16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015 Lille FRANCE

Référence : 1

CATEGORIE : Stérilisation

Type de présentation souhaitée : Oral Abstract

TITRE:

IMPACT ASSESSMENT OF RESIDUAL MOISTURE IN SURGICAL SETS AFTER STERILIZATION

AUTEURS :

CAMILLE FAYARD[1]

(1) CENTRE HOSPITALIER METROPOLE SAVOIE, STERILISATION, 73000, CHAMBERY, FRANCE

RESUME:

OBJECTIVE. Ambient air and dust are germ carriers. After sterilization, air passes through the packaging which content remains sterile until the expiration date. When this sterile composition presents traces of moisture, a potential risk of re-contamination is suspected. Re-contamination may occur during storage and until use. Our study aims to assess the impact of the residual moisture in the surgical set after sterilization.

METHODS. The study was focused on two series of six compositions to compare two types of packaging : container and nonwoven. Each of the six compositions tested contained 15 ceramic carriers promoting the adhesion of microorganisms. After a sterilization cycle (135 °C-18 minutes) without a drying phase to obtain residual water, the compositions are stored under adverse conditions. Residual water and ceramics were recovered aseptically and grown at 35 ± 1°C for 14 days. Positive controls, consisting in perforated packaging, were performed in parallel. Each series was repeated 5 times to assess contamination after 0, 1, 3, 7 and 14 days of storage.

RESULTS. Over the 210 cultured tubes, and regardless of the type of packaging, no contamination was revealed. This first study on the subject shows that, in presence of residual water, conservation of sterility is maintained for 14 days in the surgical set whether packed in a container or nonwoven double packaging.

CONCLUSIONS. These results provide the first answers to the possible use of humid compositions.

Nom : FAYARD
Prénom : Camille
Ville : AIX LES BAINS
Pays : FRANCE

E-mail : camille.fayard@ch-chambery.fr

Référence : 2

CATEGORIE : Stérilisation

Type de présentation souhaitée : Oral Abstract

TITRE:

CRITICAL PARAMETERS, PARAMETRIC RELEASE AND SUPERVISION OF STEAM STERILIZATION

AUTEURS :

GOULLET DOMINIQUE[1]

(1) LYONS HOSPITALS, CENTRAL SERVICE, 69800, SAINT PRIEST, FRANCE

RESUME:

The sterilization of medical devices is a scientific activity obeying phenomena, thus measurable and reproducible parameters.
The parametric release joins perfectly in this logic.
But what mean exactly these terms?
Are the critical parameters limited to the measure of exposure time, temperature and pressure?
What is the role of non condensable gases on the hollow instruments ? Is not it from now on a parameter to be taken into account to pass of the notion of steam saturation in the sterilizer chamber to the notion of local saturation in the channel of an instrument?
Is the parametric release sufficient to be in all the conditions of a reliable sterilization?
Why do we use still widely in the world of biological indicators for steam sterilization?
What can be defined as a real supervision ? Can we make a parametric release without a real supervision ? Can we perform a parametric release from the data of the only equipments of measure of the sterilizers?

So many questions as we did not settle in so thorough a way to recent years, and for which the proposals of answers can be now brought.

Nom : Dominique
Prénom : GOULLET
Ville : SAINT BONNET DE MURE
Pays : FRANCE

E-mail : dominique.goullet@laposte.net

Référence : 5

CATEGORIE : Qualité

Type de présentation souhaitée : Oral Abstract

TITRE:

Lean Six Sigma in the CSSD, What is Lean Six Sigma and how can you use these techniques and tools on a modern CSSD? An introduction of Lean Six Sigma on the CSSD

AUTEURS :

BART VAN OOST[1]

(1) ERASMUS MC, CSSD, 3000 CB , ROTTERDAM, THE NETHERLANDS

RESUME:

Objective

In 1986 Motorola developed a set of techniques and tools for process improvement called 'Six Sigma'. In 1995 General Electric (GE) made Six Sigma central to his business strategy. Six Sigma seeks to improve the quality of process outputs by identifying and removing the causes of defects and minimizing variability in manufacturing and business processes.

The CSSD of the Erasmus Medical Centre in Rotterdam, the Netherlands uses several tools (derived from the industry) to optimize their sterile supply processes. After the introduction of the Theory of Constraints to increase the flow of the instrument trays through the sterilisation process, the Lean Six Sigma method was used to minimize errors and complaints.

Methods

Six Sigma projects follows the project methodologies inspired by Deming's Plan-Do-Check-Act Cycle, including statistical methods: DMAIC

The DMAIC project methodology has five phases:

1.Define the system, the voice of the customer and their requirements, and the project goals, specifically.

2.Measure key aspects of the current process and collect relevant data.

3.Analyze the data to investigate and verify cause-and-effect relationships. Determine what the relationships are, and attempt to ensure that all factors have been considered. Seek out root cause of the defect under investigation.

4.Improve or optimize the current process based upon data analysis using techniques such as design of experiments, or mistake proofing, and standard work to create a new, future state process. Set up pilot runs to establish process capability.

5.Control the future state process to ensure that any deviations from the target are corrected before they result in defects. Implement control systems such as statistical process control, production boards, and continuously monitor the process.

Results

Nom : van Oost
Prénom : Bart
Ville : Rotterdam
Pays : the Netherlands

E-mail : B.vanoost@erasmusmc.nl

Through its Lean Six Sigma project: Error reduction, the CSSD of the Erasmus MC has been able to achieve a 75% reduction on complaints and errors. The project team, which consisted of 6 CSSD technicians, 2 operation theatre technicians and a project leader, succeeded to achieve this result in 3 months by analysing and investigation, with an unexpected root cause

Conclusions

With dedicated members in project teams a whole new approach occurs for looking at your CSSD, using the customers to set reasonable goals will harmonize the interaction between CSSD and theatre, it can give new impulses to the CSSD team to work even harder on quality and patient safety.

