Operational Manual

# PROCESSING OF MEDICAL DEVICES IN PRIMARY HEALTH CARE

## Introduction

The thorough processing of medical devices is one of the pillars of control and prevention of healthcare associated infections (HAI), regarding not only the guarantee of microbial reduction or elimination, but also the maintenance of their functionality and integrity.

With the increase of outpatient care in primary health care, it is necessary to also evaluate the medical devices processing quality in these places.

This material is an adaptation of the validated base document developed by Graziano and colleagues (2006). It as an integral component of the "Manual for Quality Assessment Practices Infection Control", available in: http:// www.cve.saude.sp.gov.br/htm/ih/IH_MANUALFAPESP06.pdf.

The adequate processing depends on physical infrastructure and technological and human resources, allowing the execution of safe actions that are based on updated scientific knowledge. To allow detailed evaluation of these processing compliance indicators were elaborated regarding the structure, working process and result evaluation for each stage of processing- cleaning (C) and preparation, packaging, sterilization, storage and distribution (PS).

The indicators are:

**Stage I – Cleaning of medical devices**

C.1- Indicator for evaluation of technical-operational resources for cleaning medical devices

C.2- Indicator for evaluation of medical devices cleaning process

C.3- Indicator for medical devices cleaning results

C.4- Indicator for evaluation of occupational accidents in medical devices cleaning

**Stage II – Preparation, packaging, disinfection/sterilization, storage and distribution of medical devices**

PS.5- Indicator for evaluation of technical-operational resources for preparation, packaging, disinfection/sterilization, storage and distribution of medical devices

PS.6- Indicator for evaluation of processes of preparation, packaging, disinfection/sterilization, storage and distribution of medical devices

PS.7- Indicator for evaluation of package sealing of medical devices

PS.8- Indicator for evaluation of disinfected medical devices conservation

PS.9- Indicator for evaluation of sterilized medical devices package conservation

## Indicators for evaluation of medical devices processing

## Indicators for evaluation of medical devices cleaning (C)

### C.1- Indicator for evaluation of technical-operational resources for cleaning medical devices

**Description**: The reception of contaminated material and the medical devices cleaning process in the Material and Sterilization Center (MSC) require adequate physical infrastructure, as well as equipment, supplies, and professional actions to ensure the effectiveness of this process and the protection of occupational health against biological hazards. The index has 22 components that intend to contemplate the necessity of skilled reception and cleaning of the items. Each of them brings, in the index, the reason for their evaluation importance.

**References:**

AORN. Association of Operating Room Nurses. **Perioperative Standards and Recommended Practices**. AORN Inc, Denver, 2012.

BRASIL. Ministério da Saúde. **RESOLUÇÃO - RDC nº 50**, de 21 de fevereiro de 2002. Regulamento técnico para planejamento, programação, elaboração e avaliação de projetos físicos de estabelecimentos assistenciais de saúde. 2002.

BRASIL. Ministério da Saúde. **RESOLUÇÃO - RDC nº 307**, de 21 de fevereiro de 2002. Altera a Resolução - RDC nº 50 de 21 de fevereiro de 2002 que dispõe sobre o Regulamento técnico para planejamento, programação, elaboração e avaliação de projetos físicos de estabelecimentos assistenciais de saúde. 2002.

BRASIL. Ministério da Saúde. **PORTARIA nº 2914,** de 12 de dezembro de 2011. Dispõe sobre os procedimentos de controle e de vigilância da qualidade da água para consumo humano e seu padrão de potabilidade. 2011.

BRASIL. ANVISA. Agência Nacional de Vigilância Sanitária. **RESOLUÇÃO - RDC nº 15**, de 15 de março de 2012. Dispõe sobre requisitos de boas práticas para o processamento de produtos para saúde e dá outras providências. 2012

BRASIL. ANVISA. Agência Nacional de Vigilância Sanitária. **RESOLUÇÃO RDC nº 55**, de 14 de novembro de 2012. Dispõe sobre os detergentes enzimáticos de uso restrito em estabelecimentos de assistência à saúde com indicação para limpeza de dispositivos médicos e dá outras providências. 2012.

GRAZIANO, K. U.; SILVA, A.; PSALTIKIDIS, E. M. (orgs) **Enfermagem em Centro de Material e Esterilização**. São Paulo: Manole, 2011.

PADOVEZE. M. C.; GRAZIANO, K. U. (coord) **Limpeza, desinfecção e esterilização de artigos em serviços de saúde**. São Paulo: APECIH – Associação Paulista de Epidemiologia e Controle de Infecção Relacionada à Assistência à Saúde, 2010.

RUTALA, W. A., WEBER, D. J. Healthcare Infection Control Practices Advisory Committee. **Guideline for Disinfection and Sterilization in Healthcare Facilities**[online]. Center for Diseases Control and Prevention.HICPAC. 2008. Available from: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed ago 09, 2011.

SÃO PAULO. **Manual de avaliação da qualidade de práticas de controle de infecção hospitalar. Secretaria de Estado de Saúde**. Divisão de Infecção Hospitalar. Centro de Vigilância Epidemiológica, 2006.

**Category of evidence:** C
**Type of evaluation:** structure
**Indicator Numerator:** accurate and applicable components of technical-operational resources for medical devices cleaning in the unit under evaluation.
**Indicator Denominator:** applicable components of technical-operational resources for medical devices cleaning in the unit under evaluation.
**Indicator Formula:**

$$\frac{Number\ of\ accurate\ and\ applicable\ components\ of\ technical-operational\ resources\ for\ medical\ devices\ cleaning}{Total\ number\ of\ applicable\ components\ of\ technical-operational\ resources\ for\ medical\ devices\ cleaning\ in\ the\ unit\ under\ evaluation} X\ 100$$

**Optimal value:** 100%
**Evaluation criteria:**
• Y (Yes): when there is correspondence, the component of the indicator under evaluation is performed;
• N (No): there is no correspondence, the component of the indicator under evaluation is not performed;
• N/A (Non-applicable): when the component under evaluation is not applicable in the unit under evaluation and, therefore, should be excluded from the calculation of the indicator.
**Information sources:** interviews with the head of the unit, records (documents, norms, etc.) and inspection. Discrimination of evaluation type of each item is available in the evaluation worksheet.
**Sample:** as it is an evaluation of the structure, there is no need for samples. If each component is evaluated once, it is enough.
**Evaluation worksheet:** next page.

PASSOS, I. P. B. D. **Adaptação e validação de indicadores de qualidade do processamento de produtos na atenção primária à saúde.** 2012. 98f. Dissertação- Universidade Federal de São Carlos, 2012. Oriented by: Profa Dra Rosely Moralez de Figueiredo- UFSCar e Profa Dra Maria Clara Padoveze- EEUSP.

