NASJONAL KOMPETANSETJENESTE
for dekontaminering

# Faglig anbefaling for kvalitetskontroll ved nyanskaffelse og installasjon av store vanndampsterilisatorer

2020-12-18 – Versjon 1

## Innhold

## Hensikt og omfang

Nyanskaffelser av store vanndampsterilisatorer er en omfattende og tidkrevende prosess for en organisasjon. Dette dokumentet er ment å kunne brukes som et verktøy, eller vise et eksempel på, hvordan en kan holde systematisk oversikt over nødvendige forhold som må avklares og dokumenteres i forberedelsesfasen og underveis i anskaffelsesprosessen. Dokumentasjonen på alle forhold er viktig ved nyanskaffelse og installasjon av store vanndampsterilisatorer. Krav til dokumentasjon gir økt grad av forpliktelse for de ansvarlige aktører.
Anskaffelsen legger ofte premisser for sterilisering av medisinsk utstyr for de neste 10-15 år. Den medfører ofte store kostnader, involverer flere ulike faginstanser og gjennomføres ved anbudskonkurranser. Ved anskaffelse er det derfor viktig med gode og effektive prosesser samt god dokumentasjon. Anbefalingen er et resultat av Nasjonal kompetansetjeneste for dekontaminering sin erfaring med anbud, nyinstallasjon og validering. Dokumentet er i hovedsak bygget på kravene i NS-EN ISO 17665 Sterilisering av helsetjenesteprodukter - Fuktig varme og NS-EN 285: 2015 Sterilisering - Vanndampsterilisatorer - Store sterilisatorer. Det er også tatt inn noen momenter fra; *Health Technical Memorandum, HTM 01-01: Management and decontamination of surgical instruments. Part C: Steam sterilization*. I tillegg er en sammenfatning av det vi ser flere leverandører benytter som dokumentasjon ved leveranse og nyinstallasjoner tatt med i vurderingen ved utarbeidelsen av dette dokumentet.

## Definisjoner og fremgangsmåte

Dokumentet kan brukes som et tillegg til kravspesifikasjonen for den aktuelle anskaffelsen samtidig som det kan fungere som en sjekkliste og protokoll for kunde og leverandør gjennom levering og nyinstallasjons perioden.
Dokumentet er ikke ment som et uttømmende dokument for enhver nyanskaffelse og installasjon, men et hjelpemiddel til å kvalitetssikre anskaffelse og installasjon.
Det er mulig å tilpasse dokumentet til egne lokale forhold. I rubrikk 16 ***Program, configuration check and test runs,*** er det rom for å definere hvilke program, konfigurasjonskontroller og tester kunden ønsker gjennomført av leverandør før installasjon anses som ferdigstilt.
Dette dokumentet har vært pilottestet ved flere anskaffelser ved OUS i 2019 og 2020. Da OUS gjør operasjonskvalifisering (OQ) og funksjonskvalifiseringen (PQ) med interne ressurser er oppsettet i rubrikk 16 tilpasset disse forhold. I den forstand har dette dokumentet vært å anse som kundens krav til leverandør for installasjonskvalifisering (IQ). Dersom kunden ønsker full IO, OQ og PQ fra leverandør kan rubrikk 16 utvides til å dekke disse forhold. Kontakt gjerne Nasjonal kompetansetjeneste for dekontaminering for veileder i bruken av dokumentet om ønskelig
Dokumentet er bevisst laget på engelsk for å unngå flere språkversjoner.

## Ansvar og utførsel

Interessenter som bør involveres i dette dokumentet kan variere i de ulike organisasjoner. Vanligvis vil dette omfatte prosjekt- og planleggingspersonell, kvalitetsansvarlig, teknisk personell (bygg, VVS, elektro), personell med valideringskompetanse, smittevernpersonell, bruker/produksjonsleder, innkjøpsansvarlig og leverandør. Annet fagpersonell kan inkluderes etter behov.

Vår erfaring har vært god med at prosjektleder har holdt tak i dette dokumentet gjennom hele prosessen.