Nom : van Oost
Prénom : Bart
Ville : Rotterdam
Pays : the Netherlands

E-mail : B.vanoost@erasmusmc.nl

16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015 Lille FRANCE

Référence : 6

CATEGORIE : Stérilisation

Type de présentation souhaitée : Oral Abstract

TITRE:

Risk analysis following the sealing controls of the containers joints in 3 Swiss institutions

AUTEURS :

FREDY CAVIN[1]

(1) CHUV, DCILM, 1011, LAUSANNE, SUISSE
(2) HUG, STERILISATION CENTRALE, 1211, GENEVE 14, SUISSE
(3) HRC, STERILISATION AIGLE, 1860, AIGLE, SUISSE

RESUME:

Following the publication of the standard FD S98-053 and the results of the first test done in several French institutions, which showed that 30% of containers were leaking, it seemed interesting to us to check the status of our containers in 3 swiss institution for comparison. The tests are in progress and the results will be presented during the congress.

The risks linked to the leaking containers during the different reprocessing cycle steps (sterilizers output, transport, storage, etc.) will be calculated, using in particular the perfect gases formula, then analysed.

Solutions will be suggested to reduce these risks, while studying their impacts on the practices of operating theatres users.

Nom : CAVIN Ville : Lausanne
Prénom : Frédy Pays : Suisse

E-mail : Fredy.Cavin@chuv.ch

16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015 Lille FRANCE

Référence : 7

CATEGORIE : Endoscopie

Type de présentation souhaitée : Oral Abstract

TITRE:

Development of cleaning agents for biofilm removal

AUTEURS :

PHILIPP STIEFEL[1]

(1) SWISS FEDERAL LABORATORIES FOR MATERIALS SCIENCE AND TECHNOLOGY (EMPA), LABORATORY FOR BIOMATERIALS, 9014, ST.GALLEN, SWITZERLAND
(2) BORER CHEMIE AG, R&D, 4528, ZUCHWIL, SWITZERLAND

RESUME:

Introduction

Flexible endoscopes are prone to contamination with biofilm (Kovaleva et al., 2013). In an ongoing R&D project, we set out to develop cleaning agents with increased biofilm cleaning capabilities.

Materials and Methods

P.aeruginosa and S.aureus biofilms are used as cleaning targets. Screening tests are carried out in 96 well microplates. Total biomass removal is quantified using crystal violet (CV) staining. Quantitation of residual viable culturable cells is done using a microplate turbidity threshold assay (MTTA). Biofilm removal is further characterized by cleaning endoscope channels with grown biofilm as described in CEN ISO/TS 15883-5, determining cell and protein reduction. Furthermore, biofilm removal will be studied in situ by optical coherence tomography (OTC). Blood cleaning efficacy is established using a qualitative immersion test with TOSI cleaning indicators. New cleaner formulas as well as existing products are being studied.

Results

S.aureus biofilms were clearly less resistant to cleaning than P.aeruginosa biofilms. An enzymatic cleaner with a protease as the sole enzyme was effective on blood and on S.aureus biofilm but not on P.aeruginosa biofilm. CV staining showed a low cleaning performance of enzymatic disinfectant-cleaners, parallelled by an equally low performance in blood cleaning. Interestingly, MTTA's revealed that one disinfectant-cleaner expectedly reduced the culturable S.aureus titre of the biofilm clearly better than pure enzymatic cleaners but reduction of P.aeruginosa titre was not better than with a NaCl solution. The best pure, near-pH-neutral cleaner formulas containing a mixture of enzymes, reduced the CV-stainable biomass by 80-90% and viable, culturable P.aeruginosa by a factor (RF) of 1.5-1.8 log10 (MTTA) relative to NaCl. Biomass reduction was thus comparable to that of the positive control, a solution containing 1% each of NaOH, NaOCl, SDS and EDTA. This solution revealed a RF of 6 log10 in the MTTA. First cleaning experiments with P.aeriginosa biofilm in endoscope channels resulted in a RF close to 3 log10 with such a formula. More results will be shown.

Discussion and Conclusion

Nom : Rosenberg
Prénom : Urs
Ville : Zuchwil
Pays : Switzerland

E-mail : urs.rosenberg@borer.ch

Disinfectant-cleaners are neither good disinfectants nor good cleaners. A well formulated, near-neutral cleaner reduces biofilm total biomass as good as a very strong alkaline solution containing surfactant, complexing agent and active chlorine.

Literature

Kovaleva et al. Clin. Microbiol. Rev. 2013, 26(2):231

Nom : Rosenberg
Prénom : Urs
Ville : Zuchwil
Pays : Switzerland

E-mail : urs.rosenberg@borer.ch

16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015 Lille FRANCE

Référence : 18

CATEGORIE : Stérilisation

Type de présentation souhaitée : Oral Abstract

TITRE:

Creation of a dematerialized platform dedicated to ancillaries

AUTEURS :

MALKI MYRIAM[1]

RESUME:

Introduction: The evolution of the techniques of surgery leads surgical teams to ask for a material dedicated to implanting, known as "ancillary", thus becoming increasingly specific. Currently, suppliers make them available through a loan or a deposit. Hence, all sterilization units are facing the same difficulties in the management of this equipment : poor distribution management, late delivery, lack of instruction booklet, difficulties to rebuild the ancillary, etc.

Materials and methods: Since 2009, a workshop was created, gathering all the French editors of software of sterilization (i.e., 10), industrial suppliers specialized in orthopedic surgery (i.e., 9) and hospital pharmacists. The scope of this project was the creation of a dematerialized platform, discussed during a multidisciplinary meeting. Thus, software editors of sterilization and head of sterilization units were working in pairs of two in order to perform functional tests. Between January, 2011 and December, 2013, several tests were conducted on 20 ancillaries provided by industrials. During this battery of tests, the objective was to be able to download the composition of trays, listing of instruments, instructions for use and videos for each ancilliary. Results: At the end of 2013, after standardized exchanges between the data from industrials, platform and sterilization software, the recovery rate reached 100% across all data. In the light of these figures, professionals, supporting the project, decided in January 13th, 2014, to allow the access to the production platform to all health care facilities. There were 700 ancillaries. 70 hospitals were involved in the project, including hospitals located outside of France (i.e. Belgium, Switzerland). The number of download recorded per month reached up to 150 ancillaries. Discussion: Ancillary's traceability is thereby highly improved, meeting the expectations of the project stakeholders (i.e., manufacturers, head of sterilization units, etc). The continuation and sustainability of the platform will rely in both, referencing new ancillaries and a wider number of users.