**EVALUATION WORKSHEET**

**C - INDICATORS FOR EVALUATION OF MEDICAL DEVICES CLEANING**

**C.1- INDICATOR FOR EVALUATION OF TECHNICAL-OPERATIONAL RESOURCES FOR CLEANING MEDICAL DEVICES**

Health Service: .....
Period: .....
Evaluator: .....
Evaluation nº: .....

| Components | Evaluation criteria | Yes | No | Non-applicable |
|---|---|---|---|---|
| C.1.1 It has an exclusive area capable of allocating furniture and equipment for the activities related to it (I). Reason: cleaning processing requires an appropriate area according to the material demand of the unit. | I | | | |
| C.1.2 It has ventilation (I). Reason: worker safety and comfort. | I | | | |
| a) If there is natural ventilation, the windows are screened (I). Reason: avoid insects from entering. | I | | | |
| b) If the ventilation is artificial, the environment is air conditioned (I). Reason: comfort for workers who use PPE. | I | | | |
| C.1.3 It has a specific location for the storage of PPE (I). Reason: worker safety. | I | | | |
| C.1.4 It has a container for disposal of perforating-cutting devices (I). Reason: worker and environmental safety. | I | | | |
| C.1.5 It has a biological material waste container (I). Reason: worker and environmental safety. | I | | | |
| C.1.6 The area is isolated from the other facilities by physical infrastructure (I). Reason: preventing cross contamination by blocking the free movement of people providing the unidirectional flow from the contaminated area to the clean one. | I | | | |
| C.1.7 The area is isolated from the other facilities, at least by technical barriers (I). Reason: preventing cross contamination by blocking the free movement of people providing the unidirectional flow from the contaminated area to the clean one. | I | | | |

| | | | | | |
|---|---|---|---|---|---|
| C.1.8 The cleaning area is well-lighted by fluorescent lamps (I). Reason: facilitates cleaning and device integrity inspection. | I | | | | |
| C.1.9 Finishing material is sturdy, washable and intact (I). Reason: the place requires concurrent and terminal cleaning with frequent exposure to liquids. | I | | | | |
| C.1.10 The room is equipped with washable workbenches (I). Reason: the handling of contaminated/wet devices, which requires recurrent cleaning and frequent exposure to liquids. | I | | | | |
| C.1.11 The room is equipped with deep washbasins and faucets (I). Reason: resources required for device cleaning. The deep washbasin decreases sparkling water to the environment. | I | | | | |
| C.1.12 There are soft bristle brushes for manual cleaning of the devices (I). Reason: the soft brushes are essential for effective device cleaning and better than sponges. | I | | | | |
| C.1.13 The water available in the faucets is drinkable (I). Reason: meeting the requirements of the Brazilian Ministry of Health Ordinance No. 2914 and the recommendation of the Association of Perioperative Registered Nurses (AORN). | I | | | | |
| C.1.14 Thick waterproof long cuff rubber gloves are individually available as required PPE (I). Reason: control/prevention of occupational accidents by contact with contaminated or toxic organic substances. | I | | | | |
| C.1.15 Medical safety glasses are individually available as required PPE (I). Reason: control/prevention of occupational accidents by contact with contaminated or toxic organic substances. | I | | | | |
| C.1.16 Masks (or face masks) are individually available as required PPE (I). Reason: control/prevention of occupational accidents by contact with contaminated or toxic organic substances. | I | | | | |
| C.1.17 Long waterproof surgical gowns are individually available as required PPE (I). Reason: control/prevention of occupational accidents by contact with contaminated or toxic organic substances. | I | | | | |
| C.1.18 Earplugs are individually available if there is an ultrasonic cleaner, as indicated by the manufacturer (I). Reason: control/prevention of occupational diseases caused by noise. | I | | | | |

| | | | | | |
|---|---|---|---|---|---|
| C.1.19 There is a clear definition and availability of the attendance flow for the professional who is a victim of an accident with perforating-cutting instruments (R). Reason: legal requirement in accordance with the NR 32 (regulatory norm). | I | | | | |
| C.1.20 Norms and routines of the area are easily accessible (R). Reason: the documentary material is a consultation source and ensures qualified standardization of procedures. | I | | | | |
| C.1.21 Norms and routines are reviewed and updated at least annually (R). Reason: the reviewed documentary material is a consultation source and ensures technical, scientific and operational updating of the standardization of procedures. | R | | | | |
| C.1.22 Professionals who perform such procedures have these activities regulated by their professional councils (R). Reason: the Material and Sterilization Center (MSC) must rely on qualified professionals to ensure service excellence. | R | | | | |
| C.1.1 It has an exclusive area capable of allocating furniture and equipment for the activities related to it (I). Reason: cleaning processing requires appropriate area according to the material demand of the unit. | R | | | | |
| C.1.2 It has ventilation (I). Reason: worker safety and comfort.<br>a) If there is natural ventilation, the windows are screened (I). Reason: avoid insects from entering.<br>b) If the ventilation is artificial, the environment is air conditioned (I). Reason: comfort for workers who use PPE. | R | | | | |

*I – Inspetion R – Register Iv - Interview*

Comments:

**Indicator calculation:**

### C.2 - Indicator for evaluation of medical devices cleaning process

**Description:** This indicator is composed of 13 components that evaluate medical devices cleaning process. Cleaning is the main factor that reduces the bacterial load of the devices, with up to 4log removal of contaminating organisms. The cleaner is a product, the lower the chances of failures in disinfection and sterilization. The guarantee of cleaning effectiveness is directly related to the appropriate work process with the aid of equally appropriate supplies and instruments. The biological substances penetrate all over the devices, especially those that are complex-shaped. When it contains dirt, the bioburden is increased and the normal cycles of sterilization are not able to ensure a Sterility Assurance Level (SAL) of 10-6.

**References:**

AORN. Association of Operating Room Nurses. **Perioperative Standards and Recommended Practices**. AORN Inc, Denver, 2012.

GRAZIANO, K. U.; SILVA, A.; PSALTIKIDIS, E. M. (orgs) **Enfermagem em Centro de Material e Esterilização**. São Paulo: Manole, 2011.

PADOVEZE. M. C.; GRAZIANO, K. U. (coord) **Limpeza, desinfecção e esterilização de artigos em serviços de saúde**. São Paulo: APECIH – Associação Paulista de Epidemiologia e Controle de Infecção Relacionada à Assistência à Saúde, 2010.

RUTALA, W. A., WEBER, D. J. Healthcare Infection Control Practices Advisory Committee. **Guideline for Disinfection and Sterilization in Healthcare Facilities**[online]. Center for Diseases Control and Prevention.HICPAC. 2008. Available from: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed ago 09, 2011

SÃO PAULO. **Manual de avaliação da qualidade de práticas de controle de infecção hospitalar. Secretaria de Estado de Saúde**. Divisão de Infecção Hospitalar. Centro de Vigilância Epidemiológica, 2006.

**Category of evidence:** B- C.2.13 and C for the other components.

**Type of evaluation:** process

**Indicator Numerator:** accurate and applicable components of the medical devices cleaning process in the unit under evaluation.

