



**KAHRMM**

Kansas Association for Healthcare  
Resource & Materials Management

**KAHRMM Newsletter  
February 2021**

**President's Message – Where did January go?**

Where did January go? It sure seems like the time is flying by. I hope this finds all KAHRMM members and families doing well and staying safe. It appears we might be starting to turn the corner a little more on the pandemic. Hopefully, we can keep the new variances of COVID-19 at bay.

A little bit of bittersweet news. The Central Plains Expo has officially made the decision to disband. There will not be a Central Plains Expo in 2021. With the help of the Kansas Hospital Association, we were able to cancel the hotel contract, by taking into consideration the uncertainty of gatherings and pandemic rules, with little to no further cost. After 35 plus years, it is sad to see it go, but when one door closes, another opens.

The KAHRMM Board is looking at this as an opportunity to do some things we have been discussing for a few years. Our vision is the possibility of doing a similar type of event, move it around the state and invite peers from within our facilities to the event with specific training and a vendor show. Stay tuned for more details in the future.

We are still hoping for education and a golf outing; however, it may be moved to a different time this year due to meeting regulations. There also may be opportunities for online or virtual meetings. Finally, the Special Olympics Basketball tournaments have been canceled this year in Hays and Topeka.

If you have things you would like to see happen or other suggestions, please do not hesitate to contact one of the board members or myself for discussion.

For now ...

--Mike Morgan

**PPE Essentials: Gowns**

Source: *By William Bagnasco, ASQ CQA, PMI CAPM, CLSSGB, Director of Quality and Regulatory Affairs, DUKAL Corporation*

What reps need to know about different types, requirements, claims and standards of gowns used in medical settings.

*December 2020*

As the novel coronavirus has spread across the globe, personal protective equipment, also known as PPE, has become the hottest topic in the medical device industry. Along with the increased demand for PPE, came an influx of new suppliers to the market. As new suppliers emerged, so did the questions related to the different types of PPE and various levels of protection that they offer.

Since the onset of the virus in early 2020, the industry has scrambled to secure appropriate product to meet the needs of health care workers required to protect themselves and patients from the spread of infection. This article will focus on the different types of gowns, the requirements and claims associated with level-rated gowns, and draw attention to the inconsistencies between AAMI's standards and those of the Food and Drug Administration (FDA).

### **Types and standards**

The American National Standards Institute (ANSI) and the Association of the Advancement of Medical Instrumentation (AAMI): ANSI/AAMI PB70 describe liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. In 2004, the FDA recognized ANSI/AAMI PB70 as the consensus standard. AAMI PB70 defines an "isolation gown" as an "item of protective apparel used to protect health care personnel and patients from the transfer of microorganisms and body fluids inpatient isolation situations," and "surgical gowns" as "devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids, and particulate material." (21 CFR 878.4040)<sup>1</sup>

The main difference between an isolation gown and a surgical gown are the critical zones identified for testing and that the back of a surgical gown may be nonprotective. Whereas the back of a level-rated isolation gown must offer full back coverage and have a barrier performance of at least a Level 1.

The ANSI/AAMI PB70 standard has 4 levels of fluid barrier protection, with Level 1 being the lowest level of protection and Level 4 being the highest. The following is a table showing the different levels of rated gowns, test methods, and the anticipated fluid exposure for each performance level.

According to the FDA, both surgical gowns and isolation gowns are considered surgical apparel and are covered under the requirements of 21 CFR 878.4040. Gowns that are not intended for use in a surgical setting are Class I devices. They are intended to protect the wearer from the transfer of microorganisms and body fluids in low-risk patient isolation situations. This includes both Level 1 & 2 isolation gowns, as well as non-rated isolation gowns.

The agency identifies gowns that are intended to be used in surgery as Class II devices that require a pre-market notification. A pre-market notification, also known as a 510k submission, ensures that a device meets specific performance standards, labeling requirements and its intended use by demonstrating substantial equivalence to another device that has been shown to be safe and effective.<sup>2</sup> The definitions used in the ANSI/AAMI PB70 standard are inconsistent with those used by the FDA, which has caused confusion in the industry. Unlike AAMI, the FDA considers both the level of barrier protection and the terminology used in the marketing and labeling of the device. In 2015, the FDA issued a guidance document clarifying their approach.

