■Concise communications

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 2005[4], and after then the third nationwide survey was conducted in the same manner in 2007 and was reported[5]. 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 ~ 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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Table 1. Validation items of Installation Qualification (IQ)

Validation items	Sterilization method	No of facilities replied	Performed by									
			Hospital personnel		Outsourcing		Manufacturer or supplier		Others		Not performed	
1. Specification for the accessories of the sterilizer and air conditioning	Steam	73	34	46.6%	2	2.7%	37	50.7%	1	1.4%	3	4.1%
	EOG	68	24	35.3%	6	8.8%	34	50.0%	4	5.9%	3	4.4%
	Plasma	46	11	23.9%	1	2.2%	28	60.9%	2	4.3%	7	15.2%
2. Sterilization process programme	Steam	75	30	40.0%	8	10.7%	38	50.7%	1	1.3%	1	1.3%
	EOG	69	24	34.8%	10	14.5%	34	49.3%	3	4.3%	1	1.4%
	Plasma											
3. Aeration time	Steam											
	EOG	68	35	51.5%	11	16.2%	23	33.8%	3	4.4%	0	0.0%
	Plasma											
4. Inquiry of MSDS	Steam											
	EOG	61	32	52.5%	8	13.1%	12	19.7%	6	9.8%	3	4.9%
	Plasma	52	24	46.2%	7	13.5%	11	21.2%	5	9.6%	5	9.6%
5. Storage condition for sterilant	Steam											
	EOG	65	35	53.8%	10	15.4%	9	13.8%	6	9.2%	5	7.7%
	Plasma	59	25	42.4%	9	15.3%	12	20.3%	3	5.1%	10	16.9%
6. Manual for booster use	Steam											
	EOG											
	Plasma	58	15	25.9%	7	12.1%	19	32.8%	3	5.2%	15	25.9%
7. Material compatibility verification of medical device/instrument for plasma sterilization	Steam											
	EOG											
	Plasma	59	26	44.1%	12	20.3%	15	25.4%	5	8.5%	5	8.5%
8. Material compatibility verification of packaging material for plasma sterilization	Steam											
	EOG											
	Plasma	59	24	40.7%	12	20.3%	17	28.8%	6	10.2%	5	8.5%
9. Calibration of measurement devices	Steam	73	18	24.7%	0	0.0%	39	53.4%	2	2.7%	16	21.9%
	EOG	68	13	19.1%	4	5.9%	32	47.1%	5	7.4%	15	22.1%
	Plasma	60	12	20.0%	1	1.7%	34	56.7%	3	5.0%	12	20.0%
10. Quality of the steam	Steam	74	37	50.0%	2	2.7%	14	18.9%	4	5.4%	19	25.7%
	EOG											
	Plasma											
11. Specification for the physical monitors used for routine process control	Steam	74	21	28.4%	4	5.4%	45	60.8%	1	1.4%	7	9.5%
	EOG	65	12	18.5%	8	12.3%	37	56.9%	3	4.6%	7	10.8%
	Plasma	57	10	17.5%	3	5.3%	35	61.4%	2	3.5%	10	17.5%
12. Manual for Bowie & Dick test	Steam	73	52	71.2%	14	19.2%	7	9.6%	0	0.0%	5	6.8%