**Indicator Denominator:** applicable components of the medical devices cleaning process in the unit under evaluation.

**Indicator Formula:**

$$\frac{Number\ of\ accurate\ and\ applicable\ components\ of\ the\ medical\ devices\ cleaning\ process}{Total\ number\ of\ applicable\ components\ of\ the\ medical\ devices\ cleaning\ process\ in\ the\ unit\ under\ evaluation} X\ 100$$

**Inclusion criteria:**

• Y (Yes): when there is correspondence, the component of the indicator under evaluation is performed;

• N (No): there is no correspondence, the component of the indicator under evaluation is not performed;
• N/A (Non-applicable): when the component under evaluation is not applicable in the MSC under evaluation and, therefore, should be excluded from the calculation of the indicator.

**Information sources:** interviews, records and inspection specified in the instrument, depending on the type of component under evaluation. Inspection should be the priority.

**Sample:** only one component of this indicator needs samples in order to be accurate and it is the evaluation of instrument cleaning, whose representation should consider a statistically significant percentage of the average volume of instrument boxes that are daily prepared. Suggestions for sampling are presented in Chapter 2.

**Evaluation worksheet:** next page.

**EVALUATION WORKSHEET**
**C - INDICATORS FOR EVALUATION OF MEDICAL DEVICES CLEANING**
**C.2- INDICATOR FOR EVALUATION OF MEDICAL DEVICES CLEANING PROCESS**

Health service: .....
Period: .....
Evaluator: .....
Evaluation nº: .....

| Components | Evaluation criteria | Yes | No | Non-applicable |
|---|---|---|---|---|
| C.2.1 The devices received in the MSC do not present coarse and dried-up dirt (no residual tissue). Reason: the processing of medical devices begins immediately after use. Ideally, coarse dirt is removed with gauze or compress bandages by the professional who performs the procedure immediately after it. | Iv, I | | | |
| C.2.2 Neutral/enzymatic/alkaline detergents or descaling soaps are used with defined criteria, according to the manufacturer's instructions, intended for hospital use and officially authorized. Reason: cleaning supplies should be adequate to the degree of dirtiness in order to optimize the action of removal. | Iv, I | | | |
| C.2.3 The switch of enzymatic detergent solution fulfills the criteria defined for saturation of the solution (when the dirtiness is not removed anymore) according to the manufacturer's recommendation. Reason: the action of enzymatic detergent depends on the amount of organic matter submerged in the solution. | Iv, I | | | |
| C.2.4 Devices that are manually processed are washed piece by piece. Reason: to ensure the dirt is completely removed. | I | | | |
| C.2.5 Thick waterproof long cuff rubber gloves are worn as obligatory PPE. Reason: control/prevention of occupational accidents by contact with contaminated or toxic organic substances. | I | | | |
| C.2.6 Medical safety glasses are worn as obligatory PPE. Reason: control/prevention of occupational accidents by contact with contaminated or toxic organic substances. | I | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| C.2.7 Masks (or face masks) are worn as obligatory PPE. Reason: control/prevention of occupational accidents by contact with contaminated or toxic organic substances. | I | | | | | |
| C.2.8 Earplugs are worn if there is an ultrasonic cleaner, as indicated by the manufacturer. Reason: control/prevention of occupational diseases caused by noise. | I | | | | | |
| C.2.9 Abrasive material, such as steel wool, is not used for manual cleaning of the devices. Reason: damages on the surface of the instrument in the medium and long term. | I | | | | | |
| C.2.10 There is at least one nurse from the Unit or from the Chain that takes part in the decision of purchasing the devices and supplies used in the area. Reason: direct users choose devices and supplies for the intended purposes with more objective and defined criteria. | Iv | | | | | |
| C.2.11 The washed devices are dried with absorbent nonwoven fabric, which is discarded after use, and/or airflow. Reason: devices that remain wet provide the growth of bacteria and fungi and interfere with the success of the sterilization process. | Iv, I | | | | | |
| C.2.12 There is a documented preventive maintenance planning for the ultrasonic cleaner. Reason: preventive maintenance ensures the operation of equipment and the continuing production of the MSC. | R | | | | | |
| C.2.13 There is a program of continuing training for professionals in the MSC. Reason: training is essential for skilled labor. | R | | | | | |

*I – Inspection R – Register Iv - Interview*

Comments:

**Indicator calculation:**

### C.3 - Indicator for medical devices cleaning results

**Description:** the evaluation of the results of cleaning by means of visual inspection carried out in the area should be satisfactory. It allows the necessary changes in order to improve practice, being important for the control of HAIs.

**References:**

AORN. Association of Operating Room Nurses. **Perioperative Standards and Recommended Practices**. AORN Inc, Denver, 2012.

GRAZIANO, K. U.; SILVA, A.; PSALTIKIDIS, E. M. (orgs) **Enfermagem em Centro de Material e Esterilização**. São Paulo: Manole, 2011.

PADOVEZE. M. C.; GRAZIANO, K. U. (coord) **Limpeza, desinfecção e esterilização de artigos em serviços de saúde**. São Paulo: APECIH – Associação Paulista de Epidemiologia e Controle de Infecção Relacionada à Assistência à Saúde, 2010.

RUTALA, W. A., WEBER, D. J. Healthcare Infection Control Practices Advisory Committee. **Guideline for Disinfection and Sterilization in Healthcare Facilities**[online]. Center for Diseases Control and Prevention.HICPAC. 2008. Available from: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf. Acessed ago 09, 2011.

SÃO PAULO. **Manual de avaliação da qualidade de práticas de controle de infecção hospitalar. Secretaria de Estado de Saúde**. Divisão de Infecção Hospitalar. Centro de Vigilância Epidemiológica, 2006.

**Category of evidence:** C

**Type of evaluation:** result

**Indicator Numerator:** medical devices found dirty after cleaning in the unit under evaluation.

**Indicator Denominator:** medical devices evaluated after cleaning in the unit under evaluation.

**Indicator Formula:**

$$\frac{Number\ of\ medical\ devices\ found\ dirty\ after\ cleaning}{Total\ number\ of\ medical\ devices\ evaluated}\ X\ 100$$

**Optimal value:** 0%

**Information sources:** devices that are difficult to clean, after undergoing the cleaning process.

**Evaluation criteria:** Visual inspection test with magnifiers for the detection of any kind of dirt in the devices. In cannulated devices, conduct testing with water jets and check if there is dirt or water with blood residue being expelled.

**Sample:** consider a statistically significant percentage of the average volume of devices that are difficult to clean and daily processed. General indices can be calculated monthly or in longer periods. Other strategies can be defined by the evaluators, but it is essential to maintain the same strategy in successive applications of the same indicator, so that the results are comparable.

**Evaluation worksheet:** next page.

## EVALUATION WORKSHEET
## C - INDICATORS FOR EVALUATION OF MEDICAL DEVICES CLEANING
## C.3- INDICATOR FOR MEDICAL DEVICES CLEANING RESULTS

Health service: .....
Period: .....
Evaluator: .....
Evaluation nº: .....
Inspected devices sample: .....
List of inspected devices: .....