The FDA considers gowns with moderate to high barrier protection (Levels 3 & 4) to be a higher-risk device than gowns that claim minimal or low levels of fluid protection (Levels 1 & 2, and non-rated gowns). The FDA automatically considers a gown to be a "surgical gown" or "surgical isolation gown" when it has a statement relating to moderate or high-level barrier protection. This means that if a gown is labeled as an AAMI Level 3 or 4, it's considered a "surgical gown" and is subject to the requirements of premarket notification. This contradicts the ANSI/AAMI PB70 standard that states that surgical gowns can be classified as Level 1-4.<sup>3</sup>

## What does this all mean?

To simplify it, a "surgical gown" that is marketed in the United States cannot claim to be AAMI Level 1 or 2 because using the word "surgical" on the label or in any marketing material implies that the gown is intended for use in a surgical setting. Any gown labeled or marketed with the words "surgical," "surgical gown" or "surgical isolation gown" is automatically elevated to a Class 2 device, requires a premarket notification and should be identified as either AAMI Level 3 or 4. On the other hand, isolation gowns can be rated AAMI Level 1-4 or they can be non-rated. There are non-rated isolation gowns that offer fluid protection which doesn't carry a level rating due to the construction features of the gowns, such as having an open back design and/or sewn seams. Any isolation gown that carries an AAMI Level 3 or 4 designation would be considered a high-risk device and would require premarket notification.

Now that we have a better understanding of the different types of gowns and the differences between FDA regulations and the ANSI/AAMI standard, we can look at what should be reviewed with regards to claims, prior to purchasing a gown.

- Level 1 Isolation Gown: The manufacturer should provide test reports, according to AATCC 42, showing that all critical areas of the gown were tested for fluid resistance and that all test requirements were met. Level 1 gowns offer protection against minimal fluid levels.
- Level 2 Isolation Gown: The manufacturer should provide test reports, according to AATCC 42 & AATCC 127, showing that all critical areas of the gown were tested for fluid resistance and that all test requirements were met. Level 2 gowns offer protection against low fluid levels.
- Level 3 & 4 Gown (Surgical and Isolation): A copy of the 510k summary should be reviewed to ensure FDA clearance. Level 3 & 4 gowns offer protection against moderate and high fluid levels respectively.

An important thing to remember is that all claims that are made with regards to fluid protection should be made on the final, finished gown including the materials, seams and points of attachment. There are gowns on the market that claim that the "material" is fluid-resistant. This is an important factor to consider when trying to select the appropriate gown based on its barrier properties. Having a better understanding of the different types of gowns, the various regulations/standards that cover these gowns and the proper supporting documentation will allow you to select the appropriate gown and ensure that the gown does in fact meet the intended use and labeling claims.

- Sections 3.13 and 3.31 of the ANSI/AAMI PB 70:2012 (citing 21 CFR 878.4040).
- <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns#g4>
- Guidance document on Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings

**SIDEBAR:**

**AAMI PB70 guidelines**

<b>ANSI/AAMI PB70 Barrier performance</b>	<b>Test method</b>	<b>Test definition</b>	<b>Requirement</b>	<b>Anticipated fluid exposure</b>	
<b>AAMI Level 1</b>	Water resistance: Impact penetration AATCC 42	AATCC 42	Measures the resistance of fabrics to the liquid penetration of water by impact	Water impact ≤ 4.5 g	Minimal fluid levels
<b>AAMI Level 2</b>	Water resistance: Impact penetration AATCC 42 Water resistance: Hydrostatic pressure AATCC 27	AATCC 42	Measures the resistance of fabrics to the liquid penetration of water by impact	Spray impact ≤ 1.0 g Hydrostatic pressure ≥ 20 cm	Low fluid levels
<b>AATCC 127</b>	Measures the resistance of fabrics of the liquid penetration of water by impact under constant and increasing hydrostatic pressures				
<b>AAMI Level 3</b>	Water resistance: Impact penetration AATCC 42 Water resistance: Hydrostatic pressure AATCC 27	AATCC 42	Measures the resistance of fabrics to the liquid penetration of water by impact	Spray impact ≤ 1.0 g Hydrostatic pressure ≥ 50 cm	Moderate fluid levels
<b>AATCC 127</b>	Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure				
<b>AAMI Level 4</b>	ASTM F1671, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System	ASTM F1671	Measures the resistance of materials used in protective clothing to penetration by blood-borne pathogens using a surrogate microbe under conditions of continuous liquid contact.	Pass	High fluid levels

Association for the  
Advancement of Medical  
Instrumentation. Liquid  
Barrier Performance and  
Classification of  
Protective  
Apparel and Drapes  
Intended for use in  
Health  
Care Facilities.  
ANSI/AAMI  
PB70:2012. Arlington,  
VA:  
AAMI.

