ON NE PEUT PAS LE STÉRILISER ? QUE VOULEZ-VOUS DIRE ?
Système de gestion des dispositifs médicaux à usage multiple

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Cet article s'inspire d'une présentation donnée lors de la conférence nationale de l'AIISOC de 2009 à St. John's, Terre-Neuve-et-Labrador.

RÉSUMÉ :

Santé Canada recommande aux hôpitaux d'établir des mesures afin de veiller à ce que les dispositifs médicaux à usage multiple (DMUM) soient nettoyés, désinfectés et aseptisés conformément aux directives du fabricant. Pour les besoins de cet article, les dispositifs médicaux à usage multiple seront désignés par le terme DMUM et incluront toute l'instrumentation et les dispositifs que le département de traitement central (DTC) aseptise afin d'être réutilisés à l'hôpital.

La sécurité des patients en chirurgie repose sur le DTC. Les directives des fabricants quant à la décontamination et l'aseptisation des instruments chirurgicaux sont de la plus haute importance pour le personnel de salle d'opération et du DTC. En raison de directives nébuleuses, trop générales ou irréalisables, le besoin de définir ce que ces directives signifient dans un cadre institutionnel était primordial pour se conformer aux normes et offrir des soins sécuritaires aux patients tout en continuant à soutenir les progrès de la technologie chirurgicale.

Le but de cet article est de décrire les défis auxquels font face une organisation à sites multiples (The University Health Network) quant à la gestion de l'aseptisation des instruments chirurgicaux. L'élaboration des directives du système de gestion par le comité interprofessionnel du réseau, soit le comité des dispositifs médicaux à usage multiple y sera traité ainsi que l'information au sujet des éléments de cet outil qui sera accompagné d'images quant à son mode d'emploi. Les principaux avantages des directives du système de gestion, y compris la façon dont son utilisation a facilité la prise de décision transparente, la communication et la collaboration concernant les questions d'aseptisation sur les sites, y seront décrits.

Les normes de l'AIISOC relatives à cet article figurent dans la publication *Normes, lignes directrices et énoncés de positions pour la pratique de soins infirmiers périopératoires autorisés* (9e édition) de l'Association des infirmiers et infirmières de salle d'opération du Canada (AIISOC) de juin 2009, section 2, p.133-134, Normes 8.1.1 et 8.2.2.

WHAT DO YOU MEAN YOU CAN'T STERILIZE IT?
The Reusable Medical Device Matrix

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This article is based on a presentation from the 2009 ORNAC National Conference in St. John's, NL.

ABSTRACT

Health Canada recommends that hospitals should have procedures in place to ensure Reusable Medical Devices (RMD) are cleaned, disinfected and sterilized according to the manufacturer's instructions. For the purpose of this paper, reusable medical devices will be referred to as RMDs and include all instrumentation and devices that the Central Processing Department (CPD) resterilizes for use in the hospital.

Patient safety in surgery begins in CPD. Manufacturer recommendations for the decontamination and sterilization of surgical instrumentation are of utmost importance to Operating Room (OR) and CPD staff. With recommendations that are unclear, nonspecific or unattainable there was a need to define what it means institutionally to meet standards and provide safe patient care while continuing to support the advancement of surgical technology.

The purpose of this paper is to describe the challenges faced by one multisite organization (The University Health Network) in managing the sterilization of surgical instrumentation. The development of The Guidance Matrix by the network's inter-professional Reusable Medical Device (RMD) Committee, will be discussed along with information about the elements of this tool and an illustration of how it is used. The key benefits of The Guidance Matrix, including how its use has facilitated transparent decision-making, communication and collaboration regarding sterilization issues across the sites, will be described.