# Installation of Large Steam Sterilizers

These Norwegian and European standards **NS-EN 285:2015 and NS EN ISO 17665:2017** together with this document state the general requirements for installation of Large steam sterilizers for use in clinical practice at …… Hospital.

The purpose of this document is to specify which tasks are mandatory during installation, and who is responsible for performing them.

It should be used as a supplementary requirements specification during the tendering process and as a checklist and protocol for supplier and users during delivery and installation. All points below should be performed unless other is stated.

## 1 Customer information

| | | |
|---|---|---|
| Name of hospital/clinic | | |
| Address | | Contact: Phone / email |
| Project leader 1 | | |
| Project leader 2 | | |
| Technical services manager | | |
| User/operator contact person: | | |

## 2 Supplier information

| | | |
|---|---|---|
| Company name | | |
| Address | | Contact: Phone / email |
| Project leader | | |
| Sales contact | | |
| Test organization (if other than supplier): | | |
| User/operator contact person: | | |

## 3 Equipment information

| | |
|---|---|
| Description | |
| Manufacturer | |
| Model | |
| Serial number | |
| Date of manufacture | |
| Date of installation | |
| Location building, floor, room | |
| Department | |

## 4 Installation information

**Installation must be performed according to NS-EN 285:2015 , NS EN ISO 17665:2017 and according to this document.**

Responsible for supplier / test organization: .....

Responsible for tests provided by customer: …… / ……

## 5 Health & Safety checks (to be performed as first check)

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 5.1 | NA | | | Emergency stop for steam generator present, labeled and functioning. |
| 5.2 | CUSTOMER | | | Emergency stop for sterilizer present, labeled and functioning. |
| 5.3 | Supplier | | | Emergency stop/anti-crush function for sterilizer door present, labeled and functioning. |
| 5.4 | Supplier | | | All warning/danger signs are placed in a clear & visible way |
| 5.5 | Supplier | | | Check that the lighting in the maintenance area is sufficient to see the danger signs |
| 5.6 | Supplier | | | Electrical power switch present and labeled |
| 5.7 | Supplier | | | Steam main inlet valve present and labeled |
| 5.8 | Supplier | | | Water main inlet valve present and labeled |
| 5.9 | Supplier | | | Air main inlet valve present and labeled |
| 5.10 | Supplier | | | Check that chamber safety valve is present and with level according to P&ID |
| 5.11 | Supplier | | | Check all steam, water, air pipes and connection for leaks. |
| 5.12 | Supplier | | | Check that all electric installation are insulated and protected to prevent electric hazard |
| 5.13 | Supplier | | | Check that all exposed pipes warmer than 60°c are sufficient insulation to prevent burns. |
| 5.14 | Supplier | | | Check that the door locking system is functioning. |
| 5.15 | Supplier | | | Check that the door movement safety system is functioning ( block door while moving) |
| 5.16 | Supplier | | | Check that the noise level is acceptable according to specifications in NS-EN 285 |
| 5.17 | Supplier | | | Check that there is protective earth between chassis, doors, pipes etc. on sterilizer and building. |

Comments: .....

## 6 Location of the machine

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 6.1 | Supplier | | | Location according to installation drawing |
| 6.2 | Supplier | | | The installation has necessary space needed for service and maintenance |
| 6.3 | Supplier | | | The installation does not block access or space needed for transport and service/maintenance for existing |
| 6.4 | Supplier | | | Biosafety barrier is maintained |
| 6.5 | Supplier | | | Check leveling and height for alignment with delivery cart for removable load carriages |

Comments: .....

## 7 Services / Supplies

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 7.1 | CUSTOMER | | | Water supply from customer to RO-system is analyzed |
| 7.2 | CUSTOMER | | | Check if water pressure and capacity is correct according to specifications |

Comments: .....