Comments:

**Indicator calculation:**

## C.4 - Indicator for evaluation of occupational accidents in medical devices cleaning

**Description:** The area is a place with potential risk of acquiring infectious diseases that are transmitted by blood or bodily fluids, not only because of the presence of large load of contaminated organic matter, but also because of the handling of perforating-cutting medical devices. The use of the Personal Protective Equipment and the incorporation of the principles of standard precautions are preventive measures.

**References:**

AORN. Association of Operating Room Nurses. **Perioperative Standards and Recommended Practices**. AORN Inc, Denver, 2012.

GRAZIANO, K. U.; SILVA, A.; PSALTIKIDIS, E. M. (orgs) **Enfermagem em Centro de Material e Esterilização**. São Paulo: Manole, 2011.

PADOVEZE. M. C.; GRAZIANO, K. U. (coord) **Limpeza, desinfecção e esterilização de artigos em serviços de saúde**. São Paulo: APECIH – Associação Paulista de Epidemiologia e Controle de Infecção Relacionada à Assistência à Saúde, 2010.

RUTALA, W. A., WEBER, D. J. Healthcare Infection Control Practices Advisory Committee. **Guideline for Disinfection and Sterilization in Healthcare Facilities**[online]. Center for Diseases Control and Prevention.HICPAC. 2008. Available from: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed ago 09, 2011.

SÃO PAULO. **Manual de avaliação da qualidade de práticas de controle de infecção hospitalar. Secretaria de Estado de Saúde**. Divisão de Infecção Hospitalar. Centro de Vigilância Epidemiológica, 2006.

**Category of evidence:** C

**Type of evaluation:** result

**Indicator Numerator:** occupational accidents with perforating-cutting devices reported and/or recorded while performing medical devices cleaning in the unit under evaluation throughout the previous year.

**Indicator Denominator:** professionals who worked in the area throughout the previous year.

**Indicator Formula:**

$$\frac{\begin{array}{c}Number\ of\ occupational\ accidents\ with\ perforating-cutting\ devices\\ reported\ and/or\ recorded\\ in\ the\ area\ throughout\ the\ previous\ year\end{array}}{Total\ number\ of\ professionals\ who\ worked\ in\ the\ area}\ X\ 100$$

Note: both sources of information (reports and records) may be a single indicator or two comparable indicators.

**Optimal value:** 0%

**Information sources:** interviews and registers.

**Evaluation criteria:**

a) Reports, elaborated by the professionals themselves, about accidents suffered, formally notified or not. The calculation of the numerator must be made by the number of reported accidents and not by the number of employees who reported accidents.
b) Formal records of the institution.
**Sample:** all registers and/or all reports by steady or substitute employees who worked in the area throughout the previous year
**Evaluation worksheet:** next page.

## EVALUATION WORKSHEET
## C - INDICATORS FOR EVALUATION OF MEDICAL DEVICES CLEANING
## C.4- INDICATOR FOR EVALUATION OF OCCUPATIONAL ACCIDENTS IN MEDICAL DEVICES CLEANING

Health service: .....
Period: .....
Evaluator: .....
Evaluation nº: .....
Number of employees who worked in the area throughout the previous year: .....

Comments:

**Indicator calculation:**

a) Reports by employees

b) Registers

## Indicators of preparation, packaging, disinfection/sterilization, storage and distribution of medical devices (PS)

### PS.5 - Indicator for evaluation of technical-operational resources for preparation, packaging, disinfection/sterilization, storage and distribution of medical devices

**Description:** The critical and semi-critical devices need to be properly prepared and packaged to enable transport and storage without the risk of recontamination. The penetration of the sterilizing agent must also be guaranteed. Therefore, adequate physical infrastructure, equipment and supplies that ensure this process are required. This processing step should be performed next to sluice and sterilization rooms. As for sterilizing, critical devices that come in contact with sterile tissue must have a sterility assurance level of $10^{-6}$. The disinfecting semi-critical items must achieve the elimination of all microorganisms in the vegetative form and some spores. The choice of the appropriate method according to the nature of each material to be process sterilized is critical to the safety of patients who need to use sterile e disinfected products relying on physical infrastructure and adequate human resources.

**References:**

AORN. Association of Operating Room Nurses. **Perioperative Standards and Recommended Practices**. AORN Inc, Denver, 2012.

BRASIL. Ministério da Saúde. **RESOLUÇÃO - RDC nº 50**, de 21 de fevereiro de 2002. Regulamento técnico para planejamento, programação, elaboração e avaliação de projetos físicos de estabelecimentos assistenciais de saúde. 2002.

BRASIL. Ministério da Saúde. **RESOLUÇÃO - RDC nº 307**, de 21 de fevereiro de 2002. Altera a Resolução - RDC nº 50 de 21 de fevereiro de 2002 que dispõe sobre o Regulamento técnico para planejamento, programação, elaboração e avaliação de projetos físicos de estabelecimentos assistenciais de saúde. 2002.

BRASIL. Ministério da Saúde. **RESOLUÇÃO - RDC nº 35**, de 16 de agosto de 2010. Dispõe sobre o Regulamento Técnico para produtos com ação antimicrobiana utilizados em artigos críticos e semicríticos. 2010.

GRAZIANO, K. U.; SILVA, A.; PSALTIKIDIS, E. M. (orgs) **Enfermagem em Centro de Material e Esterilização**. São Paulo: Manole, 2011.

PADOVEZE. M. C.; GRAZIANO, K. U. (coord) **Limpeza, desinfecção e esterilização de artigos em serviços de saúde**. São Paulo: APECIH – Associação Paulista de Epidemiologia e Controle de Infecção Relacionada à Assistência à Saúde, 2010.

RUTALA, W. A., WEBER, D. J. Healthcare Infection Control Practices Advisory Committee. **Guideline for Disinfection and Sterilization in Healthcare Facilities**[online]. Center for Diseases Control and Prevention.HICPAC. 2008. Available from:

http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed ago 09, 2011.

SÃO PAULO. **Manual de avaliação da qualidade de práticas de controle de infecção hospitalar. Secretaria de Estado de Saúde**. Divisão de Infecção Hospitalar. Centro de Vigilância Epidemiológica, 2006.