Conclusion: The next stage of development is the dematerialization of the data sheet and information relating to the return logistics ancillary to industrial, the first trials are planned in February 2015. The uniqueness of the project lies in the universality of such a system, leading to a widespread use of this platform in Europe for a better management of ancillaries.

Nom : Myriam
Prénom : Malki
Ville : Montreuil
Pays : France

E-mail : malki_myriam01@hotmail.fr

16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015
Lille FRANCE

Référence : 22

CATEGORIE : Hygiène

Type de présentation souhaitée : E Poster

TITRE:

Monitoring of cleaning and antimicrobial products used in health-care settings In Minas Gerais - Brazil

AUTEURS :

ENI ROSA MESIANO[1]

(1) NATIONAL HEALTH SURVEILLANCE AGENCY - ANVISA, GENERAL MANAGEMENT OF SANITIZING, 70.752-020, BRASILIA, BRAZIL

RESUME:

Misuse of disinfectants in health care has attracted the attention due to the increased number of cases of infections by Rapid-Growth Mycobacteria–RGM in patients undergoing surgical procedures and diagnoses. As containment measure of infections and to assess the quality of products in post marketing, it was signed in 2008 an agreement between the National Health Surveillance Agency, Public State Laboratory and one State Sanitary Surveillance Department. The agreement was initially planned for two years and analysis of at least 200 samples, but was extended until December 2014. Perform quality monitoring program of cleaning and antimicrobial products used in a sample of health-care settings-HCS.

VISA/MG started the samples collecting in July 2008, that were sent to FUNED for analysis. Due to the difficulty of collecting in HCS, the samples were obtained directly in distributors.

From the 243 samples were found: 28 sterilizing, 16 enzymatic detergents, 12 other detergent categories, 24 alcohol of general purpose cleaner, 39 disinfectants for fixed surfaces, 09 high-level disinfectants, 01 intermediate-level disinfectant, 70 bleaches and 44 other disinfectants. One of the products collected was not regularized at ANVISA. 80% of products analyzed had at least one unsatisfactory item where the label represented 70% of the total. Non-conformities in the label were related as inclusion or exclusion of mandatory sentences. Nonconformities of pH and labeling represented 51% of the unsatisfactory items. The remaining is distributed among: appearance, active content, microbiology, etc. It was detected the component formaldehyde in 3 samples, which is prohibited in sanitizing products by government. The test for proving the efficacy against M. massiliensis was not done because it was mandatory to pass in all parameters for the analysis to be carried out.

Although liquid chemical sterilization have been banned in this state as a precautionary and containment measure against cases of infection by RGM, several samples were collected with such indication. On the other hand, according to the different results informed when at the registration of products in a government department, the pH change may damage items and surfaces, resulting in increased hospital costs.

Thus, the adoption of monitoring and control measures of sanitizing at post-marketing can ensure efficacy and safety, as well as improving care provided to patients and reducing hospital infections.

Nom : MESIANO Ville : BRASILIA
Prénom : ENI ROSA Pays : BRAZIL

E-mail : ROSA.AIRES@ANVISA.GOV.BR

16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015 Lille FRANCE

Référence : 23

CATEGORIE : Stérilisation

Type de présentation souhaitée : Oral Abstract

TITRE:

Functional controls of the rigid endoscopes and light guides in Central Sterilisation Service Department

AUTEURS :

MELANIE BOMBAIL[1]

(1) CENTRE HOSPITALIER D'AVIGNON, PHARMACIE, 84902, AVIGNON, FRANCE
(2) HOSPICES CIVILS DE LYON, STERILISATION, 69 808 , SAINT PRIEST, FRANCE
(3) HOSPICES CIVILS DE LYON, STERILISATION, 69 808 , SAINT PRIEST, FRANCE

RESUME:

Assess surgical instrument functionality is one of the objectives of Central Sterilisation Service Department (CSSD), in order to reassembling safe and effective medical devices for patients and surgical staff. These functional checks are however a real problem. In fact, very few documents accurately describe the controls to be performed. In this context, few papers were published about recommended controls of functionality on rigid endoscopes and light guides.

The objective of this study conducted in CSSD is to evaluate and to compare marketed devices of functionality controls of rigid endoscopes and light guides. For light transmission, two devices were compared: luxmeter (Anklin, Switzerland) for rigid endoscopes and light guides and analogical controller (Crimo, France) only for light guides. For image transmission, two devices (magnifying glass- Sterilmed, France- and specific cylindrical controller- Fibroptic, France-) were compared to visual control without device. Comparisons are based on practicability of control method for light transmission and on capacity to detect defaults on rigid endoscopes for image transmission.

For light transmission (luxmeter and analogical controller), control with luxmeter needs lot of manipulations with real risk for endoscopes and is not precise. Analogical controller is easy and quick to use (10s compared to 5 min with luxmeter). For image transmission, controls with magnifying glass and cylindrical controller were compared to visual control on 95 rigid endoscopes. With cylindrical controller, description of default on endoscope is more precise than with magnifying glass or visual control in 54 %, but it present a real interest only in 6 % of tested endoscopes.

For light transmission, luxmeter and analogical controller give an objective result, but analogical controller seems to be preferred to luxmeter. For image transmission, magnifying glass is easy to use without limits on endoscope characteristics. Cylindrical controller present real risks for endoscopes for a small benefit compared to the magnifying glass or visual controls. Both of them give a subjective result.

The results show that only some of marketed devices are suitable for routine controls and allow overcoming the subjectivity. This work involved functional checks protocols for the control of endoscopes and light guides to ensure an optimal management for these devices.

