Survey on Sterilization Validation Practice in Japanese Hospitals

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Introduction

Adequate sterilization of medical instruments is one of the important practices to prevent healthcare associated infections. Japanese private study group "The Forum on Infection Prevention and Medical Instruments" founded in April 1995, conducted nationwide survey on sterilization and sterilization assurance practice among 500 hospitals in 1998^{1} and 2002^{2} after the publication of the first guideline from Japanese Society of Medical Instrumentation (JSMI) for sterilization assurance in healthcare settings in 2000^{3} . The guideline revised in 2005⁴), and after then the third nationwide survey was conducted in the same manner in 2007 and was reported⁵⁾. As revised guideline in one of the questionnaires the implementation of the sterilization process validation in hospitals was asked to reply. As a result, 207 hospitals (45.4%) responded that sterilization process validation was implemented. To investigate the details of the practices of sterilization process validation and its responsibility in these 207 hospitals, an additional survey was conducted.

1. Method

In the third survey, a questionnaire was sent to Japanese hospitals with over 400 beds or which certified sterilization technicians were belonging to. 456 hospitals replied and 207 (45.4%) had implemented sterilization process validation. Additional questionnaire was prepared to investigate the details of the practices of sterilization process validation recommended in JSMI guideline published in 2005^{5} and its responsibility. The questionnaire was sent to those 207 hospitals.

2. Result

79 hospitals replied to the additional questionnaires sent to 207 hospitals. The reply ratio is 38.2%. Survey results are shown in Table 1 \sim 3. Installation qualifications (IQ) are fairly well implemented in most hospitals. In each item of IQ, number of hospitals where it is not performed is approximately less than 30 % except some items. 78.9% of steam sterilizers, and 74.3% of ethylene oxide gas (EOG) sterilizers and also 74.3% of hydrogen peroxide gas plasma sterilizers (plasma) had been installed before the publication of the guideline 2005.

Operational qualifications (OQ) are well implemented except the check of the temperature and pressure variation in the chamber, identification of the cold spot, biological indicator (BI) test at the points other than the cold spot. Leak test is not performed in almost 35% of the hospitals for all three kinds of sterilizers.

Implementations of performance qualifications (PQ) showed poorly low compliance rates compared to IQ and OQ.

Although in many hospitals all qualifications were performed by hospital sterilization technicians, rather large number of hospitals has requested to be performed by manufacturers and suppliers.

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		Plasma	4	0	0.0%	0	0.0%	0		2	50.0%	2	50.0%