Sterilization processes in Central Processing Departments (CPD) include chemical indicators, dated load indicators, and tamperproof locks and filters. The lack of an indicator of sterilization can be a frustrating experience for an OR Nurse. But do we really understand the critical importance of all these indicators? The foundation of sterilizing reusable medical devices (RMDs) begins with proper processes, standards and subsequent scientific validation from the vendors. According to AORN, patient safety is vital and it begins with proper cleaning and processing of the surgical instruments. Surgical site infections can increase the length of stay and the cost of the patients' hospitalization, as well as increased risk, morbidity and even mortality.[1]

Today's patients are far more informed than they were in the past. They can gather information from the internet as well as from television, radio, and print media. This knowledge empowers the patient to expect that their healthcare providers are practicing due diligence. It is the ethical duty and responsibility of nurses to provide safe, competent care while protecting the rights of the patient and being accountable to the professional governing bodies. In other words, we are advocates for both our patients and the healthcare system.[2]

Using both new and innovative instruments in the OR was, in the past, as simple as a surgeon requesting an instrument, the perioperative nurse ordering the instrument and CPD processing it for use in the OR. That is no longer the case. With a wide range of more complex instrumentation and an increasing focus on sterilization strategies, healthcare facilities have had to adopt a more rigorous approach.

There are many challenges in the world of sterile processing. A common one, faced on a regular basis, is the provision of vague, inaccurate reprocessing recommendations from the medical device manufacturer. Canadian centres are not able to meet European standards for reprocessing. European cycles, often referred to as "Fractionated Steam Cycles", are different than the pre-vacuum steam cycles run in Canada.

The University Health Network Approach

How can an organization take on the responsibility of using an instrument that is designed to be sterilized in a completely different cycle than that which is recommended? In response to all challenges the UHN Reusable Medical Device (RMD) Committee (comprising three facilities – Toronto General, Princess Margaret and Toronto Western) recognized a need for clarity of guidelines relating to the purchasing of new equipment and the replacement of old instrumentation. Various challenges were being experienced in this area. Fine Statinsky clamps that had been, for years, sterilized for 4 minutes at 270° Celsius were now arriving with manufacturer recommendations to sterilize for 5 minutes at 270° Celsius.

While the addition of a minute might not seem like a huge factor, such variations in cycle times cause an impact on workflow, instrument availability and resources of CPD. The RMD Committee made the decision to request validation reports from the manufacturer in order to prove that the instrument/tray/medical device actually went through a process of testing to ensure the validity of the new recommendations. The committee discovered that some companies were not willing to share this information with the health care facility and continually stated that they were, "just follow hospital protocol". This generic answer provides no clarification as to the need for the change nor does it help reduce the concerns of health care facilities. At the end of the day, patient safety and organizational accountability are at stake, hence the need to explore best practice. In the end, we must be satisfied we are proceeding with the patient's best interest in mind.

The OR and CPD's at UHN base their respective practices on numerous standards (see Page 25). According to the Canadian Nurses Association (CNA) Code of Ethics nurses should take actions to prevent or minimize harm to the patient. Nurses should collaborate with other teams to reduce future risks.[3] One method of

achieving this goal is for perioperative nursing and central processing departments to work cohesively, and respectfully, when providing patient care.

University Health Network (UHN) was one of eight hospitals selected by the World Health Organization (WHO) to trial the new WHO Surgical Safety Checklist. The nurse, surgeon and anaesthetist utilized this checklist prior to each operation during 500 procedures. One of the several items specified on the checklist is clarification that all sterility indicators have been checked.

According to the Operating Room Nurses Association of Canada's (ORNAC) Beliefs and Professional Standards, it is the nurse's obligation to implement and maintain a safety and risk management program that protects the patient.[4] Despite this fact, UHN experienced several issues in trying to address sterilization of surgical instrumentation.

As one example, parameters were received from the vendor for a St. Mark's Retractor that the OR needed to purchase. The CPD Manager approved the parameters but, when the instrument arrived, the written information indicated a different set of parameters based on the European Sterilization guidelines. The manufacturer would not issue a letter indicating if the instrument could be sterilized safely using the UHN standard protocol nor would they accept the item as a return and provide reimbursement of the purchase price.

In response to this, and other, issues, frustrations and confusion around how to proceed when faced with difficult situations regarding sterilization, in addition to the challenges of conforming to new standards and best practices, the UHN Reusable Medical Device (RMD) Committee was created in 2004. This committee reports to the Surgical Program Quality of Care Committee (SPQCC) that is chaired by the Chief of Surgery and has membership comprising various members of the surgical services team including surgeons, managers and hospital administrators.

