Missed the Windy City? Hot Topics from the 2009 AORN National Congress

Prepared May, 2009 by Martha Young and Rose Seavey
Welcome!

**Facilitator:** Tammy Torbert, Attest™ Sterile U Team Leader

**Speakers:** Martha Young, 3M Technical Service and Rose Seavey, Seavey Healthcare Consulting

**Housekeeping:**
- Questions;
  - Mute feature (*7= unmute; *6= mute)
  - "Chat" feature
- Technical difficulties
- CE Credits
- Post session follow-up

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Join Today!
Today we are going to discuss the Hot topics presented at the AORN Annual meeting in March, 2009 at the Specialty Assembly for Sterile Processing and Materials Management.
Here are the coordinating council members of the AORN Specialty Assembly for SPD and MM.

Because of the formation of this Specialty Assembly chapter, non RNs may now join AORN and become a member by going to the website.
Objectives

Provide an objective and open discussion on various topics that impact the Operating Room, Sterile Processing and Material Management departments

Educational information

1 hour program

5 Hot Topics

The objective of the presentation is to provide an objective and open discussion on various topics that impact the operating room, sterile processing and material management departments.

There are 5 hot topics.
This is the list of hot topics we will discuss.

- Count sheets in surgical trays
- New product selection/Class 6
- AAMI ST79 A1:2008 updates
- TASS
- Certification of SPD Staff
Count Sheets in Surgical Trays

**History**
- Used for accuracy of set instruments
- Maintain standardized tray setup & quantity of instruments
- Tracking and quality
- Patient safety tool - prevention of loss & retention of instrument in a patient’s cavity
- Counts in OR before case starts, before wound closure and if feasible, at the time of permanent relief of the scrub person and/or circulating nurse
- No requirement to be sterile

Discuss the reasons that count sheets have been historically used.

Count sheets are used to ensure the correct instruments and the correct number of those instruments are in each standardized set.

It also identifies who made the set and can be used for monitoring the quality of sets by when missing instruments are noted on the count sheet that helps with a quality improvement processes of identifying the reason for missing instruments.

Count sheets are used in the OR to ensure that instruments are not left in the patient.

Instrument counts are done when the room is set up, after the wound is closed and when the scrub person and/or circulating nurse is permanently relieved from the case.

There has never been a requirement that count sheets be sterile.
Count Sheets in Surgical Trays

Problems

- Validation of medical grade paper and ink
- The possibility of shedding fibers from the paper
- Do the count sheets trap air and inhibit air removal and steam penetration?
- Problems with ink transfer
- Placement of count sheets
  - Need them but where do they go?

The problems with placing count sheets inside of trays is that everything that is placed inside a tray should be validated.

Was the medical grade paper and ink validated?

Does the paper shred? Since most paper used now is recycled there is more shedding which is a concern if the paper sheds are left in the patient.

Do the multiple layers of count sheets retain air and inhibit air removal and steam penetration?

The ink does transfer? Is it toxic to the patient?

You need the count sheets so where do place them?
Ink transfer from Count Sheets

Courtesy of IMS

Here is an example of some ink transfer that is the concern for patient safety
Count Sheets in Surgical Trays


Does not discuss count sheets specifically

- 8.3.2 ink should be nontoxic (labeling pens)
- 8.3.4 no paper/plastic pouches inside trays or containers

AAMI ST79 does not discuss the use and placement of count sheets.

It does state that the ink used in pens for marking packages should be nontoxic so that toxins are not deposited on packs or instruments. There are sharpie pens that are validated and nontoxic for this use.

You cannot place count sheets inside of place paper/plastic pouches inside trays or containers because they inhibit air removal and steam penetration.

So that is not an option for count sheets.
Count Sheets in Surgical Trays


“Count sheets should not be placed inside wrapped sets or rigid containers. Although there are no know reports of adverse events related to sterilized count sheets, there is no available research regarding the safety of toners and/or various papers subjected to any sterilization method. Chemicals used in the manufacturer of paper and toner ink pose a theoretical risk of reaction in some sensitized individuals.”

AORN in 2008 stated in the Recommended Practices for Selection and Use of Packaging Systems for Sterilization that count sheets should not be placed inside of wrapped trays or rigid containers.