	Sterilization	No of Performed by										
Validation items	method	facilities		pital	Outso	urcing		acturer	Oth	iers	Not per	rformed
		replied		onnel		-	or supplier					
1. Bowie & Dick test	Steam	78	40	51.3%	31	39.7%	6	7.7%	0	0.0%	6	7.7%
	EOG	\sim	\sim	\sim	\sim	\sim	$\langle \rangle$	\sim	\sim	\sim		\sim
	Plasma	\sim		00.0%	\leq	0.7%		0.4.7%		1.0%		07.00
2. Leak test	Steam	75	15	20.0%	5	6.7%	26	34.7%	1	1.3%	28	37.3%
	EOG	65	9	13.8%	8	12.3%	21	32.3%	4	6.2%	23	35.4%
	Plasma	61	7	11.5%	4	6.6%	26	42.6%	3	4.9%	21	34.4%
3. Check of the minimum pressure	Steam	77	38	49.4%	19	24.7%	17	22.1%	1	1.3%	7	9.1%
during air removal phase	EOG	67	28	41.8%	18	26.9%	12	17.9%	3	4.5%	8	11.9%
-	Plasma	60	17	28.3%	14	23.3%	19	31.7%	3	5.0%	12	20.0%
4. Check of the number of pulsations during air removal phase	Steam	78	37	47.4%	21	26.9%	17	21.8%		1.3%	7	9.0%
	EOG	\sim	\sim	\sim	\sim	\sim	\sim	\sim	\sim	\sim	\sim	\sim
	Plasma	78	35	44.9%	22	28.2%	18	23.1%		1.3%	7	9.0%
F. Ohardhaff at an annah	Steam	18	35	44.9%	- 22	28.2%	18	23.1%		1.3%		9.0%
5. Check of steam supply	EOG	\sim	\sim	\sim	\sim	\sim	$\langle \rangle$	\sim	\sim	\sim	\sim	\sim
	Plasma	78	43	55.1%	26	33.3%	10	12.8%	0	0.0%	4	5.1%
6. Check of the temperature during	Steam	78 69	43 32	55.1% 46.4%	26	33.3%	10	12.8%	3	4.3%	4	5.1% 8.7%
sterilization phase	EOG	69	20	46.4% 32.8%	16	26.2%	12	10.1%	3	4.3%	11	8.7%
	Plasma	78	20 41	32.8% 52.6%	24	26.2%	9	19.7%	3	4.9%	7	9.0%
7. Check of the pressure during	Steam	78 69	32	52.6% 46.4%	24	30.8%	9	10.1%	3	4.3%	7	9.0%
sterilization phase	EOG		21	46.4%	18	30.4% 29.5%	12	10.1%	3	4.3%	10	16.4%
	Plasma	61 76	37	34.4% 48.7%	25	29.5% 32.9%	12	19.7%	0	0.0%	7	9.2%
8. Check of the time(duration) of sterilization phase 9. Check of the aeration time	Steam	76	37		25		7		3		7	
	EOG	61	18	45.7%	19	34.3%	-	10.0%	3	4.3% 4.9%		10.0%
	Plasma	01	18	29.5%	19	31.1%	13	21.3%	3	4.9%	11	18.0%
	Steam			EA EN		10.0%		2.61		1.0%		2.6%
	EOG	55	30	54.5%	22	40.0%	2	3.6%	1	1.8%	2	3.6%
10. Door safety (not open at the pressure other than the atmospheric)	Plasma							17.4%				
	Steam	70	35	50.0%	24	34.3%	12	17.1%		1.4%	3	4.3%
	EOG	\sim		\sim	\sim	\sim			\sim	\sim		\sim
	Plasma		<u> </u>	7.0%		3.1%	6	0.41		2.10		70.1%
11. Check of the temperature variation in the chamber	Steam	64 58	5 5	7.8% 8.6%	2	3.1%		9.4% 1.7%	2	3.1% 3.4%	50 48	78.1% 82.8%
	EOG	58	2	4.0%	0	0.0%	1	0.0%	4	3.4% 8.0%	48	82.8%
	Plasma	50	4	4.0%	1	1.7%	3	5.1%	2	3.4%	44 50	84.7%
12. Check of the pressure variation in	Steam		4			1.770	0		2	3.4%	45	86.5%
the chamber		E0	2		0	2.0%			4	3.8% 8.3%		
the champer	EOG	52	3	5.8%	2	3.8%	-	0.0%		0.3/0		
the chamber	Plasma	48	2	4.2%	0	0.0%	0	0.0%		0.5%	42	87.5%
	Plasma Steam	48 71	2 18	4.2% 25.4%	0 10	0.0% 14.1%	0	0.0% 19.7%	6	8.5%	24	33.8%
13. Identification of the cold point	Plasma Steam EOG	48 71 67	2 18 18	4.2% 25.4% 26.9%	0 10 8	0.0% 14.1% 11.9%	0 14 11	0.0% 19.7% 16.4%	6	9.0%	24 25	33.8% 37.3%
	Plasma Steam EOG Plasma	48 71 67 58	2 18 18 9	4.2% 25.4% 26.9% 15.5%	0 10 8 5	0.0% 14.1% 11.9% 8.6%	0 14 11 12	0.0% 19.7% 16.4% 20.7%	6 7	9.0% 12.1%	24 25 25	33.8% 37.3% 43.1%