	EOG											
	Plasma											
13. Leak test procedure	Steam	73	17	23.3%	3	4.1%	30	41.1%	3	4.1%	20	27.4%
	EOG	65	8	12.3%	6	9.2%	31	47.7%	5	7.7%	15	23.1%
	Plasma	57	5	8.8%	2	3.5%	31	54.4%	4	7.0%	15	26.3%
14. Maintenance of sterilizer	Steam	74	34	45.9%	1	1.4%	37	50.0%	2	2.7%	3	4.1%
	EOG	66	22	33.3%	6	9.1%	33	50.0%	4	6.1%	3	4.5%
	Plasma	60	22	36.7%	2	3.3%	30	50.0%	2	3.3%	7	11.7%
15. Installation of sterilizer	Steam	73	35	47.9%	3	4.1%	34	46.6%	4	5.5%	3	4.1%
	EOG	66	27	40.9%	7	10.6%	28	42.4%	6	9.1%	1	1.5%
	Plasma	61	24	39.3%	2	3.3%	27	44.3%	4	6.6%	8	13.1%
16. Documentation for IQ	Steam	72	28	38.9%	4	5.6%	27	37.5%	4	5.6%	12	16.7%
	EOG	64	21	32.8%	8	12.5%	20	31.3%	5	7.8%	12	18.8%
	Plasma	59	16	27.1%	5	8.5%	20	33.9%	6	10.2%	15	25.4%
17. Record for IQ	Steam	72	29	40.3%	10	13.9%	22	30.6%	3	4.2%	10	13.9%
	EOG	64	25	39.1%	11	17.2%	15	23.4%	4	6.3%	10	15.6%
	Plasma	59	18	30.5%	9	15.3%	14	23.7%	5	8.5%	14	23.7%
18. Installation after the publication of the guideline in 2005	Steam	38	4	10.5%	1	2.6%	2	5.3%	1	2.6%	30	78.9%
	EOG	35	4	11.4%	2	5.7%	2	5.7%	1	2.9%	26	74.3%
	Plasma	35	5	14.3%	1	2.9%	1	2.9%	2	5.7%	26	74.3%
19. Others	Steam	6	2	33.3%	0	0.0%	1	16.7%	1	16.7%	2	33.3%
	EOG	5	0	0.0%	1	20.0%	1	20.0%	1	20.0%	2	40.0%
	Plasma	4	0	0.0%	0	0.0%	0		2	50.0%	2	50.0%

Table 2. Validation items of Operational Qualification (OQ)

Validation items	Sterilization method	No of facilities replied	Performed by									
			Hospital personnel		Outsourcing		Manufacturer or supplier		Others		Not performed	
1. Bowie & Dick test	Steam	78	40	51.3%	31	39.7%	6	7.7%	0	0.0%	6	7.7%
	EOG											
	Plasma											
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 during air removal phase	Steam	77	38	49.4%	19	24.7%	17	22.1%	1	1.3%	7	9.1%
	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	1.3%	7	9.0%
	EOG											
	Plasma											
5. Check of steam supply	Steam	78	35	44.9%	22	28.2%	18	23.1%	1	1.3%	7	9.0%
	EOG											
	Plasma											
6. Check of the temperature during sterilization phase	Steam	78	43	55.1%	26	33.3%	10	12.8%	0	0.0%	4	5.1%
	EOG	69	32	46.4%	23	33.3%	7	10.1%	3	4.3%	6	8.7%
	Plasma	61	20	32.8%	16	26.2%	12	19.7%	3	4.9%	11	18.0%
7. Check of the pressure during sterilization phase	Steam	78	41	52.6%	24	30.8%	9	11.5%	1	1.3%	7	9.0%
	EOG	69	32	46.4%	21	30.4%	7	10.1%	3	4.3%	7	10.1%
	Plasma	61	21	34.4%	18	29.5%	12	19.7%	3		10	16.4%
8. Check of the time(duration) of sterilization phase	Steam	76	37	48.7%	25	32.9%	11	14.5%	0	0.0%	7	9.2%