The concern is the toxicity of the toners or ink and the paper.
So FDA did a very limited study as requested by the AORN that was published in the AORN journal in March 2009.

The result was the ink does not appear to generate significant cytotoxicity but the study does not guarantee this is a safe practice.

But the ink is hard to remove.

The study also does not address the concern with linting or piling of paper material.

The study does suggest that the count sheet could be placed in a paper/paper pouch that is validated for this use (Healthmark has a product as do others).

The conclusion was a larger sample size study needs to be done.
Count Sheets in Surgical Trays

“Steam Sterilization and Internal Count Sheets: Assessing the Potential for Cytotoxicity” AORN Journal, March 2009

Note from the AORN Center for Nursing Practice:
AORN recommends to central service managers that only medical products for which steam sterilization has been validated to be safe and efficacious be placed in the steam sterilizer. Evaluation processes should be implemented to weigh the risks and benefits of placing a non-validated product in the instrument trays against the concerns for inventory control and instrument count procedures. At this time, placing preprinted count sheets into steam sterilized instrument sets needs to be an individual decision for each health care organization.

The recommendation from the AORN Center for Nursing Practice is:
- only use medical products for which steam sterilization has been validated
- Weight the risks and benefits and using non-validated product
- what you do should be an individual health care organization decision
Count Sheet Placement Ideas

Inventory lists can be:

- Taped to the outside of the wrapper, or
- Wrapped around the handle of a rigid container

Here are some examples of where you could put the count sheets.
Count Sheet Placement Ideas

Computerize - never place in or with tray-OR prints out count sheet when case carts arrive

Other ideas?

Another option is to computerize the system. The OR prints out the count sheets when the case cards arrive in the OR.

Does anyone want to share what they are doing?
New Product

Due Diligence with all key players (IP, OR, SPD, RM)

- Look at product literature, package insert and 510K clearance on FDA website
- Look at peer reviewed literature
- Look at current standards and guidelines (AAMI, AORN, and CDC)
- Legal implications in a law suit if not meeting standards and guidelines

Now let's talk about the process of deciding on purchasing new products.

You need to do your due diligence with all the key players.

You need to look at the product literature, package insert and 510 clearance which you can do using the FDA website listed on this slide.

Look at peer reviewed literature which can take up to 2 years to get published after a product goes on the market.

Look at what the current standards and guidelines say and consider the legal implications if your facility is not meeting these.
Sterilization Processes and Malpractice Litigation - Robert R. Gorbold, Attorney at Law

- Medical malpractice is generally defined as a violation of the applicable standard of care
- Experts testify to applicable regulations and recommendations for patient care and whether the policies and practices of the hospital and surgery center comply
- Today’s recommendations that are supported by industry experts and recognized professional organizations may be used as evidence in court of the standard of care, even though not yet required by statute or regulation

http://www.3m.com/2008SterilizationLeadershipConference

Here is another reason why it is important to follow recommended practices.

From a paper based on A Legal Perspective: The Ramifications of Errors in Patient Care Presented by Mr. Gorbold at a Sterilization Leadership Conference in 2008. The conference took place in St. Paul, MN at the 3M Innovation Center and his presentation is available online at 3M: http://www.3m.com/2008SterilizationLeadershipConference
Lit # 70-2010-7156-3

Mr. Gorbold stated that if a hospital is sued and the patient’s lawyer brings in an expert witness that states the hospital did not follow recommended practices and standards the hospital will settle the law suit because they know they cannot win.

So even though AAMI, AORN and CDC recommended practices and standards are not law except AAMI in NJ, they are considered best practices for patient care in a law case.
New Product

Due Diligence with all key players (IP, OR, SPD, RM)

- Talk to experts (Dr. Rutala-disinfectionandsterilization.org, and OR Manager Jan 09)
- Make an informed decision

Also talk to experts. I have added a website and an OR Manager article that has some quotes about usage of Class 6 emulating indicators by Dr. Rutala, U of North Carolina, Chapel Hill, pas president of APIC, and a member of the Healthcare Infection Control Practices Advisory Committee (HICPAC).

In summary, make an informed decision.
Chemical Indicators Class 6: Emulating Indicators

“Emulating indicators are cycle verification indicators which shall be designed to react to all critical variables for specified sterilization cycles. The SVs are generated from the critical variables of the specified sterilization process.”