Filed Under: [2020-12](#)

--Randy Lott

### **We Love It that YOU Are a KAHRMM Member!**

It's February and love is in the air! KAHRMM loves having you as a member and invites you to [renew your 2021 membership](#) if you haven't received an email notice from me in December advising that your 2020 membership dues are extended through 2021.

To date, we have 68 active members across the state of Kansas. If you haven't yet renewed your membership, please complete the membership form included in this newsletter and submit it to Chrissy Fink, KAHRMM Treasurer, Salina Regional Health Center. If you had included your AHRMM membership renewal dues with your KAHRMM dues, please send your AHRMM renewal invoice to Chrissy Fink at [cfink@srhc.com](mailto:cfink@srhc.com), and she'll send payment to AHRMM. May this month bring continued health and safety to you and your loved ones.

--Lori Knoeber

### **KAHRMM Board Report**

The KAHRMM Board met via conference call on Jan. 20, with Mike Morgan calling the meeting to order.

Education for KAHRMM members is a top priority for the board, and much of the meeting was spent brainstorming ideas to bring offer education to our membership. Many challenges still remain due to the pandemic. The board continues to research and investigate all possibilities to continue education and networking for our membership. Discussion will continue with the possibilities of future in-person and virtual meetings. "Golf For Education" continues to be a topic as well. Members and vendors enjoy this time for networking, building relationships and seeing if anyone's game has improved.

If you have any ideas, suggestions for your board and/or organization, please do not hesitate to contact any KAHRMM Board member. Stay tuned for future updates.

### **Hospitals Keep Kansas Healthy and Economically Strong**

The following article was taken from the Jan. 15 issue of *KHA's Current Report Newsletter*. The article was written by Chad Austin, president, and CEO, Kansas Hospital Association.

*The Kansas Hospital Association works yearly with the Office of Local Government, K-State Research and Extension, to produce [The "Importance of the Health Care Sector to the Kansas Economy."](#) New data confirms the health care sector is among the fastest-growing in the economy. The entire health sector in Kansas employs more than 240,000 people and is the third-largest aggregate employer in Kansas.*

*Kansas hospitals alone employ nearly 100,000 people, or five (5.0) percent of all job holders in the state. These jobs are essential to serve our communities, but also have a ripple effect on the Kansas economy. For every job in a Kansas hospital, nearly another job (.96) was created in other businesses and industries in the state. Kansas hospitals have a total impact of 195,677 jobs.*

*According to the report, hospitals generated approximately \$7.5 billion in total income. For every \$1 of income generated by hospitals, another \$.64 is generated in other businesses and industries in the state's economy. As a result, hospitals have an estimated total impact on income throughout all business and industry of nearly \$12.3 billion. Funds spent to buy goods and services flow from hospitals to businesses and ripple throughout the economy. The impact on area retail sales generates nearly \$4.1 billion in the Kansas economy each year. Additionally, the hospital sector generates more than \$270 million in state sales tax. The state uses these critical funds for important programs such as education and transportation.*

*This report documented the relative importance of hospitals and the health care sector to the Kansas economy. While the estimates of economic impact are substantial, they are only a partial accounting of the benefits health care in general, and community hospitals in particular, provide to the state. Kansas community hospitals help to not only stabilize the population base, but also invigorate their communities and contribute significantly to the quality of life.*

*Kansas community hospitals are major employers and business partners throughout the state. As we continue to look for opportunities to enhance our state's economy and stabilize our population, a strong health care system, anchored by well-supported community hospitals, is essential.*

*In addition to this statewide report released this week, [county economic impact reports](#) are linked on the KHA website. These county reports will be updated with new data later this year. We encourage our members to use these reports as you discuss the economic impact of hospitals with your staffs, boards and communities.*

**KAHRMM Calendar of Events**  
**Virtual, On-Demand Now through June 2021**  
AHRMM20+ Virtual Attendees

**Aug. 9-11, 2021**

AHRMM21 Conference & Exhibition  
Boston, MA

**Sept. 9-10, 2021**

KHA Annual Convention & Trade Show  
Overland Park

**Oct. 3-9, 2021**

National Health Care Supply Chain Week

**The KAHRMM Bulletin Board**

**Message from AHRMM:** "After speaking and consulting with the AHRMM Chapter Relations Committee, we at AHRMM have made the decision to WAIVE CHAPTER RECOGNITION WORKBOOKS FOR THE 2021 YEAR. We realize that this past year has been extraordinary and this coming year looks to be no different. We hope this gives you the time to focus your attention where it's needed most."