The RMD Committee is multi-site and interprofessional with membership including representatives from CPD, OR, Medical Engineering, Infection Control, Risk Management and the purchasing group. Each member brings a different expertise to the table in order to ensure the group is able to make fully informed decisions regarding what instrumentation will enter the healthcare facilities, what risk is associated with any purchasing decisions, and whether infection control issues might surface as a result of use.

The RMD Committee soon realized that a guidance tool was required to aid in decision making regarding equipment that was difficult to clean and sterilize.

A working group was formed, as a result, comprising members of the RMD Committee who represented Infection Prevention and Control (IPAC), Medical Engineering and CPD. This working group developed the Guidance Matrix document, in 2006, as a means of guiding future decisions relating to difficult instrumentation.

The Guidance Matrix (see Page 20-24) is a comprehensive document comprising three sections. It is now used by the RMD Committee to review all reusable medical devices in a structured fashion.

The first section (A) details background information on the instrument including required method of sterilization, length of suggested cycle, who wants it and for what purpose, and whether it is a new or a replacement device.

The second section (B) lists the mandatory Health Canada and Canadian Standards Association (CSA) requirements. These include accessibility to validation reports or sign off by a senior official from the vendor in lieu of this report, compliance with CSA guidelines and the medical device license number.

The third section (C) documents 37 weighted criteria, focused on challenges related to instrument construction (undercuts, ball and socket joints), cleaning, disassembly, and infection control. Each criterion has a fixed weight value that ranges from 0 to3, with 3 representing the greatest challenges. The fixed weight value was determined by assessing the impact of each criterion against patient safety, cleaning and sterilization practices and best practices. Each criterion has a fixed weight value (predetermined) and a rate value is assigned by the assessor to each criterion. A rate value is then assigned using a scale of 0 to2, with 2 representing the greatest challenge for sterilization. The score for each item is derived by multiplying the rate and the weight value.