Nom : BOMBAIL
Prénom : Mélanie
Ville : Avignon Cedex 09
Pays : FRANCE

E-mail : bombail.melanie@ch-avignon.fr

Référence : 24

CATEGORIE : Stérilisation

Type de présentation souhaitée : Oral Abstract

TITRE:

Biological indicators role in CSSD equipment qualification and monitoring

AUTEURS :

PAULO LARANJEIRA[1]

(1) USP, NURSING SCHOOL, 05403-000, SÃO PAULO, BRAZIL

RESUME:

Hospital steam sterilization cycles using the overkill approach to achieve the required sterile assurance level must rely on indicators to have their cycle approved or rejected. Studies have proven that sterilization cycles controlled by using temperature and pressure information, need also to monitor the amount of non-condensable gases (NCG). The presence of NCG is particularly critical in lumen loads, and cannot be detected by common sterilization equipment, creating a significant obstacle in using parametric release technic. There are in the market a series of new devices that were developed to achieve the goal of clearing a sterilization cycle in a worst-case scenario, simulating lumen penetration, coupled to a chemical indicator; however, some studies have proven that these chemical indicators have limitations. Biological indicators (BI) are being used now a day as an important tool for equipment qualification in half cycle challenges, especially because it is the only way to evaluate if the mathematical calculations done during the qualification are correct. It is important to observe that despite biological indicators be considered a well-known product, new rapid readouts based on enzyme activities are in the market, and close attention has to be taken towards lethality calculation. Looking into BI´s construction, in order for the saturated steam to penetrate into the housing and reach the spore strip, it is necessary to remove all NCG from its housing. This situation is very similar to lumen penetration challenge requirements, therefore the usage of BIs for monitoring NCG should be considered. Medical devices are continuously improving and even if the sterilization cycle is the same for many years, special attention should be taken in how these medical devices are processed, specially devices with lumens, and which indicators are chosen to monitor the cycles. Based on BIs characteristics, it should not only be used during equipment qualification, but also as a key indicator for monitoring loads.

Nom : Laranjeira
Prénom : Paulo
Ville : Santana de Parnaiba
Pays : Brazil

E-mail : prlaranjeira@gmail.com

16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015 Lille FRANCE

Référence : 31

CATEGORIE : Stérilisation

Type de présentation souhaitée : Oral Abstract

TITRE:

ACTIVITIE AND COSTS OF FRENCH STERILIZATION : A NEW APPROACH

AUTEURS :

ANNETTE CUBERTAFOND[1]

(1) CHU DUPUYTREN, PHARMACY, 87042, LIMOGES, FRANCE
(2) STER06, STERILIZATION, 06800, CAGNES SUR MER, FRANCE
(3) CHU, TRANSVERSAL STERILIZATION, 37044, TOURS, FRANCE

RESUME:

In France, sterilization departments did not have a standardized method to characterize their activities, to calculate their production costs, and to define their requirements in human resources. Thus, a reliable comparison between hospitals was not possible. The goal of the work initiated by the French Association of Sterilization (AFS) was to propose a tool that could be used by every sterilization departments in order to measure their operational costs and their quality level.

The study was undertaken by a group of 9 persons. Initially, a mapping of the sterilized medical devices groups was elaborated according complexity: final users (surgery room, dental units, care units...), constraints for each stage of the sterilization process, number of medical devices by group. A weight coefficient allowing to calculate the work units and human resources was added to each groups. Then, an accounting standard resulting from the national rules was elaborated including all the direct costs. It allowed then to calculate a cost for each work unit, and thus to each medical devices group. In addition, quality and management indicators were proposed.

In order to test the robustness of the indicators, a first step was to apply the method to some sterilization departments to adjust the weighting coefficients. Then the tests were extended to 32 sterilization departments. The tests showed reliability with or without data-processing software. This allows to consolidate the tool and the relevance of the work unit.

This work allows to replace the french various existing calculation methods using as such autoclave volume or the packaging type, without taking into account the whole sterilization process and the complex features of treatment.

The tool and its results have been included in the handbook of the activity indicators of the Hospital Pharmacy and published by the French Society of Clinical Pharmacy (SFPC). They were integrated in the efficiency analysis of the sterilization process which will be diffused by the National Agency of Support to Performance (ANAP). These tools are available on the French Association of Sterilization (AFS) website.

Nom : CUBERTAFOND Ville : LIMOGES
Prénom : ANNETTE Pays : FRANCE

E-mail : annette.cubertafond@chu-limoges.fr

16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015 Lille FRANCE

Référence : 32

CATEGORIE : Maitrise de l'environnement

Type de présentation souhaitée : Oral Abstract

TITRE:

Benchmarking to improve hygiene and environmental controls in sterilization unit

AUTEURS :

AURÉLIE REITER-SCHATZ[1]

(1) STRASBOURG UNIVERSITY HOSPITAL, PHARMACY-STERILIZATION, 67091, STRASBOURG, FRANCE

RESUME:

Introduction

The sterilization process needs to be performed in a controlled environment. Particle and microbiological contaminations must be prevented and monitored to keep the risk of proliferation low.

The "Good Practices in a Hospital Pharmacy" (BPPH), French guidelines for sterilization, specify the necessity to train staff about work clothes, hygiene, hand washing, area restriction and environmental controls. Our practices also include the guidelines from the French Association of Sterilization (AFS) "Mastering and controlling the environment in sterilization", which explains sample collection, air and water checks and staff behavior. Our process is also completed by ISO standards, for example NF EN ISO 14644, NF EN ISO 13485 and NF S 90-351.

Aim of the study

During last year, the microbiological controls of furniture and equipment surfaces in our sterilization unit revealed contamination not in compliance with our standards. It happened despite staff training on hygiene and cleaning technique and a review of the cleaning organization. The aim of this work is to perform a benchmarking on hygiene and cleaning practices with different French sterilization specialist establishments in order to improve our own organization.

Material and methods

A questionnaire entitled "study of hygiene and control in sterilization unit" was released February 4, 2015 through the French Association of Sterilization website. Participants replied on a voluntary basis. Several topics were covered: staff hygiene (work clothes, mask or glove wearing, hand washing), premises cleaning (assigned staff, specialized equipment, frequency), control type (particle and microbiological, air and surface, assigned staff, warning level) and their frequency.

Results and discussion

Completed questionnaires are expected by the end of February 2015. These data will establish a picture of hygiene and environmental control practices in French sterilization units.