	EOG	70	32	45.7%	24	34.3%	7	10.0%	3	4.3%	7	10.0%
	Plasma	61	18	29.5%	19	31.1%	13	21.3%	3	4.9%	11	18.0%
9. Check of the aeration time	Steam											
	EOG	55	30	54.5%	22	40.0%	2	3.6%	1	1.8%	2	3.6%
	Plasma											
10. Door safety (not open at the pressure other than the atmospheric)	Steam	70	35	50.0%	24	34.3%	12	17.1%	1	1.4%	3	4.3%
	EOG											
	Plasma											
11. Check of the temperature variation in the chamber	Steam	64	5	7.8%	2	3.1%	6	9.4%	2	3.1%	50	78.1%
	EOG	58	5	8.6%	2	3.4%	1	1.7%	2	3.4%	48	82.8%
	Plasma	50	2	4.0%	0	0.0%	0	0.0%	4	8.0%	44	88.0%
12. Check of the pressure variation in the chamber	Steam	59	4	6.8%	1	1.7%	3	5.1%	2	3.4%	50	84.7%
	EOG	52	3	5.8%	2	3.8%	0	0.0%	2	3.8%	45	86.5%
	Plasma	48	2	4.2%	0	0.0%	0	0.0%	4	8.3%	42	87.5%
13. Identification of the cold point	Steam	71	18	25.4%	10	14.1%	14	19.7%	6	8.5%	24	33.8%
	EOG	67	18	26.9%	8	11.9%	11	16.4%	6	9.0%	25	37.3%
	Plasma	58	9	15.5%	5	8.6%	12	20.7%	7	12.1%	25	43.1%
14. BI test at the cold point	Steam	77	35	45.5%	21	27.3%	8	10.4%	2	2.6%	18	23.4%
	EOG	71	30	42.3%	20	28.2%	5	7.0%	2	2.8%	19	26.8%
	Plasma	63	18	28.6%	18	28.6%	8	12.7%	4	6.3%	19	30.2%
15. CI test at the cold point	Steam	77	35	45.5%	21	27.3%	7	9.1%	2	2.6%	18	23.4%
	EOG	71	30	42.3%	20	28.2%	4	5.6%	2	2.8%	19	26.8%
	Plasma	63	19	30.2%	17	27.0%	7	11.1%	4	6.3%	19	30.2%
16. BI test at the points other than the cold point	Steam	75	20	26.7%	12	16.0%	7	9.3%	2	2.7%	36	48.0%
	EOG	68	19	27.9%	13	19.1%	4	5.9%	3	4.4%	30	44.1%
	Plasma	61	12	19.7%	10	16.4%	6	9.8%	4	6.6%	30	49.2%
17. CI test at the point other than the cold point	Steam	76	30	39.5%	16	21.1%	8	10.5%	2	2.6%	23	30.3%
	EOG	69	27	39.1%	16	23.2%	4	5.8%	3	4.3%	21	30.4%
	Plasma	62	16	25.8%	14	22.6%	6	9.7%	4	6.5%	24	38.7%
18. Documentation for OQ	Steam	76	40	52.6%	8	10.5%	8	10.5%	1	1.3%	22	28.9%
	EOG	69	32	46.4%	12	17.4%	4	5.8%	3	4.3%	21	30.4%
	Plasma	62	27	43.5%	5	8.1%	7	11.3%	3	4.8%	22	35.5%
19. Record of OQ	Steam	75	36	48.0%	23	30.7%	8	10.7%	0	0.0%	13	17.3%
	EOG	69	27	39.1%	24	34.8%	4	5.8%	2	2.9%	14	20.3%
	Plasma	60	19	31.7%	18	30.0%	8	13.3%	2		15	25.0%
20. Others	Steam	7	2	28.6%	1	14.3%	1	14.3%	0	0.0%	3	42.9%
	EOG	6	1	16.7%	1	16.7%	1	16.7%	0	0.0%	3	50.0%
	Plasma	4	0	0.0%	0	0.0%	0	0.0%	0	0.0%	4	100.0%

Table 3. Validation items of Performance Qualification (PQ)

Validation items	Sterilization method	No of facilities replied	Performed by									
			Hospital personnel		Outsourcing		Manufacturer or supplier		Others		Not performed	