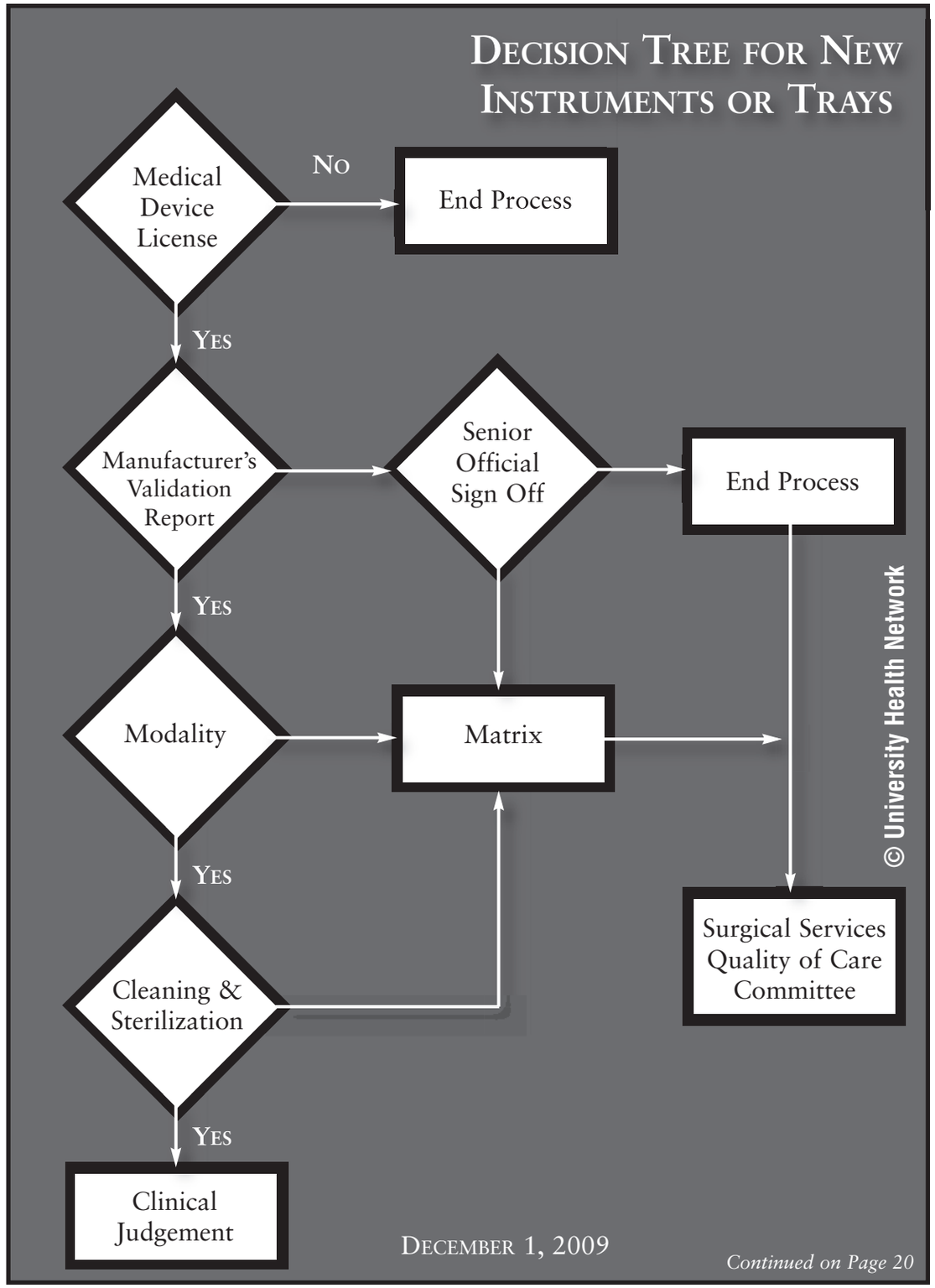
An example of one criterion is "Unable to disassemble RMD". On the Guidance Matrix this status has a fixed weight value of 3 and would be considered very high risk in this criterion. After assessing the RMD, if the overall rate value of 2 is assigned, which represents a high risk or greatest challenge, the score for this particular area would be 3 x 2 = 6. At the end of the assessment the score column, for all the criteria, is totaled. A higher value will indicate a higher degree of difficulty, or challenges, in reprocessing the RMD. The maximum possible score on the Guidance Matrix is 150. The final score provides guidance to the RMD committee. When a device has a high matrix score (50 or greater) it is recommended that the device be brought to the SPQCC for further discussion.

Following the creation of this matrix, the RMD Committee re-examined the St Mark's Retractor mentioned earlier. It scored 21/150 on the Guidance Matrix and as a result the committee approved the instrument for use. This is one example of how the Matrix assisted in eliminating roadblocks in a collaborative manner. Given the multidisciplinary expertise of the members who sit on the RMD committee (Infection Control, Risk Management, Medical Engineering, CPD and OR) UHN feels confident that any low score that is derived from using the Guidance Matrix has been fully examined by the above professionals and a mutual decision is made to process the equipment or not.

For instruments where there is a high score on the Guidance Matrix, the RMD committee brings the item forward to the SPQCC for review and discussion. The surgeon who requested the device is invited to participate in this review and outline how the item will be used, the volume of patients on which it will be used, and what the benefit of use.

As a result of this process, the UHN Reusable Medical Device Committee has experienced a stronger understanding of this area among all those dealing with RMDs. As there is more to the creation of a sterile instrument than merely wrapping it and putting it through the sterilizer, an understanding of the challenges has an impact on both the OR and CPD departments. Collaboration between OR and CPD can only improve understanding and increase respect between those from both areas. UHN believes that the RMD Committee and Matrix has helped improve this collaboration by providing a transparent decision-making process regarding sterilization issues. In conclusion, University Health Network has dealt with reprocessing challenges by implementing a structured and transparent process (the RMD Guidance Matrix). This process has helped guide a multidisciplinary team in decision-making regarding RMD purchasing decisions as they relate to sterilization issues. In a constantly changing environment, where innovation and improved technology are becoming more and more prevalent, it is important that organizations have structures and processes in place to support collaboration, consistent decision-making and patient safety.