13. Identification of the cold point	Plasma Steam EOG Plasma Steam	48 71 67 58 77	2 18 18 9 35	4.2% 25.4% 26.9% 15.5% 45.5%	0 10 8 5 21	0.0% 14.1% 11.9% 8.6% 27.3%	0 14 11 12 8	0.0% 19.7% 16.4% 20.7% 10.4%	6 7 2	9.0% 12.1% 2.6%	24 25 25 18	33.8% 37.3% 43.1% 23.4%
	Plasma Steam EOG Plasma Steam EOG	48 71 67 58 77 71	2 18 18 9 35 30	4.2% 25.4% 26.9% 15.5% 45.5% 42.3%	0 10 8 5 21 20	0.0% 14.1% 11.9% 8.6% 27.3% 28.2%	0 14 11 12 8 5	0.0% 19.7% 16.4% 20.7% 10.4% 7.0%	6 7 2 2	9.0% 12.1% 2.6% 2.8%	24 25 25 18 19	33.8% 37.3% 43.1% 23.4% 26.8%
13. Identification of the cold point	Plasma Steam EOG Plasma Steam EOG Plasma	48 71 67 58 77 71 63	2 18 18 9 35 30 18	4.2% 25.4% 26.9% 15.5% 45.5% 42.3% 28.6%	0 10 8 5 21 20 18	0.0% 14.1% 11.9% 8.6% 27.3% 28.2% 28.6%	0 14 11 12 8 5 8	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 12.7%	6 7 2 2 4	9.0% 12.1% 2.6% 2.8% 6.3%	24 25 25 18 19 19	33.8% 37.3% 43.1% 23.4% 26.8% 30.2%
13. Identification of the cold point 14. BI test at the cold point	Plasma Steam EOG Plasma Steam EOG Plasma Steam	48 71 67 58 77 71 63 77	2 18 18 9 35 30 18 35	4.2% 25.4% 26.9% 15.5% 45.5% 42.3% 28.6% 45.5%	0 10 8 5 21 20 18 21	0.0% 14.1% 11.9% 8.6% 27.3% 28.2% 28.6% 27.3%	0 14 11 12 8 5 8 7	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 12.7% 9.1%	6 7 2 2 4 2	9.0% 12.1% 2.6% 2.8% 6.3% 2.6%	24 25 25 18 19 19 18	33.8% 37.3% 43.1% 23.4% 26.8% 30.2% 23.4%
13. Identification of the cold point	Plasma Steam EOG Plasma Steam EOG Plasma Steam EOG	48 71 67 58 77 71 63 77 71	2 18 9 35 30 18 35 30	4.2% 25.4% 26.9% 15.5% 45.5% 42.3% 28.6% 45.5% 42.3%	0 10 8 5 21 20 18 21 20	0.0% 14.1% 11.9% 8.6% 27.3% 28.2% 28.6% 27.3% 28.2%	0 14 11 12 8 5 8 7 4	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 12.7% 9.1% 5.6%	6 7 2 2 4 2 2 2 2	9.0% 12.1% 2.6% 2.8% 6.3% 2.6% 2.8%	24 25 25 18 19 19 18 19	33.8% 37.3% 43.1% 23.4% 26.8% 30.2% 23.4% 26.8%
13. Identification of the cold point14. BI test at the cold point15. CI test at the cold point	Plasma Steam EOG Plasma Steam EOG Plasma EOG Plasma	48 71 67 58 77 71 63 77 71 63	2 18 9 35 30 18 35 30 19	4.2% 25.4% 26.9% 15.5% 45.5% 42.3% 28.6% 45.5% 42.3% 30.2%	0 10 8 5 21 20 18 21 20 17	0.0% 14.1% 11.9% 8.6% 27.3% 28.2% 28.6% 27.3% 28.2% 27.3% 28.2% 27.0%	0 14 11 12 8 5 8 7 4 7	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 12.7% 9.1% 5.6% 11.1%	6 7 2 2 4 2 2 2 2 4	9.0% 12.1% 2.6% 2.8% 6.3% 2.6% 2.8% 6.3%	24 25 25 18 19 19 18 19 18 19 19	33.8% 37.3% 43.1% 23.4% 26.8% 30.2% 23.4% 26.8% 30.2%
 13. Identification of the cold point 14. BI test at the cold point 15. CI test at the cold point 16. BI test at the points other than 	Plasma Steam EOG Plasma Steam EOG Plasma EOG Plasma Steam	48 71 67 58 77 71 63 77 71 63 75	2 18 9 35 30 18 35 30 19 20	4.2% 25.4% 26.9% 15.5% 45.5% 42.3% 28.6% 45.5% 42.3% 30.2% 26.7%	0 10 8 5 21 20 18 21 20 17 12	0.0% 14.1% 11.9% 8.6% 27.3% 28.2% 28.6% 27.3% 28.2% 27.0% 16.0%	0 14 11 12 8 5 8 7 4 7 7 7	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 12.7% 9.1% 5.6% 11.1% 9.3%	6 7 2 4 2 2 4 2 2 4 2 4 2	9.0% 12.1% 2.6% 2.8% 6.3% 2.6% 2.8% 6.3% 2.7%	24 25 25 18 19 19 18 19 19 19 19 36	33.8% 37.3% 43.1% 23.4% 26.8% 30.2% 23.4% 26.8% 30.2% 48.0%