**Category of evidence:** B- PS.5.4, PS.5.8, PS.5.9, PS.5.10, PS.5.11, PS.5.16, and C for the other components.
**Type of evaluation:** structure
**Indicator Numerator:** accurate and applicable components of technical-operational resources for preparation, packaging, sterilization, storage and distribution of medical devices in the unit under evaluation.
**Indicator Denominator:** applicable components of technical-operational resources for preparation, packaging, sterilization, storage and distribution of medical devices in the unit under evaluation.
**Indicator Formula:**

$$\frac{Number\ of\ accurate\ and\ applicable\ components\ of\ technical-operational\ resources\ for\ preparation/\ packaging/\ sterilization/\ storage\ and\ distribution\ of\ medical\ devices}{Total\ number\ of\ applicable\ components\ of\ technical-operational\ resources\ for\ preparation/\ packaging/\ sterilization/\ storage\ and\ distribution\ of\ medical\ devices\ in\ the\ unit\ under\ evaluation}\ X\ 100$$

**Optimal value:** 100%
**Information sources:** registers, interviews and inspection, specified in the evaluation instrument in accordance with the type of component.
**Evaluation criteria:**
• Y (Yes): when there is correspondence, the component of the indicator under evaluation is performed;
• N (No): there is no correspondence; the component of the indicator under evaluation is not performed;
• N/A (Non-applicable): when the component under evaluation is not applicable in the MSC under evaluation and, therefore, should be excluded from the calculation of the indicator.
**Sample:** as it is an evaluation of the structure, there is no need for samples. If each unit of analysis is evaluated once, it is enough.
**Evaluation worksheet:** next page

**EVALUATION WORKSHEET**
**PS - INDICATORS OF PREPARATION, PACKAGING, DISINFECTION/STERILIZATION, STORAGE AND DISTRIBUTION OF MEDICAL DEVICES**
**PS.5 - INDICATOR FOR EVALUATION OF TECHNICAL-OPERATIONAL RESOURCES FOR PREPARATION, PACKAGING, DISINFECTION/STERILIZATION, STORAGE AND DISTRIBUTION OF MEDICAL DEVICES**

Health service: .....
Period: .....
Evaluator: .....
Evaluation nº: .....

| Components | Evaluation criteria | Yes | No | Non-applicable |
|---|---|---|---|---|
| PS.5.1 There is an exclusive area in the MSC for the preparation, packaging and sterilization of supplies. Reason: preparation, packaging and sterilization require an appropriate area according to the demand for supplies and number of procedures | I | | | |
| PS.5.2 Minimum area for allocating furniture and equipment for the activities related to it. Reason: an area with the appropriate size optimizes the time and the movement of employees performing this task. | I | | | |
| PS.5.3 It has ventilation. Reason: worker safety and comfort. | I | | | |
| a) If there is natural ventilation, the windows are screened. Reason: avoid insects from entering. | I | | | |
| b) If the ventilation is artificial, the environment is air conditioned. Reason: comfort for workers who use PPE. Fresh air in the environment is essential for occupational health. | I | | | |
| PS.5.4 The area is provided with undamaged workbenches made of easy-to-clean material (stainless steel, melamine laminate, granite). Reason: the surface used for preparation and packaging of the supplies must be rigorously cleaned after every manipulation. | I | | | |
| PS.5.5 The preparation and packaging area is well-lighted by fluorescent lamps. Reason: facilitates cleaning and device integrity inspection. | I | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| PS.5.6 The preparation and packaging workbench has image intensifier lens (magnifiers used in aesthetic medicine and microsurgeries, for instance) of at least 8X. Reason: lenses allow better visualization of cleaning effectiveness and device integrity. | I | | | | | |
| PS.5.7 There are forced drying devices and final checking of the cleaning of cannulated and complex-shaped devices. Reason: Compressed air may reveal previously unidentified residual dirt in cannulated and complex-shaped devices. | I | | | | | |
| PS.5.8 No accumulation of coarse dust, trash, and presence of rodents or insects. Reason: contamination risk. | I, R | | | | | |
| PS.5.9 The area is cleaned daily and whenever necessary. Reason: contamination risk. | Iv | | | | | |
| PS.5.10 Sterilized supplies are stored in an exclusive site, away from water sources, open windows and exposed pipes. Reason: the site should provide conditions to prevent dust accumulation and moisture penetration and avoid insects and rodents from entering in the storage areas. | I | | | | | |
| PS.5.11 There are records of package sealing equipment maintenance. Reason: guaranteed quality of sealing, which interferes with the maintenance of sterility during transport and storage. | R | | | | | |
| PS.5.12 Solutions approved by the competent bodies are provided for chemical disinfection compatible with the supplies to be processed. Reason: all germicides used must be approved and registered by ANVISA (Brazilian Health Surveillance Agency). | I | | | | | |
| PS.5.13 The sterilization room is provided with at least a pre-vacuum steam autoclave and stoves are not used. Reason: every heat-resistant article must be autoclaved. The pre-vacuum autoclave ensures the removal of residual air from the chamber and the packages. | I | | | | | |
| PS.5.14 The steam autoclave is validated. Reason: to ensure the monitoring of the process and that all parameters were met, so that the process will produce supplies that meet predetermined specifications. | R | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| PS.5.15 There are corroborative reports that demonstrate the effectiveness of the water treatment system that serves the steam autoclaves, meeting the manufacturer's specifications. If water is purchased, the reports are available upon requests. Reason: packages and surgical instruments are negatively affected by deposition and reaction with chemical contaminants, causing stains and rust and making the material more porous. | R | | | | |
| PS.5.16 There is a documented preventive maintenance planning of equipment used for sterilization. Reason: preventive maintenance ensures the operation of equipment and the continuing production of the MSC. | R | | | | |
| PS.5.17 Norms and routines of the area are easily accessible. Reason: the documentary material is a consultation source and ensures qualified standardization of procedures. | R | | | | |
| PS.5.18 Norms and routines are reviewed and updated at least annually. Reason: the reviewed documentary material is a consultation source and ensures technical, scientific and operational updating of the standardization of procedures. | R | | | | |
| PS.5.19 There are resources for hand hygiene: sinks with liquid soap and absorbent paper towel that do not release particles and do not stick to hands and easy access to alcohol hand gel. Reason: the supplies must be handled with clean hands so that they are not recontaminated. | I | | | | |
| PS.5.20 Professionals who perform such procedures have these activities regulated by their professional councils. Reason: the MSC must rely on qualified professionals to ensure service excellence. | R | | | | |
| PS.5.21 There is a clearly described evaluation plan for the package integrity of the processed article. Reason: adverse events may affect the sterility of the processed article. | Iv, I, R | | | | |

*I – Inspection R – Register Iv - Interview*

Comments:

**Indicator calculation:**

## PS.6 - Indicator for evaluation of processes of preparation, packaging, disinfection/sterilization, storage and distribution of medical devices

**Description:** preparation, packaging, sterilization and storage of critical medical devices in the unit require equipment, supplies and actions to ensure the effectiveness of this process. The controversial question of sterility expiry date of those devices is directly linked to the quality of the packages used, conditions of storage and minimal handling. There are several factors that affect the guarantee of device sterility. All sterilizers must be validated before use and annually after that. The load of devices to be processed by the machine also needs validation. All cycles should be monitored by mechanical, chemical and biological monitors. Preventive maintenance of equipment should be performed. Human failures can affect the security of the process. In this sense, routines should be developed to standardize the sterilization process and continuing training should keep the professionals updated.