Class 6 Emulating Indicators CI Strips
- 270°F/132°C, 4 min. prevacuum, express

Class 6 Emulating Indicator PCD
- 270°F/132°C, 4 min. prevacuum, express

FDA cleared for market but done not approve products

Lets briefly discuss Class 6 emulating indicators.

Class 6 emulating indicators measure all critical variables for a specified sterilization cycle and could be used as internal chemical indicators for the cycles they are designed for.

An example one of the Class 6 emulating indicators and process challenge devices on the market is shown on this slide.

See how specifically they are labeled with the time, temperature, and type of air removal cycle that the product can be used in. That is the only cycle it can be used in.

It is important to remember that FDA cleared this product for market but it does not approve products.
Class 6 Emulating Indicators

Discussion comments at AORN

- How confusing and difficult it would be to get the correct CI in the package and load
- Not enough different CI products to cover all cycles used, especially extended cycles
- Will not replace the use of the BIs with CIs, not even for monitoring implant loads because would not meet recommended practices and standards and would create a risk to the patient

Discuss the comments made during the discussion at the AORN Speciality Assembly?

Does anyone else have comments or questions?
New AAMI ST79 Ammendments

To download follow these instructions

HTTP://WWW.AAMI.ORG

At Market Place News Click on AAMI ST79 Book

Find it on list of products and add to shopping cart

Download free product (ST79 Amendments 1-PDF)

Print and save to your hard drive

Now lets discuss the new amendments A1:2008 to AAMI ST79.
You can download these amendments free using these instructions.

The A2 amendments should be out in June 2009 and they cannot also be downloaded free.
7.5.5 Verification of the cleaning process

“Although validation of the cleaning process may be unrealistic in health care facilities, verification is possible (see Annex D). However, few methods are currently available to ensure that medical devices are clean and free from soil and microorganisms. One simplistic method involves exposing the cleaned medical device to a 2% hydrogen peroxide solution to verify that all catalase-containing material (e.g., eukaryotic cells and some bacterial cells) has been removed. If the solution bubbles...indicates that cleaning was inadequate.”

AAMI ST79 will start to put more emphasis on cleaning verification. This section discusses the use of one technology for that which uses 2% hydrogen peroxide. As an example, this test would be used to verify the effective cleaning of lumens.
### AAMI ST79 A1:2008 Amendments

In Annex D User verification of cleaning processes

Table D.2 In-use tests available to assess efficacy of washer-disinfector used for medical device reprocessing

<table>
<thead>
<tr>
<th>Test Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visible test soil</td>
</tr>
<tr>
<td>Coagulated blood test (Blood and Protein)</td>
</tr>
<tr>
<td>Peroxidase reaction (Hemoglobin)</td>
</tr>
<tr>
<td>Protein test pyromol-test (Protein)</td>
</tr>
</tbody>
</table>

Annex D which summarizes cleaning verification processes now listed two additional test methods.
**AAMI ST79 A2:2009 Amendments
Really Hot News**

Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs. A major repair is a repair that is outside the scope of routine preventive maintenance and that significantly affects the performance of the equipment. Examples include replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, or computer control or an upgrade to software.

No the really hot news is that in AAMI ST79 A2:2009 there will now be a requirement that states you should verify your mechanical cleaning equipment is working by testing it:
- upon installation
- weekly (preferably daily)
- during routine use and
- after major repairs.

A major repair is considered a replacement of the:
- water pumps
- detergent delivery system
- heating system
- water delivery system of
- computer control or an upgrade to software
AAMI ST79 A1:2008 Amendments

10.5.3.2 Using biological indicators

- Biological indicators should be used with PCDs for routine sterilizer efficacy at least weekly, but preferably every day that the sterilizer is in use. Additionally, BIs with PCDs should be used to monitor every load containing implants.