13. Identification of the cold point14. BI test at the cold point15. CI test at the cold point	Plasma Steam EOG Plasma Steam EOG Plasma Steam Steam EOG	48 71 67 58 77 71 63 77 71 63 75 68	2 18 9 35 30 18 35 30 19 20 19	4.2% 25.4% 26.9% 15.5% 45.5% 42.3% 28.6% 45.5% 42.3% 30.2% 26.7% 27.9%	0 10 8 5 21 20 18 21 20 17 17 12 13	0.0% 14.1% 11.9% 8.6% 27.3% 28.2% 28.6% 27.3% 28.2% 27.0% 16.0% 19.1%	0 14 11 12 8 5 8 7 4 7 7 7 4	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 12.7% 9.1% 5.6% 11.1% 9.3% 5.9%	6 7 2 4 2 2 4 2 2 4 2 3	9.0% 12.1% 2.6% 2.8% 6.3% 2.6% 2.8% 6.3% 2.7% 4.4%	24 25 25 18 19 19 18 19 19 19 36 30	33.8% 37.3% 43.1% 23.4% 26.8% 30.2% 23.4% 26.8% 30.2% 48.0% 44.1%
 13. Identification of the cold point 14. BI test at the cold point 15. CI test at the cold point 16. BI test at the points other than the cold point 	Plasma Steam EOG Plasma Steam EOG Plasma Steam EOG Plasma Steam Steam	48 71 67 58 77 71 63 77 71 63 75 68 61	2 18 9 35 30 18 35 30 19 20 19 12	4.2% 25.4% 26.9% 15.5% 45.5% 42.3% 28.6% 45.5% 45.5% 45.5% 45.5% 45.7% 20.2% 26.7% 27.9% 19.7%	0 10 8 5 21 20 18 21 20 17 12 13 10	0.0% 14.1% 11.9% 8.6% 27.3% 28.2% 28.6% 27.3% 28.2% 27.3% 27.0% 16.0% 19.1% 16.4%	0 14 11 12 8 5 8 7 4 7 7 7 4 6	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 12.7% 9.1% 5.6% 11.1% 9.3% 5.9% 9.8%	6 7 2 4 2 2 4 2 4 2 3 4	9.0% 12.1% 2.6% 2.8% 6.3% 2.6% 2.8% 6.3% 2.7% 4.4% 6.6%	24 25 25 18 19 19 18 19 19 19 36 30 30	33.8% 37.3% 43.1% 23.4% 26.8% 30.2% 23.4% 26.8% 30.2% 48.0% 44.1% 49.2%
 13. Identification of the cold point 14. BI test at the cold point 15. CI test at the cold point 16. BI test at the points other than the cold point 17. CI test at the point other than the 	Plasma Steam EOG Plasma Steam Steam	48 71 67 58 77 71 63 77 71 63 75 68 61 75	2 18 9 35 30 18 35 30 19 20 19 12 30	4.2% 25.4% 26.9% 15.5% 45.5% 42.3% 28.6% 45.5% 42.3% 20.2% 26.7% 27.9% 19.7% 39.5%	0 10 8 5 21 20 18 21 20 17 12 13 10 16	0.0% 14.1% 11.9% 8.6% 27.3% 28.2% 28.6% 27.3% 28.2% 27.0% 16.0% 19.1% 16.4% 21.1%	0 14 11 12 8 5 8 7 4 7 7 4 7 7 4 6 8	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 12.7% 9.1% 5.6% 11.1% 9.3% 5.9% 9.8% 10.5%	6 7 2 4 2 2 4 2 4 2 3 4 2 3 4 2	9.0% 12.1% 2.6% 2.8% 6.3% 2.6% 2.8% 6.3% 2.7% 4.4% 6.6% 2.6%	24 25 25 18 19 19 18 19 19 36 30 30 23	33.8% 37.3% 43.1% 23.4% 26.8% 30.2% 23.4% 26.8% 30.2% 48.0% 44.1% 49.2% 30.3%
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 13. Identification of the cold point 14. BI test at the cold point 15. CI test at the cold point 16. BI test at the points other than the cold point 17. CI test at the point other than the 	Plasma Steam EOG Plasma Steam EOG Plasma Steam EOG Plasma Steam EOG Plasma	48 71 67 58 77 71 63 77 71 63 75 68 61 75 68 61 76 69 62	2 18 18 9 35 30 18 35 30 19 20 19 20 19 12 30 27 16	4.2% 25.4% 26.9% 15.5% 45.5% 42.3% 28.6% 45.5% 42.3% 30.2% 26.7% 27.9% 9.7% 39.5% 39.1%	0 10 8 5 21 20 18 21 20 17 12 13 10 16 16 14	0.0% 14.1% 11.9% 8.6% 27.3% 28.2% 28.6% 27.3% 28.2% 27.0% 16.0% 19.1% 16.4% 21.1% 23.2% 22.6%	0 14 11 12 8 5 8 7 7 4 7 7 4 7 7 4 6 8 8 4 6	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 9.1% 5.6% 11.1% 9.3% 5.9% 9.8% 9.8% 5.8% 9.7%	6 7 2 4 2 4 2 4 2 3 4 4 2 3 3 4 4	9.0% 12.1% 2.6% 2.8% 6.3% 2.8% 6.3% 2.8% 4.4% 6.6% 2.6% 4.3% 6.5%	24 25 25 18 19 19 19 19 36 30 30 23 21 24	33.8% 37.3% 43.1% 23.4% 26.8% 30.2% 23.4% 26.8% 30.2% 48.0% 44.1% 49.2% 30.3% 30.3% 30.4% 38.7%
