## Result of the NWIP for reusable textile wrappers:

<table>
<thead>
<tr>
<th>No.</th>
<th>Contact Information</th>
<th>Comment</th>
<th>Response to Comment</th>
</tr>
</thead>
</table>
| 1   | Joe Przepiorka  
Vice President, Marketing - Acute Care  
Encompass Group, LLC          | We were recently informed that there has been a proposal to undertake a new work item on reusable surgical wrappers for the US, “STN135_NWIP on reusable wrappers.” As a U.S.-based manufacturer and distributor of reusable surgical wrappers, Encompass Group wholeheartedly supports the development and adoption of a U.S.-based AAMI-developed standard for this class of product.  
If adopted, this standard would give healthcare providers and other users of sterilization wrappers a choice for the products and tools that meet established standards and fit their needs the best, including those that prefer a reusable option that could help them reduce their medical waste stream and disposal costs.  
Please let us know how we may be able to assist in the development of the standard, and what potential next steps would be. We are interested in assisting in any way we can, to our abilities. |                     |
| 2   | Jacqueline Daley  
Director Infection Prevention and Control  
Sinai Hospital of Baltimore | Good afternoon Hae. I am voting for yes on the NWIP. I am guessing that there is not another document that covers this. I am not a formal member of this group so I do not have access to the other standards/recommended practices by this group. |                     |
| 3   | Janet Prust | Director - Standards and Global Business Development  
3M Infection Prevention Division | I would be interested in participating in the group.                                                                                                                                         |                     |
| 4   | Chuck Hughes  
VP, Infection Prevention Consulting Services  
SPSmedical Supply Corp. | Yes, I am interested in participating in this new WG. I live in Rochester, NY where a large number of local hospitals use reusable textile wrappers as well as many of our international customers. |                     |
<p>| 5   | Glenn Lankin | We are a manufacturer of reusable surgical wrappers selling into the |                     |</p>
<table>
<thead>
<tr>
<th>Quality and Regulatory Coordinator</th>
<th>American marketplace. Having reviewed the proposed new work item STN135_NWIP on reusable wrappers, we can state that we support the adoption of this work item by AMMI. Please let me know further details concerning how we may participate in the review process.</th>
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<tbody>
<tr>
<td>Donna Swenson</td>
<td>Here is the response from Synergy Health in regards to the NWIP on reusable wrappers. <strong>We do agree that further elaboration on Requirements for Termally Sterilized Reusable Textile Wrappers is needed. However, one standardized directive (i.e. ANSI/AAMI/ISO 11607) would be an option that we would vote for, rather than creating a new separate standard.</strong> If it is the decision of AAMI to move forward with this NWIP, Synergy Health will support the creation of this AAMI standard. Our comments on the draft document are attached.</td>
</tr>
<tr>
<td>6 Donna Swenson</td>
<td></td>
</tr>
<tr>
<td>Clinical Operations Manager SPD at Mount Sinai Hospital Chicago, IL</td>
<td></td>
</tr>
<tr>
<td>Synergy Health</td>
<td></td>
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<tr>
<td>7 Jackie Daly Johnson</td>
<td>It is not appropriate to develop this new standard for several reasons. Most importantly- the other types of sterile barrier systems, ones that are certainly more predominantly used in the US, do not have stand-alone US standards. Multiple types of sterile barrier systems are incorporated into ISO 11607 and the 16775 draft and that is the course we should take on this proposal. ISO 11607 already contains some information on reusable textiles, so the person submitting this proposal should instead propose a US sponsored work item for the anticipated 2015 revision work of ISO 11607. He would have the chance to present his draft at the April 2014 AAMI meeting, and that would give the US mirror group about a year to reach consensus on the specifics of the work item proposal before presenting it to the ISO committee. Along with his alterations of ISO 11607 he will also need to submit his suggested revisions to 16775, as the two are linked and must be considered together.</td>
</tr>
<tr>
<td>President Beacon Converters, Inc.</td>
<td></td>
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</tbody>
</table>
| 8 | Jeff Courey  
COO  
George Courey, Inc.  
