

**Ministerial Notification No. 112, Appendix Table, No.3- 487**  
**Essential Principles Checklist ( Nuclear medicine system workstation etc. )**

Essential Principles in Japan: Version2014		Applied / Not applied	Identity of Specific Documents	
<b>Chapter 1 General Requirements</b>				
Article1		Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004;JIS T 14971:	
Article2		Applied	JIS T 14971:	
Article3		Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004	
Article4		Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004;JIS T 14971:	
Article5		Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004;JIS T 14971:	
Article6		Applied	JIS T 14971: That the following items satisfying the design specification shall be shown. (1) Processing function of image and information (2) Image display function (3) I/O function with external devices	
<b>Chapter 2 Requirements for design and manufacture</b>				
Article7	1			
		1	Partially applied JIS C 62368-1:2018;JIS T 0601-1:	
		2	Not applied	
		3	Applied JIS C 62368-1:2018;JIS T 0601-1:	
	2		Not applied	
	4	first	Not applied	
		second	Not applied	
	5		Not applied	
	6		Not applied	
	7		Applied JIS C 62368-1:2018;JIS T 0601-1:	
Article8	1		Not applied	
		1		
		2		
	3			
	2		Not applied	
	3		Not applied	
	4		Not applied	
	5		Not applied	
	6		Not applied	
	7		Not applied	
8		Not applied		
9		Not applied		
10		Not applied		
Article9	1	Applied	JIS T 14971;Dicom;JIS T 0601-1:	
	2	Applied	PFSB Notification No. 1002-8 dated October 2, 2014;JIS T 0601-1:	
	3	Not applied		
	4			
		1	Applied	JIS C 62368-1:2018;JIS T 0601-1:
		2	Applied	JIS T 14971:
		3	Not applied	

	4	Not applied	
	5	Applied	JIS T 14971:
	6	Applied	JIS C 62368-1:2018;JIS T 0601-1:
	7	Not applied	
	8	Not applied	
	9	Not applied	
	5	Applied	JIS C 62368-1:2018;JIS T 0601-1:
	6	Applied	JIS T 14971:
	7	Applied	JIS T 14971:
Article10	1	Applied	JIS T 14971;;MHLW Ministerial Ordinance No. 169 dated December 17, 2004
	2	Not applied	
	3	Not applied	
	4	Applied	JIS T 14971:
	5	Applied	JIS T 14971:
Article11	1	Not applied	
	2	Not applied	
	3	Not applied	
	4	Not applied	
	5	Not applied	
	6	Not applied	
	7	Not applied	
	8	Not applied	
	9	Not applied	
	10	Not applied	
Article12	1	Applied	JIS T 14971;;JIS C 62368-1:2018;JIS T 0601-1:
	2	Applied	JIS T 14971;;JIS T 2304:
Article13	1	Applied	JIS T 14971;;JIS C 62368-1:2018;JIS T 0601-1:
	2	Not applied	
	3	Not applied	
	4	Not applied	
	5	Applied	JIS T 14971;;JIS T 0601-1-2;;CISPR 32:
	6	Applied	JIS T 14971;;JIS T 0601-1-2:又は、;CISPR 24:
	7	Applied	JIS C 62368-1:2018;JIS T 0601-1:
Article14	1	Applied	JIS C 62368-1:2018;JIS T 0601-1:
	2	Not applied	
	3	Partially applied	JIS T 14971:
	4	Partially applied	JIS T 14971:
	5	Applied	JIS C 62368-1:2018;JIS T 0601-1:
	6	Not applied	
	7	Applied	JIS C 62368-1:2018;JIS T 0601-1:
Article15	1	Not applied	
	2	Not applied	
	3	Not applied	
Article16	1	Not applied	
	2	Not applied	
	3	Not applied	
Article17	1	Applied	JIS C 62368-1:2018;JIS T 0601-1;;JIS T 0601-1-2;;CISPR 32;;CISPR 24;;PFSB Notification No. 1002-8 dated October 2, 2014;JIS T 14971:

Article18	1		Applied	PFSB Notification No. 1120-8 dated November 20, 2014
	2		Not applied	
	3	first	Partially applied	MHLW Ministerial Ordinance No. 38 dated March 23, 2005
		second	Applied	MHLW Ministerial Ordinance No. 135 dated September 22, 2004

DRAFT