**AHRMM Conference 2021:** [Click here](#) to sign up for updates for the AHRMM21 Conference & Exhibition.

**AHRMM:** [AHRMM20+ Conference & Exhibition](#) is now available on-demand. For additional information, please see [AHRMM's website](#).

**KAHRMM Membership:** The KAHRMM Board has elected to extend your membership into the year 2021 if you have paid your 2020 membership or pay them before the end of 2020. The new amount for dues is \$50.00 and \$75.00 after Sept. 30. Please see the [2021 KAHRMM Membership Form](#) on [KAHRMM's website](#).

**AHRMM MEMBERSHIP:** Consider becoming an [AHRMM member](#) for access to abundant information and resources. Explore [AHRMM's website](#).

**AHRMM Update on COVID-19:** For up-to-date information coming from AHRMM and AHA concerning the COVID-19, visit [www.ahrmm.org/ahrmm-covid-19](http://www.ahrmm.org/ahrmm-covid-19).

If you have updates from your Supply Chain you would like to share with your KAHRMM peers, please send them to [Cindy Howard Reeves](#).

**PLEASE VISIT the [KAHRMM WEBSITE](#).**



## **KAHRMM Mission**

The Mission of the Kansas Association for Healthcare and Resource Management is to advance the profession of health care purchasing and materials management by:

- Assisting members through training and mentoring opportunities which promote excellence
- Establishing proactive, collaborative partnerships through networking
- Promoting high ethical standards

## **KAHRMM Board of Directors**

[Mike Morgan](#), CMRP, President, McPherson, (620) 241-2251

[Lori Knoeber](#), CMRP, President-Elect, Salina, (785) 452-7497

[Craig Rohleder](#), Immediate Past President, Hays, (785) 623-5838

[Teresa McHenry](#), Secretary, NW Representative, Ellsworth, (785) 472-3111

[Chrissy Fink](#), RN, CMRP, Treasure, SC Representative, Salina, (785) 452-7949

[Lisa Feil-Neavitt](#), NE Representative, Atchison, (913) 360-5555

[Tammy Jackson-Noland](#), NC Representative, Parsons, (620) 820-5362

[Mick Pond](#), SE Representative, Neodesha, (620) 325-8367

[Pat Tabor](#), FAHRMM, FACHE, SW Representative, Lawrence, (785) 505-6131

[Larry Wenthe](#), Vendor Representative, Tescott, (785) 392-7644

**Ambassador:** [Cindy Howard-Reeves](#), Ulysses

## **Advisory Council**

- [Rebecca Flora](#), Phillipsburg;
- [Randy Lott](#), Salina;
- [Dale Montgomery](#), FAHRMM, Hays;
- [Corey Schmidt](#), CMRP, Shawnee; and
- [Cindy Howard-Reeves](#), Ulysses

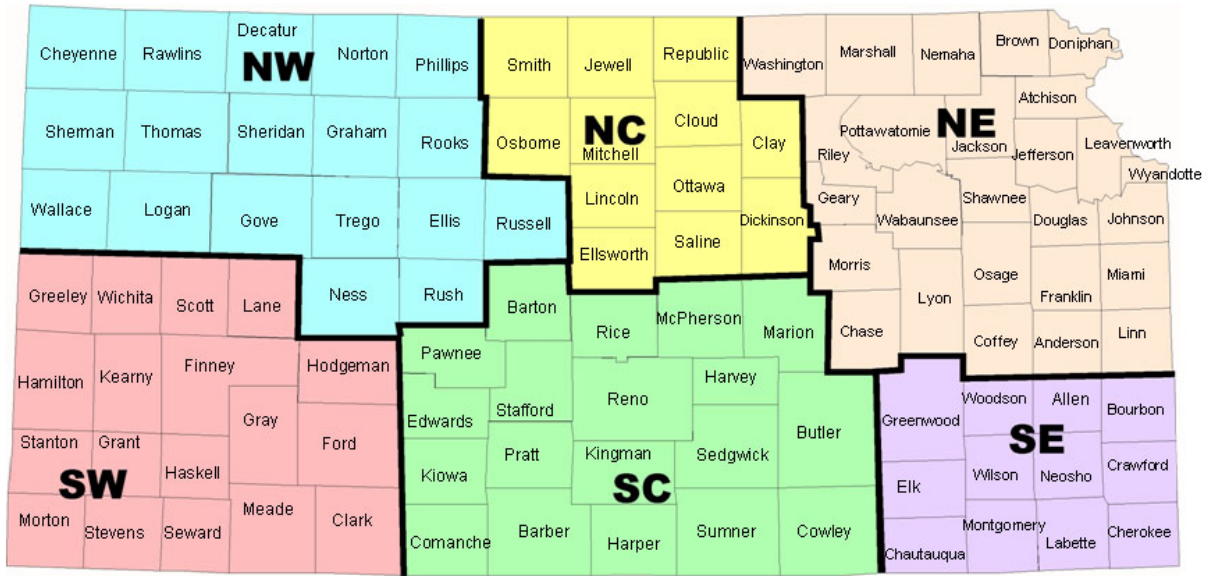
**KHA Liaison:** [Bruce Frerking](#), Overland Park