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 13. Identification of the cold point 14. BI test at the cold point 15. CI test at the cold point 16. BI test at the points other than the cold point 17. CI test at the point other than the cold point 	Plasma Steam EOG Plasma Steam	48 71 67 58 77 71 63 77 63 75 68 61 76 69 62 76 69 62	2 18 9 35 30 18 35 30 19 20 19 12 30 27 16 40 32 27	4.2% 25.4% 26.9% 15.5% 42.3% 28.6% 42.3% 20.2% 26.7% 27.9% 19.7% 39.5% 39.1% 25.8% 52.6% 46.4% 43.5%	0 10 8 5 21 20 18 21 20 17 12 13 10 16 16 14 8 12 5	0.0% 14.1% 11.9% 8.6% 27.3% 28.2% 28.6% 27.3% 28.2% 16.0% 19.1% 16.4% 21.1% 23.2% 22.6% 17.4% 8.1%	0 14 11 12 8 5 5 8 7 4 7 4 7 4 6 8 8 4 6 8 8 4 7	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 12.7% 9.1% 5.6% 11.1% 9.3% 5.9% 9.8% 10.5% 5.8% 10.5% 5.8% 11.3%	6 7 2 4 2 2 4 2 2 4 2 3 4 2 3 4 2 3 4 1 3 3 3	9.0% 12.1% 2.6% 2.8% 6.3% 2.6% 2.8% 6.3% 2.7% 4.4% 6.6% 2.6% 4.3% 6.5% 1.3% 4.3%	24 25 25 18 19 19 19 19 19 36 30 30 23 21 24 22 21 22	33.8% 37.3% 43.1% 23.4% 26.8% 30.2% 23.4% 26.8% 30.2% 48.0% 44.1% 49.2% 30.3% 30.4% 30.3% 30.4% 33.5%
 13. Identification of the cold point 14. BI test at the cold point 15. CI test at the cold point 16. BI test at the points other than the cold point 17. CI test at the point other than the cold point 18. Documentation for OQ 	Plasma Steam EOG Plasma Steam EOG Plasma Steam EOG Plasma Steam EOG Plasma Steam EOG Plasma Steam EOG Plasma Steam	48 71 67 58 77 71 63 75 68 61 76 69 62 75	2 18 9 35 30 18 35 30 19 20 19 20 19 12 30 27 16 40 32 27 36	4.2% 25.4% 26.5% 45.5% 42.3% 28.6% 42.3% 42.3% 42.3% 42.3% 42.3% 42.3% 42.3% 42.3% 42.3% 42.3% 42.3% 42.3% 42.3% 42.6% 43.5% 48.0%	0 10 8 5 21 20 18 21 20 17 12 13 10 16 16 14 8 12 5 23	0.0% 14.1% 11.9% 27.3% 28.2% 28.6% 27.3% 28.2% 27.0% 16.0% 19.1% 16.0% 19.1% 16.4% 22.6% 10.5% 17.4% 8.1% 30.7%	0 14 11 12 8 5 5 8 7 7 4 7 7 7 7 4 6 8 8 4 6 8 8 4 6 8 8 4 7 7 8	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 12.7% 9.1% 5.6% 5.9% 9.3% 5.9% 9.8% 9.7% 10.5% 5.8% 9.7% 10.5% 5.8% 9.7%	6 7 2 4 2 2 4 2 2 4 2 3 4 2 3 4 2 3 3 4 1 3 3 0	9.0% 12.1% 2.6% 2.8% 6.3% 2.6% 2.8% 6.3% 2.7% 4.4% 6.6% 2.6% 4.3% 6.5% 1.3% 4.3% 0.0%	24 25 25 18 19 19 19 19 36 30 30 23 21 24 22 21 22 21 22 13	33.8% 37.3% 43.1% 23.4% 26.8% 30.2% 23.4% 26.8% 30.2% 48.0% 44.1% 30.2% 30.3% 30.4% 30.3% 30.4% 30.5% 35.5% 17.3%
 13. Identification of the cold point 14. BI test at the cold point 15. CI test at the cold point 16. BI test at the points other than the cold point 17. CI test at the point other than the cold point 	Plasma Steam EOG Plasma	48 71 67 58 77 71 63 77 63 75 68 61 76 69 62 76 69 62 75 69	2 18 9 35 30 18 35 30 19 20 19 20 19 12 30 27 16 40 32 27 36 27	4.2% 25.4% 26.9% 15.5% 42.3% 28.6% 45.5% 42.3% 28.6% 42.3% 20.7% 27.9% 19.7% 39.1% 25.8% 52.6% 46.4% 39.1% 39.1%	0 10 8 5 21 20 18 21 20 17 12 13 10 16 16 14 8 12 5 23 24	0.0% 