**References:**

AORN. Association of Operating Room Nurses. **Perioperative Standards and Recommended Practices**. AORN Inc, Denver, 2012.

Associação Brasileira de Normas Técnicas (ABNT). **NBR 14028: Roupa hospitalar** – confecção de campos duplos. Rio de Janeiro; 1997.

BRASIL. Ministério da Saúde. **RESOLUÇÃO - RDC nº 50**, de 21 de fevereiro de 2002. Regulamento técnico para planejamento, programação, elaboração e avaliação de projetos físicos de estabelecimentos assistenciais de saúde. 2002.

BRASIL. Ministério da Saúde. **RESOLUÇÃO - RDC nº 307**, de 21 de fevereiro de 2002. Altera a Resolução - RDC nº 50 de 21 de fevereiro de 2002 que dispõe sobre o Regulamento técnico para planejamento, programação, elaboração e avaliação de projetos físicos de estabelecimentos assistenciais de saúde. 2002.

GRAZIANO, K. U.; SILVA, A.; PSALTIKIDIS, E. M. (orgs) **Enfermagem em Centro de Material e Esterilização**. São Paulo: Manole, 2011.

Internacional Organization for Standardization- ISO. **ISO 11140-1- Sterilization of health care products —Chemical indicators**. Genebra, 2005.

PADOVEZE. M. C.; GRAZIANO, K. U. (coord) **Limpeza, desinfecção e esterilização de artigos em serviços de saúde**. São Paulo: APECIH – Associação Paulista de Epidemiologia e Controle de Infecção Relacionada à Assistência à Saúde, 2010.

Rodrigues E. **Avaliação do uso e reuso de tecido de algodão como embalagem de artigos médico-hospitalares na esterilização por calor úmido**. São Paulo; 2000. [Tese de Doutorado] – Escola de Enfermagem da Universidade de São Paulo.

RUTALA, W. A., WEBER, D. J. Healthcare Infection Control Practices Advisory Committee. **Guideline for Disinfection and Sterilization in Healthcare Facilities**[online]. Center for Diseases Control and Prevention. HICPAC. 2008.

Available from: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed ago 09, 2011.

SÃO PAULO. **Manual de avaliação da qualidade de práticas de controle de infecção hospitalar. Secretaria de Estado de Saúde**. Divisão de Infecção Hospitalar. Centro de Vigilância Epidemiológica, 2006.

**Category of evidence:** A- PS.6.13; B- PS.6.1, PS.6.6, PS.6.11, PS.6.14 to PS.6.16, PS.6.18 to PS.6.21, PS.6.23 to PS.6.33; and C for the other components.
**Type of evaluation:** process
**Indicator Numerator:** accurate and applicable components of the process of preparation, packaging, sterilization, storage and distribution of medical devices in the unit under evaluation.
**Indicator Denominator:** applicable components of the process of preparation, packaging, sterilization, storage and distribution of devices in the unit under evaluation.
**Indicator Formula:**

$$\frac{Number\ of\ accurate\ and\ applicable\ components\ of\ the\ process\ of\ preparation/\ packaging/\ sterilization/storage\ and\ distribution\ of\ medical\ devices}{Total\ number\ of\ applicable\ components\ of\ the\ process\ of\ preparation/\ packaging/\ sterilization/\ storage\ and\ distribution\ of\ medical\ devices\ in\ the\ unit\ under\ evaluation} X\ 100$$

**Optimal value:** 100%
**Information sources:** registers, interviews and inspection, specified in the evaluation instrument in accordance with the type of component.
**Evaluation criteria:**
• Y (Yes): when there is correspondence, the component of the indicator under evaluation is performed;
• N (No): there is no correspondence, the component of the indicator under evaluation is not performed;
• N/A (Non-applicable): when the component under evaluation is not applicable in the MSC under evaluation and, therefore, should be excluded from the calculation of the indicator.
**Sample:** although in some components the evaluation aims to inspect or observe more than one unit of the production process, defining a representative sample of the total volume is not practicable or necessary. The evaluation of a certain period allows the implication of the occurrence of the same mode of production of the component under evaluation. Only one unit of analysis of this indicator (PS.6.27- hand hygiene before unloading the autoclave) requires more than one evaluation for compliance. Consider a sample that represents the average daily performance of this process and evaluate it at all periods, because an employee may not behave in the same way the other does.
NOTE: Use “Yes” when at least 80% of these procedures are correct.
**Evaluation worksheet**: next page

**EVALUATION WORKSHEET**
**PS - INDICATORS OF PREPARATION, PACKAGING, DISINFECTION/STERILIZATION, STORAGE AND DISTRIBUTION OF MEDICAL DEVICES**
**PS.6 - INDICATOR FOR EVALUATION OF PROCESSES OF PREPARATION, PACKAGING, DISINFECTION/STERILIZATION, STORAGE AND DISTRIBUTION OF MEDICAL DEVICES**

Health service: .....
Period: .....
Evaluator: .....
Evaluation nº: .....

| Components | Evaluation criteria | Yes | No | Non-applicable |
|---|---|---|---|---|
| PS.6.1 In these areas, stringent inspections of the cleaning are made under a fluorescent lamp and magnifying lens, checking the conditions of supply conservation and finding points of rust and stains, as well as the operation of rack and pinion of instruments, packaging and identification of packages, boxes and trays. Reason: evaluation of cleaning, functionality and integrity is needed to ensure the safe use of the article. | I | | | |
| PS.6.2 For chemical disinfection, solutions are prepared according to manufacturer's instructions. Reason: legal requirement (BRASIL, 2010). | I | | | |
| PS.6.3 During chemical disinfection, chemical tests are frequently performed and recorded according to specific norms of the Unit or manufacturer's recommendations. Reason: to prove the efficiency of disinfection processes. | R | | | |
| PS.6.4 There are plastic containers with lids for immersing the material, considering that, in case of hypochlorite use, the plastic is not transparent. Reason: hypochlorite undergoes inactivation by ultraviolet radiation. | I | | | |
| PS.6.5 The containers are washed with soap and water whenever the solution is changed. Reason: to prevent biofilm formation. | Iv, I | | | |
| PS.6.6 The products are dried before being immersed in a disinfecting solution. Reason: residual water would hyper-dilute the solution, which could affect the process. | I | | | |

PASSOS, I. P. B. D. **Adaptação e validação de indicadores de qualidade do processamento de produtos na atenção primária à saúde.** 2012. 98f. Dissertação- Universidade Federal de São Carlos, 2012. Oriented by: Profa Dra Rosely Moralez de Figueiredo- UFSCar e Profa Dra Maria Clara Padoveze- EEUSP.