Conclusion

As part of the ISO 9001/13485 certification, we work on improving our hygiene practices and microbiological quality inside our sterilization department. This benchmarking aims at improving the management of non-conform environmental controls. Analyzing the practices in place in the different establishments which filled in the questionnaire will allow us to optimize our own practices.

Nom : REITER-SCHATZ Ville : STRASBOURG
Prénom : Aurélie Pays : FRANCE

E-mail : aurelie.schatz@chru-strasbourg.fr

Référence : 37

CATEGORIE : Qualité

Type de présentation souhaitée : Oral Abstract

TITRE:

How do you ensure your loan kit is clean and sterile

AUTEURS :

JANE BUTLER[1]

(1) THE PRINCE CHARLES HOSPITAL, BRISBANE, AUSTRALIA

RESUME:

How do we ensure the loan kits we receive into the CSD are clean and sterile for use .
Annual PQ of our sterilisers to ensure sterilisation
Accessing the kit
Have you had previously received the kit
Don't have time to validate each loan set in the washer or steriliser
Processes we have implemented to ensure cleanness
Assessing the material of loan instruments, product families,
Identify how complex the instrument is.
Material of loan instruments, penetration time for ensure sterilisation

Nom : Jane
Prénom : Butler
Ville : Brisbane
Pays : Australia

E-mail : gjbutler@optusnet.co.au

16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015 Lille FRANCE

Référence : 45

CATEGORIE : Stérilisation

Type de présentation souhaitée : Oral Abstract

TITRE:

Validation of hydrogeneperoxide Sterilizers following ISO 14937

AUTEURS :

KLAUS ROTH[1]

(1) SMP GMBH PRÜFEN VALIDIEREN FORSCHEN, VALIDATION AND RESEARCH, 72072, TUEBINGEN, GERMANY

RESUME:

Low temperature sterilization Systems based on hydrogen peroxide (hp) came into the hospitals in the 1990ies well known under the name Sterrad. Meanwhile more than 20.000 hp sterilization systems are installed worldwide. In the last years more companies came on the market as well. Since 15 years SMP is testing hp sterilization Systems. To compare the systems specific biological indicators have been developed, which allows defining lumen claims not only depending on the length and diameter of the process challenging device. Also the influence of the material to the sterilization effect can be tested. As a test organism geobacillus stearothermophillus is used, which already has shown his resistance again hp and is published in several publication.

ISO 14937 is dealing about the development, validation and routine control of sterilization processes for medical devices. As no specific standard for hp systems exist, ISO 14937 has to be applied for. To validate the processes the set points when the sterilizer stop the process has to be find out. The possible deviation of the temperature, of the injected volume of the sterilizing agent, the maximum weight of the load and the material of the load has to be regarded during the validation. In a half cycle mode all biological indicators (BI) should show no growth while the chemical indicator (CI) should not change his color completely.

To simulate the load silicone mats with enlarged surfaces are used. The mats are packed in containers which are double wrapped in suitable wrapping material. Silicone is none for absorbing the hp and the concentration of the sterilizing agent inside the chamber may be too low during the process due to the absorption. When the size of the silicone mat is once evaluated a so called challenge pack (CP) is defined. The BI inside the CP should show no growth when exposed in the half cycle mode and the CI should not completely change his color. After defining the CP it will be used also in half cycles with simulated failures: low temperature, low dosing of sterilizing agent etc. The failures should be beneath the set points for interrupting the cycle to achieve additional safety.

In the meantime has performed such tests in 10 systems from 5 different manufacturers. CP for the routine control has been developed, a basic for the validation of the cycles. Additionally material and design tests of surgical instruments have been done.

Nom : Roth
Prénom : Klaus
Ville : Tuebingen
Pays : Germany

E-mail : kroth@smpgmbh.com

Référence : 48

CATEGORIE : Bloc opératoire

Type de présentation souhaitée : Oral Abstract

TITRE:

the supply chain of sterile medical devices in your hospital: improving patient safety and gaining efficiency on stock control

AUTEURS :

TOM PEREBOOM[1]

(1) ZIEKENHUIS AMSTELLAND, HOSPITAL, 1186 AM, AMSTELVEEN, THE NETHERLANDS

RESUME:

In 2014 the OR department of the Hospital Amstelland improved their supply chain of sterile medical devices. The new system gives the OR a tool to scan all items used by the patient in the electronic patient file. Its almost like in the supermarket. The results are:

1) automated recall on all implants and medical devices used during the OR on specific patient. Within 1 minute a recall can be made and patient is identified. Patient safety is improved.

2) Quality on stock items has been improved. The automated system controls all items on “sterile until date”. The system is effectively implanted in the organization of the OR reducing the change on picking out of date implants.

3) With active supply chain control items are always available for scheduled operations. The cancellation of an OR due to the lack of implants has lowered to a minimum. This improves patient kindness.

4) With active stock control inventory has been optimized, reducing costs of having stock and lowering waste. Cost of care has been lowered.

Each implant and medical device disposable used by the patient is provided by a unique barcode with specific information over this item. The supply chain is supported by an ERP system.

The challenge for the OR is dealing with this new task of active stock control. Improving the supply chain of an hospital needs the input of the complete organization: logistics, procurement, finance and the end user. By using the business case of GS1 the Netherlands commitment has been created by the board. The return on investment was 1 year.