Montreal, Canada | We are a supplier of reusable linens for nursing homes, long-term care homes, healthcare laundries and hospitals throughout North America and have been since 1910. I am in support of this new work item because I am a huge believer in reusable linens for surgical functions. This is not because I am in the business of selling reusable surgical linen, it is because I am a citizen of North America with a concern for the fiscal stability of our healthcare system as well as the sustainability of our planet. Not only are disposable products damaging to the environment, they also cost the end user a tremendous amount of money in the long term. I am in support of any modification to standards that reduces the disparity between reusable and disposable products. |
To add more rows to the following chart, go to the last cell (bottom row, "Comments" column) and hit your Tab key.

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<th>Name &amp; Affiliation</th>
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<th>Type</th>
<th>Comment</th>
<th>Proposed change</th>
<th>OBSERVATIONS OF THE Co-Chairs on each comment submitted</th>
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| Donna Swenson, Synergy Health PLC      | Page 2           | 3rd paragraph | E    | Comment/Objection: Change edition from 2012 to 2013  
Rationale: a new version of the AORN Recommended Standards has been published. | Alternative Text: AORN Perioperative Standards and Recommended Practices 2013 Recommendation IV. |                                                       |
|                                        |                  |           |      |                                                   |                                                                                                         |
|                                        | Page 3           | 3.11      | T    | Comment/Objection: Dates should be expressed in the YYYY-MM-DD format as per Final UDI Rule  
Rationale: dates should the follow the format of the Final UDI Rule | Alternative Text: 3.11 expiry date should be in the YYYY-MM-DD format  
Indication of the date, by which the product should be used, expressed in the Final UDI Rule format, YYYY-MM-DD |                                                       |
|                                        | Page 5           | Section 4.2.1 | NOTE | Comment/Objection: ISO 9001 applies to any industry covering generic quality management system requirements.  
Recommend compliance with ISO 13485, as this standard applies to medical device industry only.  
In this case the applicable design control clause would be 7.3 from ISO 13485. Remove ISO 9001 from the note.  
Rationale: ISO 13485 standard applies to the medical device industry only. | Alternative Text: NOTE – FDA 21CFR 820.30 and ISO 13485 clause 7.3 contain requirements for suitable design control requirements. |                                                       |
|                                        | Page 5           | Section 4.3.1 | NOTE | Comment/Objection: Remove ISO 9001  
Rationale: This standard applies to any industry, while ISO 13485 applies to medical device industry only. | Alternative Text: NOTE – 21 CFR 820 Quality Systems Regulations and ISO 13485 contain requirements for suitable quality systems. |                                                       |
|                                        | Page 6           | Section 4.4 | NOTE | Comment/Objection: Update ANSI/Z1.4-1993 to ANSI/ASQ Z1.4, and make it more generic as the current version of this standard is ANSI/ASQ Z1.4-2003 (R2013). Remove MIL Standard 105 as this standard was cancelled in 1995.  
Rationale: Cite current standards | Alternative Text: NOTE – Examples of suitable sampling plans are provided in ANSI/ASQ Z1.4, ISO 2859-1 or ISO 186. |                                                       |
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|                   | Page 11         | B.2.2     | T    | Strength | Comment/Objection: Add Tearing Strength of Fabrics by Trapezoid Procedure ASTM D5587, and ASTM D3787 Test Method for Bursting Strength of Textiles – Constant-Rate-of Traverse (CRT) Ball Burst Test Standards. Rationale: additional tests that should be used for testing wrapper strength | Alternative Text:  
   f) Tearing Strength ASTM D5587 “Test Method for Tearing Strength of Fabrics by Trapezoid Procedure”  
   g) Bursting Strength ASTM D3787 “Test Method for Bursting Strength of Textiles-Constant-Rate-Traverse (CRT) Ball Burst Test” | |
|                   | Page 11         | B.2.3     | T    |         | Comment/Objection: Add sensitization test requirement Rationale: additional test that should be performed | Alternative Text:  
   f) Sensitization Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization | |
|                   | Page 11         | B.2.6     | T    |         | Comment/Objection: Add 210 CFR 1610 Standard for the Flammability of Clothing Textiles Rationale: additional test that should be performed | Alternative Text:  
   c) Textile Flammability 210 CFR 1610 “Standard for the Flammability of clothing Textiles” | |
|                   |                 |           |      |         | Comment/Objection: Rationale: | Alternative Text: |