1. Definition of reference load	Steam	66	20	30.3%	9	13.6%	4	6.1%	1	1.5%	34	51.5%
	EOG	62	15	24.2%	10	16.1%	4	6.5%	3	4.8%	32	51.6%
	Plasma	54	8	14.8%	7	13.0%	5	9.3%	4	7.4%	31	57.4%
2. Loading contents of reference load	Steam	67	24	35.8%	7	10.4%	5	7.5%	3	4.5%	29	43.3%
	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	4.5%	27	40.3%
	EOG	63	19	30.2%	9	14.3%	4	6.3%	3	4.8%	29	46.0%
	Plasma	55	14	25.5%	8	14.5%	4	7.3%	5	9.1%	25	45.5%
4. Temperature measurement inside the reference load	Steam	65	11	16.9%	1	1.5%	5	7.7%	2	3.1%	46	70.8%
	EOG	61	9	14.8%	3	4.9%	4	6.6%	2	3.3%	43	70.5%
	Plasma	54	8	14.8%	0	0.0%	4	7.4%	4	7.4%	38	70.4%
5. Definition of Process Challenge Device(PCD)	Steam	65	20	30.8%	13	20.0%	3	4.6%	3	4.6%	29	44.6%
	EOG	61	18	29.5%	12	19.7%	2	3.3%	4	6.6%	28	45.9%
	Plasma	53	12	22.6%	8	15.1%	3	5.7%	5	9.4%	27	50.9%
6. Temperature measurement inside the PCD	Steam	64	3	4.7%	2	3.1%	6	9.4%	4	6.3%	49	76.6%
	EOG	59	3	5.1%	5	8.5%	3	5.1%	3	5.1%	45	76.3%
	Plasma	52	3	5.8%	1	1.9%	4	7.7%	5	9.6%	39	75.0%
7. Temperature measurement at multiple points in the chamber	Steam	59	4	6.7%	1	1.7%	2	3.3%	2	3.3%	51	85.0%
	EOG	56	3	5.4%	3	5.4%	1	1.8%	1	1.8%	48	85.7%
	Plasma	48	2	4.2%	0	0.0%	1	2.1%	4	8.3%	41	85.4%
8. Pressure measurement at multiple points in the chamber	Steam	56	2	3.6%	0	0.0%	1	1.8%	2	3.6%	51	91.1%
	EOG	52	3	5.8%	2	3.8%	0	0.0%	1	1.9%	46	88.5%
	Plasma	45	2	4.4%	0	0.0%	0	0.0%	4	8.9%	39	86.7%
9. Identification of cold point in the reference load	Steam	63	13	20.6%	6	9.5%	8	12.7%	5	7.9%	31	49.2%
	EOG	60	12	20.0%	6	10.0%	7	11.7%	4	6.7%	31	51.7%
	Plasma	51	8	15.7%	4	7.8%	5	9.8%	7	13.7%	27	52.9%
10. BI test at the point identified by 9.	Steam	65	21	32.3%	14	21.5%	3	4.6%	1	1.5%	29	44.6%
	EOG	61	17	27.9%	13	21.3%	2	3.3%	1	1.6%	30	49.2%
	Plasma	53	13	24.5%	10	18.9%	4	7.5%	4	7.5%	23	43.4%
11. CI test at the point identified by 9.	Steam	65	24	36.9%	14	21.5%	3	4.6%	1	1.5%	26	40.0%
	EOG	61	21	34.4%	12	19.7%	2	3.3%	1	1.6%	27	44.3%
	Plasma	53	15	28.3%	9	17.0%	4	7.5%	4	7.5%	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%	14	23.0%	2	3.3%	0	0.0%	27	44.3%
	Plasma	53	13	24.5%	7	13.2%	4	7.5%	4	7.5%	25	47.2%
13. CI test at cold point in PCD	Steam	64	25	39.1%	13	20.3%	4	6.3%	1	1.6%	24	37.5%
	EOG	61	23	37.7%	13	21.3%	2	3.3%	0	0.0%	26	42.6%
	Plasma	53	13	24.5%	7	13.2%	4	7.5%	4	7.5%	25	47.2%
14. BI test at the point other than cold point	Steam	65	18	27.7%	10	15.4%	3	4.6%	2	3.1%	35	53.8%