14.1% 11.9% 8.6% 27.3% 28.2% 28.6% 27.3% 28.2% 28.6% 27.3% 28.2% 28.6% 27.3% 28.2% 28.6% 27.0% 16.0% 19.1% 16.4% 21.1% 22.6% 10.5% 17.4% 8.1% 30.7% 34.8%	0 14 11 12 5 8 5 8 7 7 7 7 7 7 7 7 7 7 7 4 6 8 8 4 6 8 8 4 7 8 8 4	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 12.7% 9.1% 5.6% 9.3% 5.9% 9.3% 5.9% 9.8% 9.7% 10.5% 5.8% 11.3% 10.7% 5.8%	6 7 2 4 2 2 4 2 2 4 2 3 4 2 3 4 2 3 4 1 3 3 0 0 2	9.0% 12.1% 2.6% 2.8% 6.3% 2.6% 2.8% 6.3% 2.7% 4.4% 6.6% 2.6% 4.3% 6.5% 1.3% 4.3%	24 25 25 18 19 19 19 19 36 30 30 30 30 23 21 24 22 21 24 22 21 3 14	33.8% 37.3% 43.1% 23.4% 26.8% 30.2% 23.4% 26.8% 30.2% 24.8% 30.2% 48.0% 44.1% 49.2% 30.3% 30.4% 38.7% 28.9% 30.4% 35.5% 17.3% 20.3%
 13. Identification of the cold point 14. BI test at the cold point 15. CI test at the cold point 16. BI test at the points other than the cold point 17. CI test at the point other than the cold point 18. Documentation for OQ 	Plasma Steam EOG Plasma	48 71 67 77 71 63 77 71 63 75 68 61 76 69 62 75 69 62 75 69 62 75 69 60	2 18 18 9 35 30 18 35 30 19 20 19 20 19 12 30 27 16 40 32 27 36 27 19	4.2% 25.4% 26.9% 15.5% 42.3% 28.6% 45.5% 42.3% 28.6% 42.3% 20.2% 26.7% 27.9% 19.7% 39.1% 39.1% 52.6% 46.4% 43.5% 52.6% 46.4% 39.1% 31.7%	0 10 8 5 21 20 18 21 20 17 12 13 10 16 16 16 14 8 12 5 23 24 18	0.0% 14.1% 11.9% 8.6% 27.3% 28.2% 28.6% 27.3% 28.2% 27.0% 16.0% 19.1% 16.4% 21.1% 23.2% 10.5% 17.4% 8.1% 30.7% 30.0%	0 14 11 12 8 5 8 7 7 4 7 7 7 7 4 6 8 8 4 6 8 8 4 4 7 8 8 4 8 8	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 12.7% 9.1% 5.6% 11.1% 9.3% 5.9% 9.8% 10.5% 5.8% 9.7% 10.5% 5.8% 11.3%	6 7 2 4 2 2 4 2 2 3 3 4 2 3 4 4 1 3 3 3 0 0 2 2	9.0% 12.1% 2.6% 5.3% 2.6% 2.8% 6.3% 2.6% 4.4% 6.6% 2.6% 4.4% 6.5% 1.3% 4.3% 4.3% 4.3% 2.9%	24 25 25 18 19 19 19 36 30 30 30 23 30 23 21 24 22 21 22 21 22 13 14 15	33.8% 37.3% 43.1% 23.4% 26.8% 30.2% 23.4% 26.8% 30.2% 48.0% 44.1% 49.2% 30.3% 30.4% 30.4% 30.4% 35.5% 17.3% 22.0%
 13. Identification of the cold point 14. BI test at the cold point 15. CI test at the cold point 16. BI test at the points other than the cold point 17. CI test at the point other than the cold point 18. Documentation for OQ 	Plasma Steam EOG Plasma	48 71 67 58 77 71 63 77 63 75 68 61 76 69 62 76 69 62 75 69	2 18 9 35 30 18 35 30 19 20 19 20 19 12 30 27 16 40 32 27 36 27	4.2% 25.4% 26.9% 15.5% 42.3% 28.6% 45.5% 42.3% 28.6% 42.3% 20.7% 27.9% 19.7% 39.1% 25.8% 52.6% 46.4% 39.1% 39.1%	0 10 8 5 21 20 18 21 20 17 12 13 10 16 16 14 8 12 5 23 24	0.0% 14.1% 11.9% 8.6% 27.3% 28.2% 28.6% 27.3% 28.2% 28.6% 27.3% 28.2% 28.6% 27.3% 28.2% 28.6% 27.0% 16.0% 19.1% 16.4% 21.1% 22.6% 10.5% 17.4% 8.1% 30.7% 34.8%	0 14 11 12 5 8 5 8 7 7 7 7 7 7 7 7 7 7 7 4 6 8 8 4 6 8 8 4 7 8 8 4	0.0% 19.7% 16.4% 20.7% 10.4% 7.0% 12.7% 9.1% 5.6% 9.3% 5.9% 9.3% 5.9% 9.8% 9.7% 10.5% 5.8% 11.3% 10.7% 5.8%	6 7 2 4 2 2 4 2 2 4 2 3 4 2 3 4 2 3 4 1 3 3 0 0 2	9.0% 12.1% 2.6% 2.8% 6.3% 2.6% 2.8% 6.3% 2.7% 4.4% 6.6% 2.6% 4.3% 6.5% 1.3% 4.3% 0.0%	24 25 25 18 19 19 19 19 36 30 30 30 30 23 21 24 22 21 24 22 21 3 14	33.8% 37.3% 43.1% 23.4% 26.8% 30.2% 23.4% 26.8% 30.2% 24.8% 30.2% 48.0% 44.1% 49.2% 30.3% 30.4% 38.7% 28.9% 30.4% 35.5% 17.3% 20.3%