## **Committees**

- **Central Plains Expo:** [Mike Morgan](#) and [Randy Lott](#)
- **Chapter Affiliation:** [Cindy Howard-Reeves](#)
- **Finance:** [Chrissy Fink](#) and [Mike Morgan](#)
- **Golf:** [Randy Lott](#) and [Dale Montgomery](#)
- **Marketing:** [Mick Pond](#)
- **Membership:** [Lori Knoeber](#)
- **Newsletter:** [Cindy Howard-Reeves](#)
- **Program and Continuing Education:** [Lisa Feil-Neavitt](#) and [Tammy Jackson-Noland](#)
- **Scholarship:** [Chrissy Fink](#), [Mike Morgan](#) and [Lisa Feil-Neavitt](#)
- **Special Olympics:** [Dale Montgomery](#) and [Randy Lott](#)



### KHA DISTRICT MAP



# KAHRMM

Kansas Association for Healthcare  
Resource & Materials Management

Allied with the Kansas Hospital Association



## 2021 Membership Form

Active, voting memberships are available to persons professionally engaged in health care purchasing, resource or materials management; group purchasing organizations; as well as medical manufacturers, vendors or distributors. Membership may also be obtained by those professionals in other healthcare related settings not mentioned.

I hereby apply for membership in KAHRMM and/or AHRMM and certify that I meet the membership requirements.

Name (please print): \_\_\_\_\_ Title: \_\_\_\_\_

Employer Name: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_ County: \_\_\_\_\_

Phone: Work \_\_\_\_\_ Cell \_\_\_\_\_ Home \_\_\_\_\_

Email: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Hospital Employee \_\_\_\_\_ Healthcare Supplier \_\_\_\_\_ AHRMM Member \_\_\_\_\_

**KAHRMM / AHRMM One-check option:** AHRMM membership is not required for KAHRMM membership. As a service to our membership, KAHRMM will coordinate your AHRMM membership renewal payment. Select your KAHRMM and AHRMM membership options below, and send one check to KAHRMM for the total amount. **When your AHRMM membership is due to renew, send your AHRMM membership renewal notice / invoice to the AHRMM Treasurer and your AHRMM dues will be paid.**

KAHRMM \$50 \_\_\_\_\_ After Sept 30th \$75 \_\_\_\_\_ New or Renewal Member (please circle)

**Note:** Due to the initial AHRMM membership questionnaire, new AHRMM applicants are encouraged to join on-line at the AHRMM website ([www.AHRMM.org](http://www.AHRMM.org)). After your first year of AHRMM membership is complete, use the One-check option to renew your AHRMM membership.

**AHRMM Renewal Membership Categories** (Select one category - see AHRMM website for membership category descriptions)

Supply Chain Provider \_\_\_\_\_ \$165.00    Affiliate / Supplier \_\_\_\_\_ \$240.00    Military \_\_\_\_\_ \$165.00  
Supply Chain Executive \_\_\_\_\_ \$220.00    Young Professional Associate \_\_\_\_\_ \$135.00  
Full-time Student \_\_\_\_\_ \$109.00    Retiree \_\_\_\_\_ \$109.00

CMRP Year Earned \_\_\_\_\_

AHRMM Fellow Year Earned \_\_\_\_\_

KAHRMM	\$ _____
Renewal AHRMM	\$ _____
<b>Total Check Amount</b>	<b>\$ _____</b>

Make check payable to **KAHRMM** and mail to:

**Chrissy Fink, RN, CMRP**  
**Materials Management**  
**Salina Regional Health Center**  
**400 S Santa Fe**  
**Salina KS 67401**

Check # \_\_\_\_\_ Date Received \_\_\_\_\_

To renew with credit card, please contact Chrissy at [cfink@srhc.com](mailto:cfink@srhc.com).