## 8 Feed water (supply to steam generator after filtering/RO-system)

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 8.1 | Supplier | | | Water supply for steam generator is analyzed and approved according to NS-EN 285:2015 annex B Water analyses according to NS-EN 285:2015 |
| 8.2 | CUSTOMER | | | Check that installation, pipe material etc. are according to specification for RO water. |

Comments: .....

## 9 Steam

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 9.1 | Supplier | | | Steam quality test according to NS-EN 285:2015 - 21<br>Documented results for superheat, dryness fraction and non-condensable gases meet acceptance criteria according to NS-EN 285:2015<br>Steam test is to be performed on site after installation |
| 9.2 | Supplier | | | Check if steam pressure supply is correct according to specifications |
| 9.3 | NA | NA | | Check if steam capacity (volume) is in accordance to sterilizer requirements |
| 9.4 | NA | NA | | Steam traps and condensate pots installed according to steam supply drawings |
| 9.5 | Supplier | | | Pressure regulating valve checked and functioning |
| 9.6 | Supplier | | | Safety valve installed in steam inlet /generator according to specifications |

Comments: .....

## 10 Condensate

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 10.1 | Supplier | | | Perform test and analyze steam condensate for contaminates.<br>Results satisfactory according to NS-EN 285:2015 13.3.4 Table 4 |

Comments: .....

## 11 Compressed air

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 11.1 | CUSTOMER | | | Air pressure supply available according to specifications for pressure and capacity |
| 11.2 | CUSTOMER | | | Dry air, without oil drops and filtered according to specifications. |
| 11.3 | NA | NA | | Local air supply according to specifications for pressure, capacity and quality installed & connected correctly |

Comments: .....

## 12 Electricity/Power supply

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 12.1 | CUSTOMER | | | Check that Electrical supply is present with Voltage, Amp and frequency according to the sterilizer specifications |
| 12.2 | CUSTOMER | | | Check that main circuit breaker and fuse for the electric supply is according to specifications for the sterilizer, and labeled with the Id of the sterilizer |

Comments: .....

## 13 Drain

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 13.1 | CUSTOMER | | | Check that Drain system can resist temperature according to specifications for drain from the sterilizer |
| 13.2 | CUSTOMER | | | Check that Drain system has capacity for the max specified flow ( liter/min ) |

Comments: .....

## 14 Ventilation

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 14.1 | CUSTOMER | | | Air ventilation in installation site has capacity to keep the room according to recommended temperature 20 -25°c (package room) and 35-75% Rh after installation |
| 14.2 | Supplier | | | Air extraction adequate to maintain an acceptable temperature at the control panel/control unit area ( <35C ) |
| 14.3 | Supplier | | | Covers and maintenance doors with air grilles that allows air circulation |

Comments: .....

## 15 Commissioning

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 15.1 | Supplier | | | Verify the function of regulation and safety pressure switches |
| 15.2 | Supplier | | | Verify error warnings caused by defect sensors |
| 15.33 | Supplier | | | Connection ports for pressure and temperature testing provided (according to NS-EN 285:2015 4.3.3) |
| 15.4 | Supplier | | | Steam test bend for steam testing provided (steam test according to NS-EN 285:2015 21) |
| 15.5 | Supplier | | | Calibration of temperature and Pressure indicators. Calibration is to be performed after installation on-site |
| 15.6 | Supplier | | | Report with reference instruments used, measured values, and correction values applied in configuration attached. |

Comments: .....

## 16 Program, configuration check and test runs

**All tests are to be performed on site after installation**

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 16.1 | Supplier | | | Date, time, language and customer specific unit name etc. are correctly set in software |
| 16.2 | Supplier | | | Check Interface and communication with central PC, and that reports, log and alarms are stored on PC/server |
| 16.3 | Supplier | | | Check that all specified programs are available, and that other programs are not accessible for the user |
| 16.4 | Supplier | | | Select and run all the programs specified according to the order |
| 16.5 | Supplier | | | All programs should be run 3 times each with a load equivalent to customers maximum standard loads, and should be completed without any error messages. |
| 16.6 | Supplier | | | Perform a Thermometric test according to **NS-EN285 16.1** |
| 16.7 | Supplier | | | Perform a Load dryness Metal test (metal load) according to **NS-EN285 20.3** |
| 16.8 | Supplier | | | Perform an Air detector calibration and function check, according to **NS-EN285 19.4** |
| 16.9 | Supplier | | | Printout from sterilizer and logger for all the test runs and thermometric test results attached. |
| 16.10 | Supplier | | | If autoclave shares supplies/steam generator etc. with other equipment, and the installation is designed to run several equipment simultaneous, a test run with the most demanding programs should be run simultaneous for all connected equipment to check if capacity is ok |