We added that biological indicator process challenge devices should be used to monitor every load containing implants where we state the routine monitoring requirements.
AAMI ST79 A1:2008 Amendments

10.7 Routine Sterilizer Efficacy Monitoring
10.8 Sterilizer Qualification Testing

Test each type of cycle with a BI PCD

<table>
<thead>
<tr>
<th></th>
<th>°C to °C</th>
<th>°F to °F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity-displacement</td>
<td>132°C to 135°C</td>
<td>270°F to 275°F</td>
</tr>
<tr>
<td>Gravity-displacement</td>
<td>121°C</td>
<td>250°F</td>
</tr>
<tr>
<td>Dynamic-air-removal</td>
<td>132°C to 135°C</td>
<td>270°F to 275°F</td>
</tr>
<tr>
<td>“Flash”</td>
<td>132°C to 135°C</td>
<td>270°F to 275°F</td>
</tr>
<tr>
<td>“Flash”</td>
<td></td>
<td>Single wrapper or other packaging</td>
</tr>
</tbody>
</table>

The AAMI ST79 2006 document says that if a sterilizer is designed and used for multiple types of cycles then each type of sterilization cycle should be tested because they each create a different challenge to the sterilization process.
AAMI ST79 A1:2008 Amendments

10.7 Routine Sterilizer Efficacy Monitoring
10.8 Sterilizer Qualification Testing

“NOTE - If a sterilizer will run the same type of cycle (e.g., dynamic-air-removal at 132°C to 135°C [270°F to 275°F] for different exposure times (e.g., 4 minutes and 10 minutes), then only the shortest cycle time needs to be tested.”

AAMI ST79:2008 will provide a new note that states that if you run a 270°F dynamic-air-removal sterilizer for 4 and 20 minutes then you only need to routinely test the 4 minute cycle.
AAMI ST79 A1:2008 Amendments

Annex N (informative)
Toxic anterior segment syndrome (TASS) and the processing of surgical instruments

AAMI also added an Annex that discusses TASS or Toxic anterior segment syndrome.
Special considerations are associated with the processing of instruments used for intraocular surgery, both because of the nature of the instruments themselves and because of the sensitive nature of the eye. Many of the intraocular instruments currently in use are complex and delicate and cannot be processed by automated methods; therefore, they must be cleaned manually. Because manual cleaning methods may be less controlled than automated cleaning methods, additional care must be taken during processing to ensure effective cleaning. The situation is further compounded by the sensitivity of ocular tissue to the introduction of foreign material into the anterior chamber of the eye, which may result in an acute inflammatory response known as toxic anterior segment syndrome (TASS). This inflammatory response may lead to severe visual impairment if it is not recognized and treated in a timely manner.
Preventing TASS

Identified causes of TASS are irritants on the surfaces of intraocular surgical instruments that have accumulated as a consequence of:

- Inadequate or inappropriate instrument cleaning
- Detergents residue
- Presence of heat stable endotoxin from overgrowth of gram-negative bacilli in water baths of ultrasonic cleaners
- Degradation of brass containing surgical instruments from plasma gas sterilization, and
- Impurities of autoclave steam

Some of the causes of TASS are related to the presence of irritants on the surface of the surgical instrument.

Read the list of causes of these irritant.

In NJ, one hospital had to wipe out their ultrasonic after each use with alcohol to eliminate the endotoxin and growth of gram-negative bacilli.

Steam quality is very important for preventing TASS.
Preventing TASS

Many eye instruments are complex and delicate and must be cleaned manually

Manual cleaning methods less controlled

Additional care must be taken during processing to ensure effective cleaning and thorough rinsing

These instruments must be manually cleared which involves the use of a lower water temperature and a less controlled method, you must be sure to effectively clean and thoroughly rinse the instruments.
Adequate inventory of eye instruments should be maintained

Keep instruments moist in OR
- Wipe with damp lint-free cloth
- Flush lumens with sterile water

Transport immediately

Adequate time must be allowed for processing instruments according to the manufacturer’s written instructions

Intraocular surgical instruments should be processed
- Separately from general surgical instruments
- In a designated cleaning area with dedicated equipment

Adequate inventory is important to allow the appropriate amount of time to clean and sterilize the instruments.

In the OR suite:
- Use a lint-free cloth so that nothing is transferred to the instruments when you wipe them off immediately after use
- Flush lumens with sterile water and transport immediately to the sterile processing department so the ophthalmic solution does not dry on the instruments

Allow adequate time to follow the instrument manufacturer’s instructions for cleaning.