ORNAC Standards pertaining to this article can be found in the Operating Room Nurses Association of Canada (ORNAC) (June 2009). Recommended Standards, Guidelines, and Position Statements for Perioperative Registered Nursing Practice (9th edition). Section 2, pg 133/134, Standards 8.1.1 and 8.2.2.



Continued on Page 20

University Health Network

Guidance Matrix for Re-usable Medical Device (RMD)

Name of Assessor: _____	Date: _____
Name of Manufacturer: _____	
Name of Reusable Medical Device (RMD): _____	

The purpose of this matrix is to assess a RMD that has not been validated to North American sterilization methods or parameters or fails to meet minimum validation requirements of a device to be used at UHN

Section A is general information regarding the RMD, and is not part of the decision matrix.

Section B lists the mandatory requirements. If any of the criteria in this section is not met, UHN will not reprocess the RMD.

Section C is a list of reprocessing challenges. This is a guide to identify the challenges associated with reprocessing the RMD. The RMD Committee will render an expert opinion.

Each criteria has been assigned a **weight value** based on the degree of challenges where 3 represents the highest challenge, 2 represents some challenges and 1 representing non-critical challenge.

The user assesses the RMD and assigns a rate (0, 1 or 2) corresponding to each criteria. The score is derived by multiplying the rate and the weight value (e.g an RMD that contains hard to reach areas that has a weight value of a 2 would be considered high risk and therefore would be rated a 2 for a weight value of a 4.)

A higher value will indicate the degree of difficulty or challenges in reprocessing the RMD. The maximum score on the decision matrix is 144.

Section A	Required Information
General Information	
• Validation to follow	
• Heat sensitive – Sterrad or EO?	
• Default 270 deg F for 4 mins failed, outlier parameter supported with validation	
• Set can be reprocessed with longer cycles eg. validation for 8 mins, UHN reprocessed @ 10 mins	
• Set requires cycle times outside existing cycles eg. 40 mins	
• Options or alternatives?	

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Guidance Matrix for Re-usable Medical Device (RMD)

• How often is it used? Frequency	
• Who wants it? Why is it needed?	
• Used for elective case?	
• Innovative procedure or instrument	
• Patient Impact (1 patient? 100 patients?) – clinical relevance	

Section B	Required Information
Mandatory Requirements:	
• Sign off by senior official (in lieu of validation report)	
• Compliance with CSA safety standards.	
• EN Fractionated steam validation and RMD contains lumens	
• Medical Device License #	

Section C				
Criteria	**Rate**	**Weight Value**	**Score**	**Comments**
Rate Scale: 0 = No / No Challenges; 1 = Moderate Challenges; 2 = Yes / Greatest Challenges				
• Is the validation report based upon an equivalence RMD set?		3		
• Is the validation based upon individual component / RMD		3		
• Is set validated to European (EN) pre-vacuum validation?		3		
• No biological indicator available for quality assurance		2		
• Was validation completed with one tray in sterilizer?		1		

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Guidance Matrix for Re-usable Medical Device (RMD)

Validation for Cleaning				
• General manual and automatic cleaning recommendations – no step by step instructions for multi-component RMD		3		
• Unable to disassemble RMD		3		
• RMD has closed ended lumens		3		
• RMD has retractable/sliding parts		3		
• RMD contains hard to reach areas eg. Undercuts		2		
• RMD has ball & socket design		1		
• Difficult to rinse materials eg. Plastics		1		
• RO water is required for rinsing for hand wash RMD		1		
Criteria	**Rate**	**Weight Value**	**Score**	**Comments**
Rate Scale: 0 = No/Not Applicable; 1 = Some Challenges; 2 = Yes / High Risk / Most challenging				
• Requires special cleaning aids/tools to clean effectively eg. cleaning adapters		1		
• Requires pre-cleaning in Operating Room		1		
Instrument Criteria				
• RMD used invasively		3		
• Special service considerations eg. calibration after 20 uses		2		
• Re-posble item (limited uses) / life		2		
• Wicking required eg. clips, bulldogs		1		
• Labour intensive preparation / set-up in CPD		1		
• Difficult lubrication process		1		