Comments: .....

## 17 Staff training

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 17.1 | Supplier | | | General description of system |
| 17.2 | Supplier | | | Operator panel function and menus |
| 17.3 | Supplier | | | Programs selection and its parameters |
| 17.4 | Supplier | | | Printer: Handling, Loading of paper and ink cartridge |
| 17.5 | Supplier | | | Safety, Emergency stop, use and function |
| 17.6 | Supplier | | | Door opening and closing. Operation and precautions |
| 17.7 | Supplier | | | Loading operation. Startup |
| 17.8 | Supplier | | | Unloading of the goods |
| 17.9 | Supplier | | | Final process operations |
| 17.10 | Supplier | | | User manual – Review, alarms, error codes |
| 17.11 | Supplier | | | Explanation of symbols and warnings |
| 17.12 | Supplier | | | Preventive maintenance: daily, weekly, yearly |
| 17.13 | Supplier | | | Validation engineer training; adjustment of air detector, modify programs. |
| 17.14 | Supplier | | | List of participants attached |

Comments: .....

## 18 Documentation and software delivery

| | Responsible | Date Performed | Sign. | |
|---|---|---|---|---|
| 18.1 | Supplier | | | Operator manual |
| 18.2 | Supplier | | | Maintenance manual |
| 18.3 | Supplier | | | Service manual |
| 18.4 | Supplier | | | Installation drawing |
| 18.5 | Supplier | | | Electrical schematics, including voltages, current, fusing, and three-phase configuration |
| 18.6 | Supplier | | | Piping and instrumentation diagrams (P&ID's) |
| 18.7 | Supplier | | | Purchased part documentation |
| 18.8 | Supplier | | | Spare parts list |
| 18.9 | Supplier | | | Pressure vessel certifications (chamber and boiler) |
| 18.10 | Supplier | | | Installation protocol incl. settings for parameters of instrumentation |
| 18.11 | Supplier | | | Calibration certificates for testing equipment |
| 18.12 | Supplier | | | Printout of program test runs |
| 18.13 | Supplier | | | Printout from Thermometric test, (sterilizer printout and logger data results) |
| 18.14 | Supplier | | | Results for Load dryness Metal test (metal load) |
| 18.15 | Supplier | | | Feed water: Analyses of results, according to NS-EN 285:2015 annex B |
| 18.16 | Supplier | | | Condensate, analyses of result according to NS-EN 285:2015 13.3.4 Table 4 |
| 18.17 | Supplier | | | Steam quality test results: superheat, non-condensable gases, dryness fraction etc. |
| 18.18 | Supplier | | | Documentation of air detectors position, adjustment and calibration |
| 18.19 | Supplier | | | Software and service-codes necessary for adjusting air detector, sensor calibration, program adjustments, |
| 18.20 | Supplier | | | Staff training: List of participants |

Date: .....

Customer's signature ..... Suppliers signature .....

## Referanser

NS-EN ISO 17665: 2006 Sterilisering av helsetjenesteprodukter - Fuktig varme,
NS-EN 285: 2015 Sterilisering - Vanndampsterilisatorer - Store sterilisatorer.
Health Technical Memorandum, HTM 01-01: Management and decontamination of surgical instruments. Part C: Steam sterilization.
Faglig anbefaling for validering av dekontamineringsutstyr - En systembeskrivelse 2020, Nasjonal kompetansetjeneste for dekontaminering 2020.