| | | | | | |
|---|---|---|---|---|---|
| PS.6.7 Supplies are completely immersed in the disinfectant solution and the whole inner surface is filled by it. Reason: filling structures prevents the formation of air bubbles which may isolate the contact of the surface of the supplies with the chemical disinfectant | I | | | | |
| PS.6.8 After immersion, the supplies are thoroughly rinsed with drinkable water. Reason: remove residues of the disinfectant agent, which can harm the user and the article itself. | I | | | | |
| PS.6.9 The disinfected article is thoroughly dried before being packed in clean and individual packages. Reason: material with residual moisture encourages the growth of fungi and bacteria. | I | | | | |
| PS.6.10 There are records of the disinfection processes (disinfectants and lot used, product type, immersion time, monitoring test performed (when indicated) and the professional who carried out the procedures), which are archived for 5 years. Reason: process traceability. | R | | | | |
| PS.6.11 For products processed in moist heat, packaging paper/film, nonwoven fabric, crepe or cotton are used as packages. Reason: these packages provide microbial barriers. | Iv, I | | | | |
| PS.6.12 Cloth packages are made of T1 or T2 twilled cotton for steam. Reason: NBR14028/1997. The cotton fabric can only be used for pressurized steam. | Iv | | | | |
| PS.6.13 If cotton is used, the number of times it is reused is registered. Reason: the number of reprocessing (washing and autoclaving) must be controlled, not exceeding 65 times. | R | | | | |
| PS.6.14 Packages to be autoclaved do not exceed the dimension of 55 X 33 X 22 cm and do not weight more than 11 kg. Reason: guarantee of sterilization and drying of the packages. | I | | | | |
| PS.6.15 Every article to be sterilized is monitored with autoclave indicator tape (class I). Reason: this indicator is a useful marker to distinguish between processed and unprocessed articles. | I | | | | |
| PS.6.16 A nurse from the Unit or from the Chain takes part in the decision of purchasing the devices and supplies used in the preparation, packaging and sterilization room. Reason: direct users choose devices and supplies for the intended purposes with more objective and defined criteria. | Iv | | | | |

| | | | | | |
|---|---|---|---|---|---|
| PS.6.17 It uses only packages that are registered in the competent bodies. Reason: the packages are controlled by the Ministry of Health through ANVISA (Brazilian Health Surveillance Agency). | I | | | | |
| PS.6.18 There is a well-defined routine for rational use of chemical integrators or emulators/simulators (5th or 6th generation). Reason: the use of these indicators allows early detection of failures in the process of sterilization of supplies by the multidisciplinary team, avoiding the unintended use of items that were not processed properly. | R | | | | |
| PS.6.19 There are records of sterilization processes (readable supplies identification, lot number, date of sterilization and professional who performed the procedures), which are archived for five years. Reason: process traceability. | R | | | | |
| PS.6.20 In pre-vacuum autoclaves, the Bowie & Dick test is conducted before the first cycle of the day. Reason: guaranteeing the power of the vacuum pump and sealing system, and consequently, the absence of air bubbles in the cycles. | R | | | | |
| PS.6.21 Temperature, pressure and duration parameters of all autoclave cycles are manually registered or microprocessed and archived for five years. Reason: the manual or microprocessed controls must be analyzed after each cycle to ensure the achievement of pre-established parameters. | R | | | | |
| PS.6.22 It uses only autoclaves registered by ANVISA (Brazilian Health Surveillance Agency). Reason: product reliability. | R | | | | |
| PS.6.23 Items to be sterilized are not stacked, but arranged vertically in the autoclave, being 25 to 50 mm apart. Reason: using wire baskets avoids excessive loading of the autoclave and the risk of the packages touching the walls of the inner chamber, as well as the unnecessary handling of hot material after sterilization. The vertical arrangement of the supplies ensures the free circulation of steam. | I | | | | |
| PS.6.24 Concave-convex articles are arranged in the autoclave baskets in vertical or inclined position, while articles such as jars, buckets and flasks should be placed upside down. The larger packages must occupy the lower position. Reason: the recommended arrangement guarantees the drying of the articles. The larger packages under the smallest ones ensure the circulation of steam through the material. | I | | | | |

| | | | | | |
|---|---|---|---|---|---|
| PS.6.25 Packages are dry when they leave the autoclave. Reason: moisture can damage the packaging, affecting its biobarrier property. | I | | | | |
| PS.6.26 Packages that are sterilized without the use of wire baskets need to cool before being transferred to the storage area. Reason: steam condensation because of temperature variation moistens the package and affects the bacterial barrier. | I | | | | |
| PS.6.27 The professional sanitizes hands before unloading the autoclave. Reason: to avoid supply contamination. | I | | | | |
| PS.6.28 In the supply storage area, packages with older dates are placed in front of the others. Reason: it reduces the possibility of sterilized packages staying on shelves for a long time. | I | | | | |
| PS.6.29 The autoclave sterilization control is performed weekly or daily by biological indicators. Reason: consensually, biological control is still essential as proof of sterilization. | R | | | | |
| PS.6.30 The autoclave sterilization control is performed three consecutive times by biological indicators after corrective maintenance and in situations of suspected malfunctioning of the autoclave. Reason: the result of a biological indicator will ensure the effectiveness of the performed maintenance and guarantee the sterilizer cycles reached the parameters for sterilization of products. | Iv, I, R | | | | |
| PS.6.31 The results of biological indicators are archived for five years. Reason: documentary evidence in cases of outbreak investigation or inquiry. | Iv, R | | | | |
| PS.6.32 There is a written report about material gathering (recall) in cases of unsatisfactory results of physical, chemical or biological controls. Reason: decrease infection risk by using doubtful material regarding sterilization. | R | | | | |
| PS.6.33 Class 5 or 6 chemical indicator is placed in the higher density packages. Reason: these indicators are designed to react to all critical parameters of the sterilization cycle and allow demonstrating the effectiveness of the process in packages that present a bigger challenge regarding sterilization. | Iv, I | | | | |
| PS.6.34 The product is distributed or stored only after process indicator inspection. Reason: ensures greater control of sterilization guarantee. | Iv, I, R | | | | |

| | | | | |
|---|---|---|---|---|
| PS.6.35 Professionals that work in the preparation and packaging of critical and semi-critical products area, wear caps. Reason: wearing a cap prevents hair from falling on the articles. | I | | | |
| PS.6.36 The integrity of packages of processed products is evaluated. Reason: event-related sterility. | Iv, R | | | |

*I – Inspection R – Register Iv - Interview*

Comments:

**Indicator calculation:**

### PS.7 - Indicator for evaluation of package sealing of medical devices

**Description:** In this indicator, failures related to the package sealing are sought. The sealing within recommended standards ensures the devices will remain airtight during storage time. This detail is also essential to determine the expiry date of devices sterility.

**References:**

AORN. Association of Operating Room Nurses. **Perioperative Standards and Recommended Practices**. AORN Inc, Denver, 2012.

SÃO PAULO. **Manual de avaliação da qualidade de práticas de controle de infecção hospitalar. Secretaria de Estado de Saúde**. Divisão de Infecção Hospitalar. Centro de Vigilância Epidemiológica, 2006.