To avoid cross contamination, wash the intraocular surgical instruments separately from other instruments in a dedicated cleaning area with dedicated equipment.
Manufacturer’s Instructions

- The manufacturer’s current written instructions for the cleaning and sterilization of eye instrument should be read, understood, and followed by those responsible for processing the instrument.
- The cleaning process should be audited to ensure that the procedures:
  - Comply with the manufacturer’s instructions
  - The personnel performing cleaning procedures have received documented training and
  - Have demonstrated competency in the cleaning process

We cannot stress enough to make sure that personnel are following the instructions for cleaning and sterilization of these instruments.

Policies and procedures need to be in place, training done, and auditing of the process to make sure it is correct. Direct demonstration is best.
Cleaning Agent

- Recommended by the manufacturer

- Specified concentration of the recommended cleaning agent and water quality should be used

- Final rinsing of the instrument should be performed with the sterile, distilled, or deionized water

- Whenever possible, single-use brushes should be used and then disposed of afterwards

Make sure the cleaning agent is used correctly.

Dilute correctly with the recommend quality of water.

Final rinsing should be with sterile, distilled, or deionized water.

Single use brushes are best to avoid cross contamination.
Sterilization

Eye instruments should be sterilized using the methods and conditions recommended in the written instrument manufacturer’s instructions.

Flash sterilization should be avoided.

The sterilization process should be monitored, and documented.

ANSI/AAMI ST79

- Provides detailed recommendations for sterilization processing, including quality control and restrictions including the use of flash sterilization.

Use the appropriate sterilization procedures and avoid flash sterilization to ensure appropriate cleaning of the instruments in a separate designated area in the sterile processing department and so instruments are properly dried before use.

Monitor the sterilization process according to AAMI ST79.
Maintenance of Processing Equipment

Cleaning and sterilization:
Equipment, Boilers, and Water filtration systems
Should be properly maintained

Otherwise, foreign materials such as endotoxin, heavy metals, or chemical contaminants or impurities may be deposited onto the instruments during processing and induce TASS.

It is also important to have proper cleaning and maintenance of equipment, boilers and water filtration systems to eliminate endotoxins, heavy metals and other chemical impurities.
Because many different materials can elicit a TASS response if they are inadvertently introduced into the anterior chamber of the eye, the importance of following the proper intraocular surgical instrument processing procedures **cannot be overemphasized**.

We cannot over emphasize the importance of following these recommendations to eliminate TASS.
Let's talk about mandatory certification of all staff in sterile processing.

AAMI states that all staff should be certified within 2 years after employment to develop the sterile processing staff because the tasks of the profession are becoming more technical and require more critical thinking skills.

We want the profession to continue to evolve.

We want to develop the staff to ensure (read the points).

The ultimate goal is to protect the patient.
Mandatory Certification for SPD

What can you do to help?

- Support the efforts in your state
- Support the effort in your SPD department
- Encourage the advancement of the SPD technicians individually and collectively
- Urge your facility to fund the attendance to their local/national meetings and the cost of the certification exam

Remember this is a career not just a job so what can you do to help?

Read the list.
Mandatory Certification for SPD

What can you do to help?

- Become a members of local CS/SPD chapter and assist in introducing a bill for mandatory certification in your state
- Template available from Ad Hoc Committee on Mandatory Certification
  [http://iahcsmm.org/pdfs/MandatoryCertificationBrochure_5page.pdf](http://iahcsmm.org/pdfs/MandatoryCertificationBrochure_5page.pdf)
- Title of template: “Achieving Mandatory Certification: Strategies for Success” - directs how to get started and steps that need to be taken

Join your local organization and become involved in introducing a bill for mandatory certification in your state.

A template to help you with this process is available on the IAHCSMM web site.

The title is “Achieving Mandatory Certification: Strategies for Success” will direct you on how to get started.
Here is a map that shows you mandatory certification efforts in each state.

We need to get people in this profession in the blue states to start the process and the rest to move to a red state.
Mandatory Certification for SPD

Who has been promoting?

- CBSPD, IAHCSMM and AORN
- New Jersey is the first state to get mandatory certification
- Several other states are now in the process

Anyone involved with this process that would like to share?

