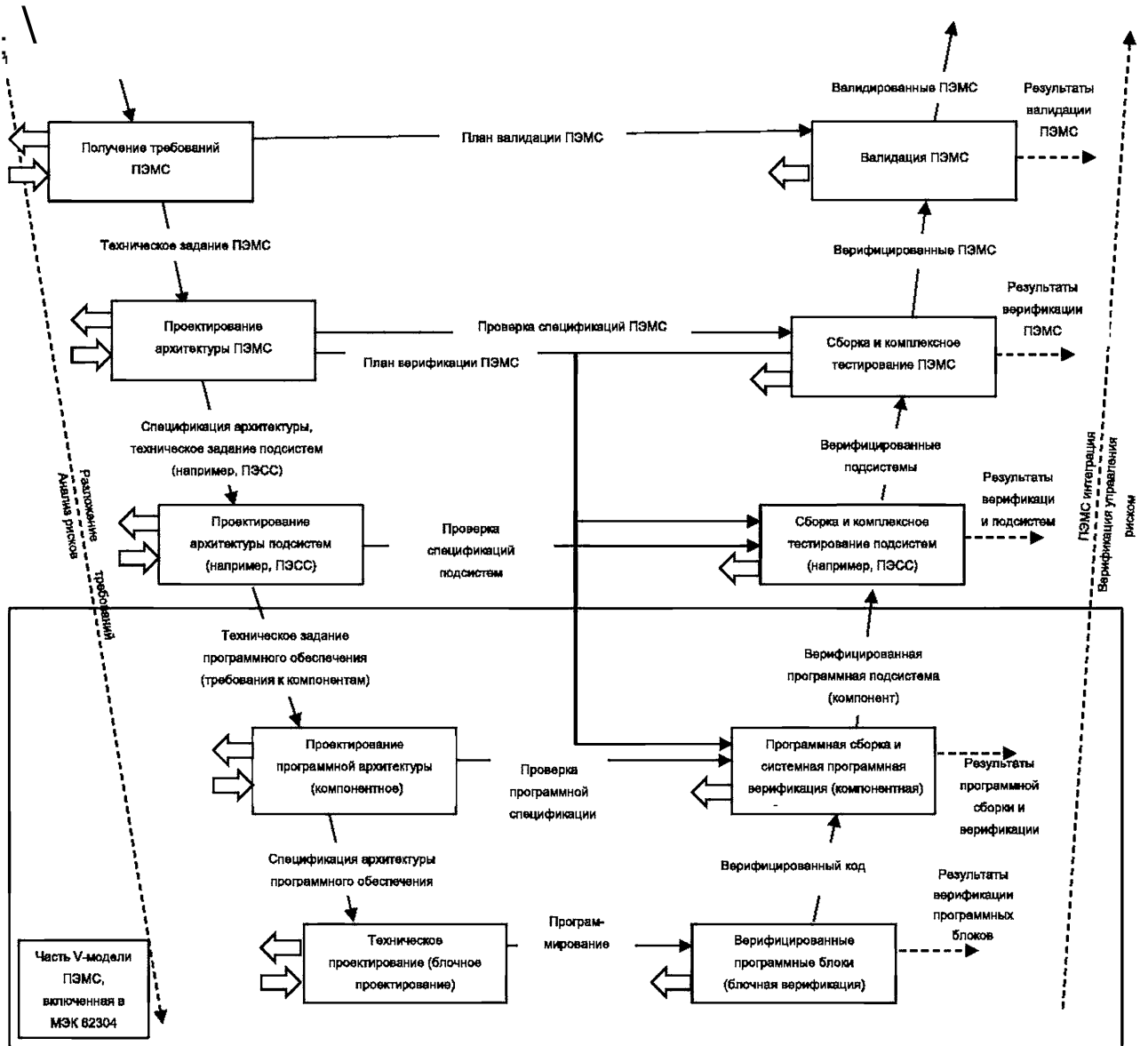
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IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012	IEC 62304,
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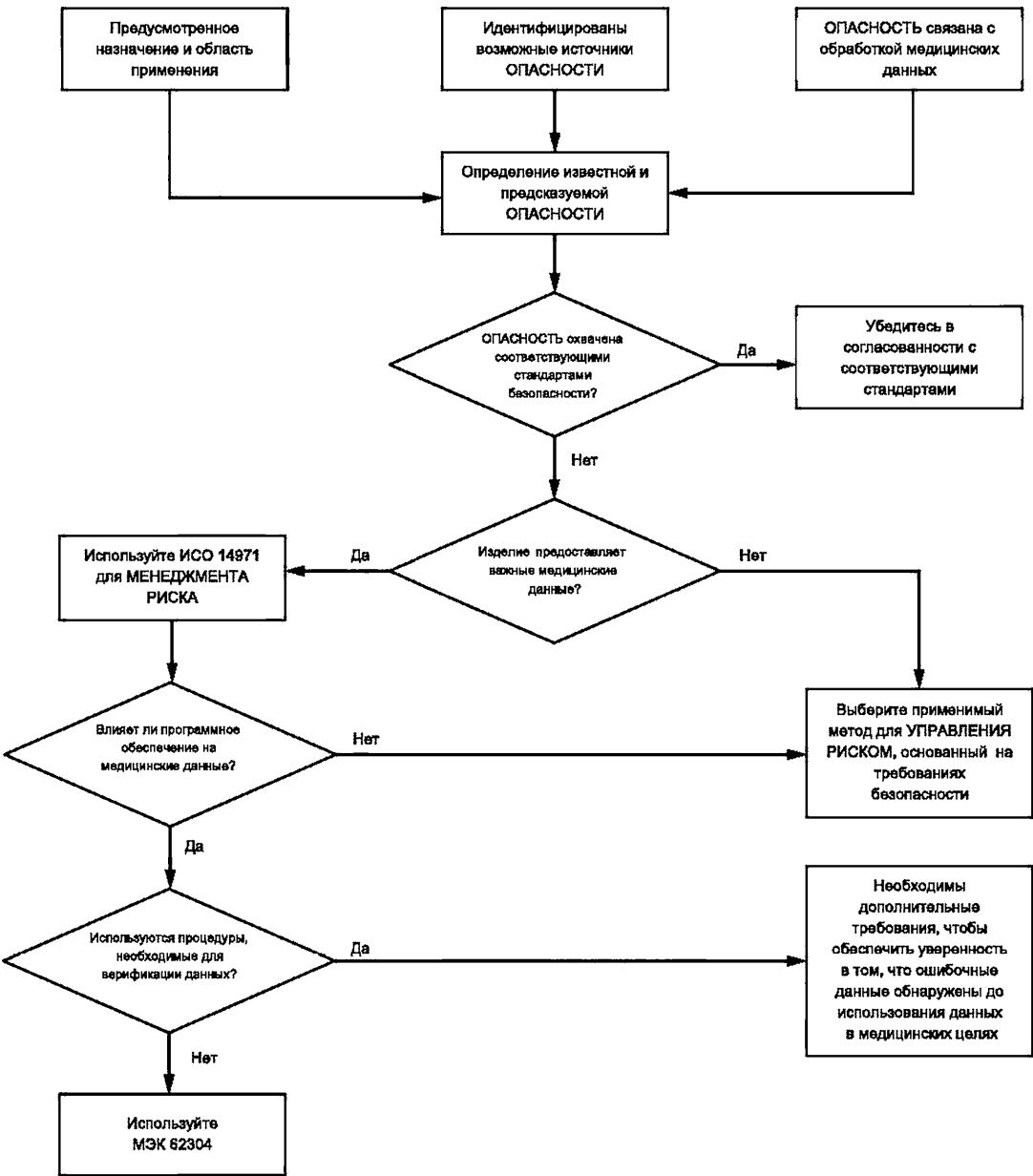


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.6 ISO/IEC 12207

ISO/IEC 12207 [9],

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ISO/IEC 12207);

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.5 — ISO/IEC 12207:2008

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