Nom : Pereboom
Prénom : Tom
Ville : Amstelveen
Pays : The Netherlands

E-mail : tope@zha.nl

16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015 Lille FRANCE

Référence : 51

CATEGORIE : Stérilisation

Type de présentation souhaitée : Oral Abstract

TITRE:

Requirements of validation of packaging systems and sterility assurance

AUTEURS :

HARTMUT DUNKELBERG[1]

(1) UNIVERSITY, PROF. DR., D-37099, GOETTINGEN, GERMANY

RESUME:

Health care personnel must have experience and understanding of how packaging systems for terminally sterilized medical devices can be optimized to reduce the risk of hospital acquired infections. The aim of this presentation is to give examples and to propose methods which are suitable for validating the efficiency of the packaging system.
According to ISO 11607 conditions such as temperature, humidity and pressure ranges and bioburden under which the packaging system is exposed in the storage environment shall be recorded and controlled. The sterile barrier system must correspondingly reflect these conditions by having specified material performance properties. The packaging systems must be validated by specific test results and proof of packaging's performance. It is emphasized that limits of performance specified in ISO 11607 such as tearing resistance, bursting strength and pore diameters are minimum requirements. These limits differ largely depending on the type of packaging material. They are not related to a specified exposure scenario. Consequently, health care personnel need to know the actual results of packaging-system performance tests to select the most suitable product. Considering specific test parameters such as loss of integrity by bursting, the packaging should be validated by using the actual on-site conditions in a worst-case configuration to determine the compliance with ISO 11607. This can be done when the same samples of about 30 sterilized packages are handled and transported repeatedly in the usual way. When the packaging's integrity is compromised by bursting a safety factor of at least 10 for the applied strain with no damage could be a base for determination of a validated exposure scenario. This recommended test is crucial because detection rates of tears by visual inspection are low, e.g. from 6.7% to 96.7% from the smallest (1.1 mm) to largest (10 mm in diameter) defect (Waked et al, 2007). Data showing the filtration efficiency against airborne particles (size range from 0.3 to 3 µm) are absolutely essential for validation of packaging systems. Test results according to DIN 58953-6 (clause 2.15) are frequently used by manufacturers to show compliance with ISO 11607. These are not suitable as microbes are fixed on a solid matrix. Considering temperature, air pressure changes and transport to different altitudes, the risk of entry of airborne microbes through porous packaging components should be calculated.

Nom : Dunkelberg
Prénom : Hartmut
Ville : Bad Sooden-Allendorf
Pays : Germany

E-mail : hdunkel1@gwdg.de

16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015 Lille FRANCE

Référence : 52

CATEGORIE : Stérilisation

Type de présentation souhaitée : Oral Abstract

TITRE:

Lean Management approach applied to Central Sterilisation Service Department (CSSD)

AUTEURS :

SEBASTIEN MAGNIN[1]

(1) HOSPICES CIVILS DE LYON, STERILISATION CENTRALE, 69808, SAINT PRIEST, FRANCE

RESUME:

CSSD co-ordinates sterilisation activities of 4 establishments located from 5 to 25km which corresponds to 32 surgical units and 129 care units.
The increase in activity corresponds currently to the treatment up to 750 surgical packs and 1800 surgical devices per day.
CSSD has had to follow the Lean Manufacturing approach in order to cope with the volume ramp up.
A lean organisation focuses on its customer needs and concentrates its business processes in order to always increase it. The overall aim is to provide the perfect added value to its customers, with regards to quality, cost and processing time.
Lean Management changes the business model and allows a better optimisation of its production flows.
The CSSD organisation is focused:

- 1 to create added value
  - a quality performance indicators (reassembling reliability: no modification of surgical pack composition between entrances and exits of CSSD in 92%)
  - b surgical pack restitution within 24h: processing time performance indicator (78% in 2013 against 97% in 2015)
  - c improvement of the various logistics collections reaching now 3 deliveries a day at each establishment
- 2 to identify all steps in the sterilisation process: process is modelled to obtain a productive ratio for each production step (31% growth since 2012). Daily analysis of performance indicators allows an optimised using of all production resources
- 3 to adapt workload (calculated as statistical value) which corresponds to the needs expressed by our customers on a daily basis (gap of 4% on 2014). This statistical method takes into account variables from each surgical unit, such as annual leave, maintenance, non-working days. Analysis of workload and ratio association balances and optimises the various process steps and allows a better management of the daily resources (variable number of personal each day)
- 4 to optimise production flows (to move from a push to a pull flow). The delivery time of each surgical pack is calculated in order to not overload our equipments and workstations
- 5 to develop its quality policy, with staff training and removing tasks without added value. Monitoring of a work zone and the analysis of problems encountered allows introduction of corrective measures

Nom : MAGNIN Ville : SAINT PRIEST
Prénom : SEBASTIEN Pays : FRANCE

E-mail : sebastien.magnin@chu-lyon.fr

In conclusion, the implementation of various actions mentioned has improved the fluidity of the processes. The deadline for return surgical packs is now respected. The improvement of adequacy between sterilisation resources and workload was essential to

Nom : MAGNIN Ville : SAINT PRIEST
Prénom : SEBASTIEN Pays : FRANCE

E-mail : sebastien.magnin@chu-lyon.fr

Référence : 53

CATEGORIE : Stérilisation

Type de présentation souhaitée : Oral Abstract

TITRE:

Peracetic Acid Gas Plasma Sterilisation

AUTEURS :

HIROYOSHI KOBAYASHI[1]

(1) TOKYO HEALTHCARE UNIVERSITY POSTGRADUATE SCHOOL, DIVISION OF INFECTION PREVENTION AND CONTROL, 141-8648, TOKYO, JAPAN

RESUME:

Introduction: As the material of the reusable medical devices is diversified, the clinical demand for low-temperature sterilisation has recently been increasing. However, some studies have pointed out that typical low-temperature sterilisation methods, ethylene oxide gas sterilisation and hydrogen peroxide gas plasma sterilisation have such problems as residue on the sterilised devices and adverse effects of the agents. This study investigated the availability of peracetic acid (PAA) sterilisation method newly developed in Japan.

Method: Equiliburium mixture containing peracetic acid was induced into the sterilisation chamber (100 L) to gaseous distribution (ca. 2.4g/m3 PAA gas) for the sterilisation. The procedure consists of evacuation, injection of PAA, distribution (sterilisation at around 50℃), 2nd evacuation, injection of PAA, distribution, plasma treatment and aeration.
Biological indicator (BI) of Geobacillus stearothermophilus ATCC 7953 with spores of 10E6 was used in the half cycle test (about 30min; n=13).
Environmental PAA concentrations (taken from the exhaust port and the chamber) were also evaluated using a gas detector (ATI C16 Porta Sens II).
Results: All BIs were found to be negative, indicating sufficient sterilisation effect of the method. Environmental concentrations were below the AEGL-1 level (0.17 ppm) of Acute Exposure Guideline Level (AEGL) provided by AEGL Committee.