**Category of evidence:** C

**Type of evaluation:** result.

**Indicator Numerator:** medical devices packages with inadequate sealing in the unit under evaluation.

**Indicator Denominator:** medical devices packages inspected in the unit under evaluation.

**Indicator Formula:**

$$\frac{Number\ of\ medical\ devices\ packages\ with\ inadequate\ sealing}{Total\ number\ of\ medical\ devices\ packages\ inspected}\ X\ 100$$

**Optimal value:** 0%

**Information sources:** sealed surgical paper/film packages and Tyvek®

**Evaluation criteria:** inspection of sealed surgical paper/film packages and Tyvek® after the sterilization process (it also allows the assessment of their condition after this process). Take into consideration that the thickness of the seal is at least 20mm and 3 cm distant from the edge.

NOTE: evaluate only the sterile packages on the same day of the assessment, due to the possibility of other factors involved in sealing: storage mode, transport conditions and handling, etc.

**Sample:** consider a representative sample of the average daily volume of sealing and sterilization of these packages in the unit under evaluation. General indices can be calculated monthly or in longer periods. Other strategies can be defined by the evaluators, but it is essential to maintain the same strategy in successive applications of the same indicator, so that the results are comparable.

**Evaluation worksheet:** next page.

## EVALUATION WORKSHEET
## PS - INDICATORS OF PREPARATION, PACKAGING, DISINFECTION/STERILIZATION, STORAGE AND DISTRIBUTION OF MEDICAL DEVICES
## PS.7- INDICATOR FOR EVALUATION OF PACKAGE SEALING OF MEDICAL DEVICES

Health service: .....
Period: .....
Evaluator: .....
Evaluation nº: .....
Number of packages: .....

Comments:

**Indicator calculation:**

**PS.8 - Indicator for evaluation of disinfected medical devices conservation**
**Description:** Disinfection may be affected if the package is damaged during its storage. The disinfected devices should be stored in individual plastic bags.
**References:**

AORN. Association of Operating Room Nurses. **Perioperative Standards and Recommended Practices**. AORN Inc, Denver, 2012.

GRAZIANO, K. U.; SILVA, A.; PSALTIKIDIS, E. M. (orgs) **Enfermagem em Centro de Material e Esterilização**. São Paulo: Manole, 2011.

PADOVEZE. M. C.; GRAZIANO, K. U. (coord) **Limpeza, desinfecção e esterilização de artigos em serviços de saúde**. São Paulo: APECIH – Associação Paulista de Epidemiologia e Controle de Infecção Relacionada à Assistência à Saúde, 2010.

RUTALA, W. A., WEBER, D. J. Healthcare Infection Control Practices Advisory Committee. **Guideline for Disinfection and Sterilization in Healthcare Facilities**[online]. Center for Diseases Control and Prevention.HICPAC. 2008. Available from: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed ago 09, 2011.

SÃO PAULO. **Manual de avaliação da qualidade de práticas de controle de infecção hospitalar. Secretaria de Estado de Saúde**. Divisão de Infecção Hospitalar. Centro de Vigilância Epidemiológica, 2006.

**Category of evidence:** C
**Type of evaluation:** result.
**Indicator Numerator:** packages of disinfected devices which were inspected and showed conservation problems in the unit under evaluation.
**Indicator Denominator:** packages of disinfected devices which were inspected in the unit under evaluation.
**Indicator Formula:**

$$\frac{Number\ of\ packages\ of\ disinfected\ devices\ with\ conservation\ problems}{Total\ number\ of\ medical\ devices\ packages\ inspected}\ X\ 100$$

**Optimal value:** 0%
**Evaluation criteria:** the devices present conservation problems when their packs are stained, crumpled, dirty or there is a suspicion of breaches or opening.
**Information sources:** all kinds of packages present in the MSC under evaluation that are stored in the storage and distribution area and with older expiry dates.
**Sample:** randomly select a representative sample of the volume of packages at the time of this evaluation.
**Evaluation worksheet:** next page.

## EVALUATION WORKSHEET
## PS - INDICATORS OF PREPARATION, PACKAGING, DISINFECTION/STERILIZATION, STORAGE AND DISTRIBUTION OF MEDICAL DEVICES
## PS.8- INDICATOR FOR EVALUATION OF DISINFECTED MEDICAL DEVICES CONSERVATION

Health service: .....
Period: .....
Evaluator: .....
Evaluation nº: .....
Sample of evaluated packages: .....

Comments:

**Indicator calculation:**

## PS.9 - Indicator for evaluation of sterilized medical devices package conservation

**Description:** The sterility expiry date may be affected if the package is "assaulted" during storage. It is a new paradigm in the sterilization area where the time factor is not the most important variable when discussing the devices sterility expiry date. The quality of the package, the propriety of sealing and minimizing the material handling to not compromise the integrity of the package favoring the maintenance of barrier properties and are the foundation of the validity of sterility undefined. The quality of packaging and sealing associated with little device handling to avoid affecting the integrity of the package are the basis of the undefined sterility expiry date.

**References:**

AORN. Association of Operating Room Nurses. **Perioperative Standards and Recommended Practices**. AORN Inc, Denver, 2012.

GRAZIANO, K. U.; SILVA, A.; PSALTIKIDIS, E. M. (orgs) **Enfermagem em Centro de Material e Esterilização**. São Paulo: Manole, 2011.

PADOVEZE. M. C.; GRAZIANO, K. U. (coord) **Limpeza, desinfecção e esterilização de artigos em serviços de saúde**. São Paulo: APECIH – Associação Paulista de Epidemiologia e Controle de Infecção Relacionada à Assistência à Saúde, 2010.

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**Category of evidence:** C
**Type of evaluation:** result.
**Indicator Numerator:** packages of sterilized devices which were inspected and showed conservation problems in the unit under evaluation.
**Indicator Denominator:** packages of sterilized devices which were inspected in the unit under evaluation.
**Indicator Formula:**

$$\frac{Number\ of\ packages\ of\ sterilized\ devices\ with\ conservation\ problems}{Total\ number\ of\ medical\ devices\ packages\ inspected}\ X\ 100$$

**Optimal value:** 0%
**Evaluation criteria:** the devices present conservation problems when their packs are stained, crumpled, dirty or there is a suspicion of breaches or opening.

**Information sources:** all kinds of packages present in the MSC under evaluation that are stored in the storage and distribution area and with older expiry dates.
**Sample:** randomly select a representative sample of the volume of packages at the time of this evaluation.
**Evaluation worksheet:** next page.

## EVALUATION WORKSHEET
## PS - INDICATORS OF PREPARATION, PACKAGING, DISINFECTION/STERILIZATION, STORAGE AND DISTRIBUTION OF MEDICAL DEVICES
## PS.9- INDICATOR FOR EVALUATION OF STERILIZED MEDICAL DEVICES CONSERVATION

Health service: .....
Period: .....
Evaluator: .....
Evaluation nº: .....
Sample of evaluated packages: .....

Comments:

**Indicator calculation:**