Mandatory certification is promoted by the Certification Board, IAHCSMM and AORN.

NJ the home of the Certification Board is the first and only state to pass mandatory certification at this time.

Is anyone in this audience working towards mandatory certification?
Join AORN and the SA for SP/MM

One of 23 AORN Specialty Assemblies
Goal is to promote communication among AORN members with unique interests
- Provide a forum for networking
- Identify and explore patient care issues
- Promote specialized education and
- Support the mission of AORN

Visit the Sterile Processing/Material Management SA online
http://www.aorn.org/Community/DiscussionBoards

If you are not an RN you can now join AORN because of the formation of the sterile processing/materials management specialty assembly.

You can visit this website to join.
Thank you.
Presenter Biography

Martha Young, BS, MS, CSPDT
Senior Technical Service Specialist, 3M Sterilization Assurance

Martha Young has over twenty five years of experience in the area of sterilization and disinfection. Ms. Young lectures around the world and has numerous publications on infection prevention with an emphasis on improving the performance of the sterilization process.

She is a member of IAHCSMM, AORN (Professional/Practice Issues Chair for AORN specialty assembly for Sterile Processing Materials Management) and APIC and a certified Central Sterile Processing and Distribution Technician. She is a member of several AAMI working group committees that are developing recommended practices and the Special Technical Editor for the 3M sponsored inservice in Managing Infection Control.

Ms. Young was named in 2007 by HPN as one of the 30 Pros to Know who are the most influential in Healthcare Sterile Processing.
Presenter Biography

Rose Seavey, RN, BS, MBA, CNOR, CSPDT
President/CEO of Seavey Healthcare Consulting

Rose Seavey RN, BS, MBA, CNOR, CRCST, CSPDT is the President/CEO of Seavey Healthcare Consulting, Inc, and formerly the Director of the Sterile Processing Department at The Children’s Hospital of Denver. Ms Seavey was elected to the Association of periOperative Registered Nurses (AORN) Board of Directors for 2008-2010. She was honored with AORN’s award for Outstanding Achievement in Clinical Nurse Education in 2001. Rose served as the President of the American Society of Healthcare Central Service Professionals (ASHCSP) in 2003 and is the 2002 recipient of ASHCSP National Educator of the Year award. Rose was selected as one of the Who’s Who in Infection Prevention in 2006 by Infection Control Today.

Ms Seavey is a member of several AAMI working group committees that are developing recommended practices and is currently a co-chair for the ANSI/AAMI Working Group for Hospital Steam Sterilizers performance standards. In addition she has lectured and authored many articles on various topics relating to perioperative services and sterile processing, locally, nationally and internationally.
Count Sheet

References Used

Count Sheets

- "Steam Sterilization and Internal Count Sheets: Assessing the Potential for Cytotoxicity" AORN Journal, March 2009


AAMI Update

References Used


- Legal opinion [http://www.3m.com/2008SterilizationLeadershipConference](http://www.3m.com/2008SterilizationLeadershipConference)

- Rutala, William, PhD, MPH. CDC sterilization, disinfection guideline, *OR Manager*, Jan 2009, Vol 24. No 1
Preventing TASS

References

- AAMI ST79 2008 Amendments
  Annex N (Informative)

- AORN Recommendations 2009 – XIV
  Special precautions for reprocessing
  ophthalmic surgical instruments

- Recommended practices for cleaning and
  sterilizing intraocular surgical instruments,

These recommended practices address processing issues to prevent TASS but the best reference is the last one and that is what we will spend time discussing.
Mandatory Certification
References Used

• IAHCSMM
  http://iahcsmm.org/pdfs/MandatoryCertificationBrochure_5page.pdf
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for completing the seminar:

3M™ Attest™ Sterile U Network Webinar
“Hot Topics from the 2009 AORN National Conference Specialty Assembly for SP/MM”

3M Health Care
Inservice Approved by the Certification Board for Sterile Processing and Distribution (CBSPD) for 1.0 Contact Hour
Approval Code # 21630WOR09
IACCM has awarded 1.0 Contact Hour
Approval Code # 0031009A

Mary Kundus, RN, BSN, MPH, CIC

Date: May 21, 2009

Location: Webinar from 3M, St. Paul, MN
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