Discussion: The study revealed that the method provided sufficient sterilisation effect. Furthermore, the results that the PAA concentrations in the environment below the AEGL-1 level, indicated that the PAA formulation used in the study was suitable for clinical use as a low-temperature sterilisation agent.

Conclusion: PAA low-temperature sterilisation is considered to be clinically available. Future development of the steriliser is highly promising as a new method of sterilisation.

Nom : Kobayashi
Prénom : Hiroyoshi
Ville : Tokyo
Pays : JAPAN

E-mail : hk@thcu.ac.jp

16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015 Lille FRANCE

Référence : 54

CATEGORIE : Stérilisation

Type de présentation souhaitée : Oral Abstract

TITRE:

Relevance of using a recomposition support tool (Ancitrak®) for loan instruments into the sterilization process in a large hospital

AUTEURS :

ANNE-CECILE DUPLOYEZ[1]

(1) CHRU LILLE, STERILIZATION, 59037, LILLE, FRANCE

RESUME:

Background:Surgical instrument tracking and traceability is now well established into the sterilization workflow, allowing greater accuracy in routine practice, and providing more safety for patient. Nevertheless, a number of instruments can not be written, especially loan sets. In this context, innovative tools have been developed. Ancitrak® is the first traceability workstation based on NO-Datamatrix technology. This device allows quick recognition of the instruments, their placement in the operating tray and informatics tracking. The aim of our study is to evaluate the relevance of using such technology in the sterilization process in our hospital.

Material and Methods:Our study will take place over a period of 6 months. Benefits of using the Ancitrak® tool will be estimated for both our sterilization department and the neurosurgical operating room which represent a global activity of 2000 operating trays per month. Preliminary settings will be required to allow good recognition of the instruments according to their weight, shape and color. The time of assembling the operating trays and the compliance rate will be determined with and without the utilization of the Ancitrak® tool, allowing direct comparison. Moreover, we will evaluate ergonomics and usability of this tool in routine practice.
Results:The setup phase is currently in progress. However, our first tests seem very encouraging. Ancitrak® appears to be an easy to use device with a good integration in the circuit of loan sets. Results of our study concerning benefits for the whole sterilization process will be available for the congress

Discussion:Ancitrak® already appears as a very interesting tool to implement in our daily practice. First tests showed great interest that we would be able to confirm with our study. Notably, Ancitrak® recently received the Innoster Prize for Innovation at the French Congress of Sterilization in 2014. This tool is announced to have a compliance rate over 95% with improvement of the time assembling in 93% of cases. Overall, this device should constitute an indispensable tool to optimize our arsenal for coming years, providing more safety for the patient, better management of all kind of surgical devices and reduce the cost management.

Conclusion:Traceability of the surgical instrument has led to real improvements in patient safety.

Nom : Duployez Ville : Lille
Prénom : Anne-Cecile Pays : France

E-mail : anne-cecile.duployez@chru-lille.fr

However, some problems could persist. Ancitrak® is an innovative and efficient tool to further improve the sterilization process.

Nom : Duployez
Prénom : Anne-Cecile
Ville : Lille
Pays : France

E-mail : anne-cecile.duployez@chru-lille.fr

Référence : 59

CATEGORIE : Maitrise de l'environnement

Type de présentation souhaitée : Oral Abstract

TITRE:

Life cycle assessment of single-use and reusable surgical instruments

AUTEURS :

ANDREAS ASKER[1]

(1) WSP SWEDEN, WSP ENVIRONMENTAL, 12188, STOCKHOLM, SWEDEN

RESUME:

Many hospitals face the challenge of choosing single-use or reusable instruments; balancing the environmental impact with cost and patient safety. A recent study in Stockholm County Council shows that the use of single-use instruments emits almost 600 times more greenhouse gases, and consumes 17 times more energy, than reusable instrument. The study shows, however, that reusable instruments come with 8 times the cost mainly due to high sterilisation costs.

Stockholm County Council is responsible for all publicly-financed healthcare and public transport in Stockholm County. Stockholm County Council has a systematic approach to reducing the County's environmental impact and execute their assignments in a climate and resource efficient way. One of the goals is to reduce the environmental impact from use of single-use devises in healthcare.

To support these goals, a life-cycle-analysis has been carried out by WSP Environmental at the Karolinska University Hospital, comparing the energy and climate impact of single-use with reusable instruments. The study has a cradle-to-grave approach, and hence including extraction of raw materials, production, transportation, sterilization, maintenance and waste handling at end-of-life. The cost assessment includes purchasing, cleaning and sterilization, maintenance and waste handling. The results in the study are based on the assumption that scissors with surgical quality is used 1000 times and compared to the use of 1000 single-use scissors.

The results clearly shows that reusable instruments have an environmental benefit, but at a higher cost. The emission of greenhouse gases from the use of single-use instruments is 588 times larger, with 17 times larger energy use compared to reusable instruments. However, reusable instruments are 8 times more expensive to maintain based on the present sterilization costs at the Karolinska University Hospital.

The results from the study will be used as decision support in future instrument procurement processes. In addition, Stockholm County Council together with several other Swedish County Councils, are currently conducting a study on how to lower resource use in the work-flow of reprocessing reusable instrument.