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Guidance Matrix for Re-usable Medical Device (RMD)

• RMD contains threaded instruments		1		
Instrument Configuration				
• Instruments in closed position during sterilization		3		
• RMD contains springs and bearings		3		
• Improper layout of RMD (eg. Metal on metal – stacking)		3		
• No container provided by manufacturer (rigid container preferred)		2		
• No instrument holders to secure instrument in tray eg. grey telescope sheaths		1		
• high mass items (weight and size)		1		
• dissimilar materials/questionable i.e. metal and composite, wood or other (pheneol)		1		
Criteria	**Rate**	**Weight Value**	**Score**	**Comments**
Rate Scale: 0 = No/Not Applicable; 1 = Some Challenges; 2 = Yes / High Risk / Most challenging				
Instrument Complexity				
• Implantable Device / RMD used directly on implantable device		3		
• Non take-apart multi-component		3		
• Custom built instrument		3		
• RMD contains blocked holes		3		
• Lumen diameter less than 3mm		2		
• Lumens with 90 degree bends		2		

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Guidance Matrix for Re-usable Medical Device (RMD)

• Lumens with more than 1 bend		2		
• Multi-layered tray/set greater than 25 lbs		1		
Total Value (max. 150)				
Conclusion of Matrix:				
☐ Process				
☐ Process with conditions (ie. removal of challenging instrument)				
☐ Do not reprocess (⟶ RMD Committee)				
RMD (Reusable Device Committee) Decision:				
RMD total value on Guidance Matrix scores 50 or greater:				
☐ Do not reprocess (⟶ SPQCC Committee)				
SSQCC (Surgical Services Quality of Care Committee) Decision:				

Assessor's Signature: _____ Date: _____

The Guidance Matrix was developed by the University Health Network's Reusable Medical Device Committee. Members include AnnMarie Assang (TGH Manager, Central Processing Department), Glen Frecker (TWH Supervisor, Medical Engineering), Marilyn Mah (TWH Manager, Central Processing Department), Karen Stockton (UHN Director, Infection Control).

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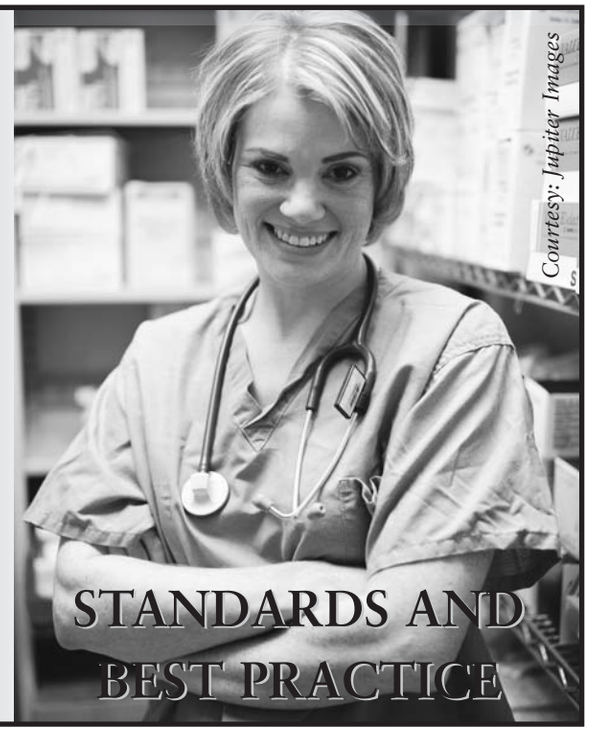
- CCSHA
- CNA CODE OF ETHICS
- CSA
- ORNAC
- PIDAC
- SAFER HEALTHCARE NOW!



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