Table 2. Validation items of Operational Qualification (OQ)

Validation items	Sterilization method	No of facilities	es Hospital		Outsourcing		Manuf	med by acturer	Others		Not per	formed
	Steam	replied 66	persc 20	30.3%	9	13.6%	0 r su 4	pplier 6.1%	1	1.5%	34	51.5%
1. Definition of reference load	EOG	62	15	24.2%	10	16.1%	4	6.5%	3		34	51.6%
	Plasma	54	8	14.8%	7	13.0%	5	9.3%	4		31	57.4%
	Steam	67	24	35.8%	7	10.4%	5	7.5%	3	4.5%	29	43.3%
2. Loading contents of reference load	EOG	63	17	27.0%	8	12.7%	4	6.3%	3	4.8%	32	50.8%
	Plasma	55	12	21.8%	8	14.5%	4	7.3%	5	9.1%	27	49.1%
3. Loading configuration of reference load	Steam	67	24	35.8%	8	11.9%	6	9.0%	3		27	40.3%
	EOG	63	19	30.2%	9	14.3%	4	6.3%	3		29	46.0%
	Plasma	55	14	25.5%	8	14.5%	4	7.3%	5		25	45.5%
4. Temperature measurement inside the reference load	Steam	65	11	16.9%	1	1.5%	5	7.7%	2		46	70.8%
	EOG	61	9	14.8%	3	4.9%	4	6.6%	2		43	70.5%
	Plasma	54	8	14.8%	0	0.0%	4	7.4%	4		38	70.4%
5. Definition of Process Challenge Device(PCD)	Steam	65	20	30.8% 29.5%	13	20.0% 19.7%	3	4.6% 3.3%	3		29	44.6% 45.9%
	EOG Plasma	61 53	18 12	29.5%	12 8	19.7%	2	5.7%	4		28 27	45.9%
	Steam	64	3	4.7%	2	3.1%	6	9.4%	4		49	76.6%
6. Temperature measurement inside	EOG	59	3	5.1%	5	8.5%	3	5.1%	3		45	76.3%
the PCD	Plasma	52	3	5.8%	1	1.9%	4	7.7%	5		39	75.0%
	Steam	59	4	6.7%	1	1.7%	2	3.3%	2		51	85.0%
7. Temperature measurement at	EOG	56	3	5.4%	3	5.4%	1	1.8%	1		48	85.7%
multiple points in the chamber	Plasma	48	2	4.2%	0	0.0%	1	2.1%	4		41	85.4%
0 Dua	Steam	56	2	3.6%	0	0.0%	1	1.8%	2		51	91.1%
8. Pressure measurement at multiple	EOG	52	3	5.8%	2	3.8%	0		1		46	88.5%
points in the chamber	Plasma	45	2	4.4%	0	0.0%	0	0.0%	4	8.9%	39	86.7%
9. Identification of cold point in the	Steam	63	13	20.6%	6	9.5%	8	12.7%	5		31	49.2%
9. Identification of cold point in the reference load	EOG	60	12	20.0%	6	10.0%	7	11.7%	4		31	51.7%
	Plasma	51	8	15.7%	4	7.8%	5		7		27	52.9%
10. BI test at the point identified by 9.	Steam	65	21	32.3%	14	21.5%	3	4.6%	1		29	44.6%
	EOG	61	17	27.9%	13	21.3%	2	3.3%	1		30	49.2%
	Plasma	53	13	24.5%	10	18.9%	4	7.5%	4		23	43.4%
11. CI test at the point identified by 9.	Steam	65	24	36.9%	14	21.5%	3	4.6%	1		26	40.0%
		61	21	34.4%	12	19.7%	2	3.3%	1		27	44.3%
	Plasma	53	15	28.3%	9	17.0%	4	7.5%	4		22	41.5%
12. BI test at cold point in PCD	Steam	65	23	35.4%	13	20.0%	4	6.2%	1	1.5%	27	41.5%
	EOG	61	21	34.4% 24.5%	14 7	23.0% 13.2%	2	3.3% 7.5%	0		27 25	44.3% 47.2%
	Plasma Steam	53 64	13 25	24.5%	13	20.3%	4	6.3%	4		25	47.2% 37.5%
13. CI test at cold point in PCD	EOG	61	23	37.7%	13	20.3%	2	3.3%	0		24	42.6%
13. Of test at cold point in 1 OD	Plasma	53	13	24.5%	7	13.2%	4	7.5%	4		20	47.2%
	Steam	65	18	27.7%	10	15.4%	3	4.6%	2		35	53.8%
14. BI test at the point other than	EOG	61	15	24.6%	10	16.4%	1	1.6%	2		35	57.4%
cold point	Plasma	52	10	19.2%	7	13.5%	4	7.7%	4		28	53.8%
	Steam	64	22	34.4%	12	18.8%	3	4.7%	2		29	45.3%
15. CI test at the point other than	EOG	60	20	33.3%	11	18.3%	1	1.7%	2		29	48.3%
cold point	Plasma	51	13	25.5%	9	17.6%	4	7.8%	4		23	45.1%