Nom : Hemström Ville : Stockholm
Prénom : Kristian Pays : Sweden

E-mail : kristian.hemstrom@sll.se

16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015 Lille FRANCE

Référence : 60

CATEGORIE : Bloc opératoire

Type de présentation souhaitée : Oral Abstract

TITRE:
Custom 3D printing spinal implant

AUTEURS :
RICHARD ASSAKER

(1) CHRU DE LILLE, NEUROCHIRURGIE, 59037, LILLE, FRANCE

RESUME:

Modern spine surgery requires sophisticated spinal implants dedicated a specific function. Spinal fusion surgery is a routine and popular surgery. Sagittal alignement is essential for optimal results after fusion. All medical devices provided to treat this type of indication have standard dimensions and do not fit with the anatomy of the patient especailly in term of lordosis (both endplate morphology, width, depth and height are approximate). To improve this a patient specific implant is considered. A 3D model of the vertebrae is generated based on the patient's CT and allows to design an implant matching exactly with the patient's vertebrae endplates in terms of morphology and dimensions.
The authors presents a specific case of a patient with a L5 fracture. Using a specific reconstruction software, the spine is generated in 3D from the patient CT. The region of interest consisting of the L5 vertebral body that has a unusaul lordotic anglethat requires a customised implant to fit this angle. A surgical planning is realized with the considered dimensions, a custom-made vertebral body replacement is designed with a specific angulation, height and endplates. The implant is then 3D printed in PolyEtherKetoneKetone (PEKK) to fit exactly with the patient's anatomy. The implant is designed such as to put bone graft during the surgery in order to reach the fusion.
The authors describe the methodology of palnning and developping the implant, the surgical technique for insertion and the results. A review of the clinical need will be described with the specific requirements for clinical use

Nom : Assaker Ville : Lille
Prénom : Richard Pays : France

E-mail : richardassaker@gmail.com

Référence : 62

CATEGORIE : Qualité

Type de présentation souhaitée : Oral Abstract

TITRE:

Training of Pharmaceutical professionals specialists and technicians in sterilization in Argentina.

AUTEURS :
HELGA SAGER

(1) FUDESA, BUENOS AIRES, ARGENTINA

RESUME:

The incorporation of new technological developments in the field of sterilization in health centers has led to specialization of pharmaceutical and technical professionals must acquire skills competencies to perform their functions determining that curricula based on grade is determined as chief a central sterilizing the professional title of pharmacist.
In the late 60s, with increasing cases of nosocomial infections, OPS suggested generating human resources with specific training for the sterilization area hosting in 1969 the first assistant course in sterilization. By 1970 the first pharmaceutical Head of a sterilization center was designated.

PROBLEM
Poor knowledge and health relevance assigned to the functions of sterilization in health centers authorities, appointment of people with low levels of instruction for performing tasks of high complexity and responsibility, lack of training activities for service members are the indicators of need of action training of professionals and technicians, who supervised the pharmaceutical professional, contribute to the proper functioning of sterilization areas.

METHOD:
In Argentina, when the specificity of professions and the need for these health centers became importance; the Foundation for the Development of Sterilization (FUDESA) was created in 1994, in order to promote the careers of pharmacist superior sterilization and sterilization technician. In 1995 starts a specialists training in sterilization aimed at pharmacists in the province of Buenos Aires continuing this training in the provinces of Mendoza, Tucuman, Misiones and Córdoba. In 2003, by decree of President's Office, technician's training in sterilization is incorporated.

CONCLUSIONS
The generation of new fields of knowledge and technological advancement in the field of health professionals led health rearranged according to new divisions of labor process. Today, Argentina has specific training to form pharmaceutical specialists and technicians in sterilization, noting that the application of scientific and technical principles by these professionals has raised the level of quality of health care in our health centers.

Nom : Simonoska
Prénom : Aneta
Ville : Skopje
Pays : Macedonia

E-mail : aneta.simonoska@gmail.com

16th World Sterilization Congress & Annual conference of AFS
7-10 OCTOBER 2015 Lille FRANCE

Référence : 68

CATEGORIE : Maitrise de l'environnement

Type de présentation souhaitée : Oral Abstract

TITRE:

Do we have the magical tool to prevent bacterial survival in hospitals - cheap copper?

AUTEURS :

ANETA SIMONOSKA[1]

(1) UNIVERSITY CLINIC FOR OPHTALMOLOGY, OR NURSE, 1000, SKOPJE, MACEDONIA

RESUME:

Introduction:

Disinfective feature of copper surfaces is already well known. In this study antimicrobial effectiveness against multi resistive biofilms was confirmed.

Anti-microbiological effectiveness of self-adhesive copper surfaces was tested in two parts. The first part was laboratory testing and second part was on site, real life situation testing.

Hospital-acquired infections caused by multidrug resistant A. baumannii has become a worldwide concern, due to persistence in the hospital environment. This pathogen is difficult to treat therapeutically as it is often multidrug resistant with some isolates classed as "completely resistant" due to great ability to form biofilm. Biofilms are a structured community of bacterial cells enclosed in a self-produced polymeric matrix and adherent to an inert or living surface.

Goal:

To determine biocide effect of copper sheets against multi resistant strains of A. baumannii and to correlate laboratory results to on site antibacterial effect.

Material and methods:

49 multiresistant A. baumannii strains suspended in saline (0.5McFarland) were inoculated on Mueller Hinton plates (Oxoid). Copper sheets were placed over the strain suspension for different time periods. Plates were incubated, afterwards biocide effect was determined following the percentage of bacterial growth inhibition. On site study was done by self adhesive copper surfaces in different hospitals. Microbological contamination was evaluated and correlated to contamination of non antimicrobial surfaces.

Results:

During study, expectations of high efficacy of cooper surfaces as antibacterial agent was confirmed. More than 50% reduction was achieved under short term exposure (1h) and near total growth inhibition under couple of hours (3h) exposure to copper surfaces.

Discussion:

Hospital-acquired infections caused by multidrug resistant A. baumannii has become a worldwide concern. This pathogen is difficult to treat therapeutically as it is often multidrug resistant with some isolates classed as "completely resistant" and with their persistent survival in hospital environment due to great ability to form biofilm. Biofilms are a structured community of bacterial cells enclosed in

Nom : Simonoska Ville : Skopje
Prénom : Aneta Pays : Macedonia

E-mail : aneta.simonoska@gmail.com

a self-produced polymeric matrix and adherent to an inert or living surface. Cheap alternative supplement with antibacterial properties, like copper surface, could be of great value at disinfection procedures in hospital environments.

Conclusion:
As survival in hospital environment and biofilm formation ability are the main tools for endemic strains to cause hospital-acquired infections, then copper can be highly effective biocide to prevent spread of multi resistant bacteria and so to prevent extremely serious, with high mortality rate and the last but not the least very expensive hospital-acquired infections.

Nom : Simonoska
Prénom : Aneta
Ville : Skopje
Pays : Macedonia

E-mail : aneta.simonoska@gmail.com