	EOG	61	15	24.6%	10	16.4%	1	1.6%	2	3.3%	35	57.4%
	Plasma	52	10	19.2%	7	13.5%	4	7.7%	4	7.7%	28	53.8%
15. CI test at the point other than cold point	Steam	64	22	34.4%	12	18.8%	3	4.7%	2	3.1%	29	45.3%
	EOG	60	20	33.3%	11	18.3%	1	1.7%	2	3.3%	29	48.3%
	Plasma	51	13	25.5%	9	17.6%	4	7.8%	4	7.8%	23	45.1%
16. BI test at the point other than cold point in the PCD	Steam	63	13	20.6%	9	14.3%	3	4.8%	3	4.8%	37	58.7%
	EOG	59	13	22.0%	10	16.9%	2	3.4%	1	1.7%	35	59.3%
	Plasma	51	8	15.7%	8	15.7%	5	9.8%	4	7.8%	27	52.9%
17. CI test at the point other than cold point in the PCD	Steam	64	14	21.9%	9	14.1%	3	4.7%	3	4.7%	37	57.8%
	EOG	60	13	21.7%	10	16.7%	2	3.3%	1	1.7%	36	60.0%
	Plasma	52	8	15.4%	8	15.4%	5	9.6%	4	7.7%	28	53.8%
18. Setup of the sterilization condition by overkill method	Steam	50	6	12.0%	4	8.0%	8	16.0%	0	0.0%	33	66.0%
	EOG	47	3	6.4%	3	6.4%	7	14.9%	0	0.0%	34	72.3%
	Plasma	44	4	9.1%	3	6.8%	7	15.9%	3	6.8%	28	63.6%
19. Setup of the sterilization condition by half-cycle method	Steam	49	1	2.0%	1	2.0%	4	8.2%	0	0.0%	43	87.8%
	EOG	47	3	6.4%	3	6.4%	5	10.6%	0	0.0%	36	76.6%
	Plasma	43	1	2.3%	1	2.3%	4	9.3%	2	4.7%	35	81.4%
20. Dryness of the reference load after sterilization	Steam	61	29	47.5%	17	27.9%	2	3.3%	1	1.6%	14	23.0%
	EOG	65	28	43.1%	17	26.2%	2	3.1%	1	1.5%	19	29.2%
	Plasma	57	23	40.4%	14	24.6%	1	1.8%	0	0.0%	20	35.1%
21. Packaging integrity of the reference load after sterilization	Steam	65	28	43.1%	17	26.2%	2	3.1%	1	1.5%	19	29.2%
	EOG	57	23	40.4%	14	24.6%	1	1.8%	0	0.0%	20	35.1%
	Plasma	50	17	34.0%	12	24.0%	1	2.0%	3	6.0%	17	34.0%
22. Documentation of PQ	Steam	66	21	31.8%	8	12.1%	6	9.1%	3	4.5%	29	43.9%
	EOG	60	17	28.3%	9	15.0%	3	5.0%	3	5.0%	29	48.3%
	Plasma	53	14	26.4%	5	9.4%	4	7.5%	5	9.4%	25	47.2%
23. Record of PQ	Steam	66	22	33.3%	13	19.7%	7	10.6%	2	3.0%	25	37.9%
	EOG	60	19	31.7%	13	21.7%	3	5.0%	2	3.3%	24	40.0%
	Plasma	53	14	26.4%	10	18.9%	4	7.5%	4	7.5%	22	41.5%
24. Others	Steam	2	1	50.0%	0	0.0%	0	0.0%	0	0.0%	1	50.0%
	EOG	2	1	50.0%	0	0.0%	0	0.0%	0	0.0%	1	50.0%
	Plasma	2	0	0.0%	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 2000[3] from JSMI and this guideline was revised in 2005 to broaden its subject from only sterilization assurance program to cleaning, packaging, sterilization, sterilization assurance[4]. And this revised JSMI guideline recommends sterilization process 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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