16 DI to at at the project of here there	Steam	63	13	20.6%	9	14.3%	3	4.8%	3	4.8%	37	58.7%
16. BI test at the point other than	EOG	59	13	22.0%	10	16.9%	2	3.4%	1	1.7%	35	59.3%
cold point in the PCD	Plasma	51	8	15.7%	8	15.7%	5	9.8%	4		27	52.9%
17. CI test at the point other than	Steam	64	14	21.9%	9	14.1%	3	4.7%	3		37	57.8%
cold point in the PCD	EOG	60	13	21.7%	10	16.7%	2	3.3%	1		36	60.0%
	Plasma	52	8	15.4%	8	15.4%	5		4		28	53.8%
18. Setup of the sterilization condition	Steam	50	6	12.0%	4	8.0%			0		33	66.0%
by overkill method	EOG	47	3	6.4%	3	6.4%	7		0		34	72.3%
	Plasma	44	4	9.1%	3	6.8%	7	15.9%	3		28	63.6%
19. Setup of the sterilization condition by half-cycle method	Steam	49	1	2.0%	1	2.0%	4		0		43	87.8%
	EOG	47	3	6.4%	3	6.4%	5	10.6%	0		36	76.6%
	Plasma	43	1	2.3% 47.5%	17	2.3%	4		2		35	81.4%
20. Dryness of the reference load after sterilization	Steam FOC	61	29	47.5%	17	27.9% 26.2%	2	3.3% 3.1%	1		14	23.0% 29.2%
	EOG Plasma	65 57	28 23	43.1%	17 14	26.2%	2	3.1%	1 0		19 20	29.2%
21. Packaging integrity of the reference load after sterilization	Steam	65	23	40.4%	14	24.6%	2	3.1%	1		19	29.2%
	EOG	57	28	40.4%	14	20.2%	1	1.8%	0		20	29.2% 35.1%
	Plasma	57	17	34.0%	14	24.0%	1	2.0%	3		17	34.0%
22. Documentation of PQ	Steam	66	21	31.8%	8	12.1%	6		3		29	43.9%
	EOG	60	17	28.3%	9	15.0%	3	5.0%	3		29	48.3%
	Plasma	53	14	26.4%	5	9.4%	4		5		25	47.2%
	Steam	66	22	33.3%	13	19.7%	7	10.6%	2		25	37.9%
23. Record of PQ	EOG	60	19	31.7%	13	21.7%	3	5.0%	2		24	40.0%
	Plasma	53	14	26.4%	10	18.9%	4	7.5%	4		22	41.5%
	Steam	2	1	50.0%	0	0.0%	0		0		1	50.0%
24. Others	EOG	2	1	50.0%	0	0.0%	0		0		1	50.0%
24. Oulers				0.0%	0	0.0%	0	0.0%	0		2	100.0%

3. Discussion

After the first survey in 1998, the first Japanese guideline for sterilization assurance in healthcare settings was published in 2000³⁾ from JSMI and this guideline was revised in 2005 to broaden its subject from only sterilization assurance program to cleaning, packaging, sterilization, sterilization assurance⁴⁾. And this revised guideline recommends sterilization process JSMI validation. As one of the other activities of JSMI, the certification program of the second class sterilization technician (Certified Sterilization Service Technician: CSST) and the first class sterilization technician (Certified Sterilization Specialist: CSS) were established by JSMI in 2000 and 2003, respectively. As of August 2008, 2,543 sterilization technicians are certified as the second class (CSST), and 124 sterilization technicians are certified as the first class (CSS).

This time the survey has been performed to investigate the impact of Japanese guideline and certification system on the actual practice in healthcare settings. In the results, most of IQ and OQ items in many hospitals responded are fairly well performed. However implementation of PQ in many hospitals is still insufficient. In order to obtain the better quality of sterilization in Japanese hospitals, the strategies to improve the compliance of PQ should be the main subjects.

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