Message from the Chair

Dhuanne Dodrill
Committee F02 Chair

April’s Committee meeting in Phoenix was the first for me as Chair and Diane Trinsey’s first as Staff Manager. Filling the incredibly capable shoes of Hal Miller and Kevin Shanahan respectively was a daunting task. My thanks to them for the amazing job that they’ve done as well as to the Subcommittee Chairs and other Executive Committee members for ensuring the transition went smoothly.

I always find the discussions during the Subcommittee meetings enlightening and a wonderful learning opportunity. April’s meeting was no exception. A summary of the subcommittee highlights can be found later in the newsletter. However, I do want to highlight that a couple of new methods were proposed for development. Anyone interested in shaping methods for sharp puncture resistance, or impulse sealing can let me know.

Ram Signal’s presentation titled, “Packaging, Too Valuable a Resource to Waste” was eye opening. He provided some very compelling information about the energy recovery options for packaging and introduced

What’s New!

(Editor’s note: Periodically, we will attempt to highlight newly approved standards from the recent Committee F02 meeting.)

ASTM F2638, Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier, was initially approved in 2007. However, the reproducibility of the test method could not be determined since multiple test units were not available for conducting an inter laboratory study (ILS). In 2012 the ILS was completed and the precision and bias (P&B) statement was appended to the method. The revision of F2638 was balloted at the subcommittee and main committee levels and accepted at the April 2012 meeting; publication is in progress and should be available shortly.

This test method was originally developed as an alternative to microbiological tests so that results could be immediate and not have to wait 7+ days for incubation results. For porous materials, data from a validated physical test method that correlates with a validated microbiological test method are considered acceptable for determining the microbial barrier properties. The validated ASTM F2638 test method gives packaging engineers a valuable tool to quickly and reliably rank various materials. Additionally, this test method lends itself to in process quality testing for sterile barrier packaging material manufacture.

Once published, the standard test method will be submitted to FDA Center for Device, CDRH, for inclusion in the agency’s list of recognized standards. In addition, it will be submitted to ISO technical committee TC198 and working group WG7 so Annex B can be updated to reflect the test method now includes a statement of precision and/or bias repeatability and reproducibility.

continued on page 2

Inside This Issue

1 Message from the Chair
1 Feature: What’s New – F2638
2 News from Committee F02 Staff Manager
3 Subcommittee Blurbs
4 Barcelona Meeting Information
5 Committee Liaisons
6 Picture Gallery
What's Happening

continued from page 1

us to the 4R’s – Reduce, Reuse, Recycle, and Recovery.

F02 is considering forming a subcommittee to address sustainability issues related to flexible barrier packaging. An exploratory committee has been formed and anyone interested in joining the committee is welcome, just let me know.

Our Committee dinner at 1130 The Restaurant continued our tradition of great food and even better company. The highlight of the evening was the presentation of ASTM’s Award of Merit to a surprised Hal Miller. The Award recognized the significant contributions Hal has made to Committee F02 and to our industry as a whole. Some of the areas highlighted included the revision of the committee structure from subcommittees organized around markets to subcommittees organized around packaging characteristics and properties, F02’s first meeting in Europe in order to facilitate the participation of more international members, and the large number of standards that Hal authored. The Award of Merit is ASTM’s highest award given to members and an honor that Hal well deserved. Congratulations Hal!

The September Meeting in Barcelona is one that shouldn’t be missed. The Subcommittee Meetings have been coupled with some very interesting guest speaker presentations. The Subcommittee Meetings themselves promise to be very lively with:

• main committee ballot results of the new method for Verifying Flexible Barrier Material Resistance to the Passage of Air;
• the results of the interlaboratory study (ILS) of the alternate approaches for performing F1929 Seal Leaks in Porous Medical Packaging by Dye Penetration; and
• the ILS results of the new method under development on Detecting Leaks in Non-porous Packages or Flexible Barrier Materials by Dye Penetration.

If that is not enough, the meeting will be taking place in a beautiful city. I look forward to seeing you there!

Congratulations to the new Committee F02 officers:

Chair Dhuanne Dodrill
Vice-Chair John Spitzley
Membership Secretary Bob Thornburg
Recording Secretary Kent Hevenor

Virtual Classroom for Members/Navigation Videos

ASTM International is pleased to offer a series of free one hour online training workshops. There are several different training sessions offered to assist you as a member, including Balloting & Handling Negative Votes, Developing & Revising a Standard, Work Item Collaboration Area Training, ASTM Online Training, New Member Orientation as well as several others. I encourage all F02 officers to register for the Roster Maintenance training!

For more details on an upcoming session and to register, please click on the appropriate link(s) below. For a list of all the sessions, please click on this link: http://www.astm.org/MEMBER_TRAINING/

Balloting & Handling Negative Votes Training Workshop
Responsibilities for Task Group Chair & Technical Contacts
Developing & Revising a Standard Training Workshop
New Member Orientation
Work Item Collaboration Area Training
ASTM Online – Training Session
Interlaboratory Studies Program
Training on WebEx Meetings
Roster Maintenance Training

NEW - Website Navigation Videos

ASTM International is pleased to offer a series of three online training videos, including Member Login, My Committee Links and Submitting a Ballot. To access the videos, use this link: http://www.astm.org/MEMBER_TRAINING/howto.html

My Committee Links

Congratulations to the new Committee F02 officers:
**Subcommittee Blurbs**

**F02.10 Permeation**  
Mike Troedel  
Subcommittee Chair

Joel Fischer acted as SC chair for this meeting. Five laboratories have been identified for the ILS of F2476 CO₂ Infrared Detector. This standard is overdue because of no P&B statement. F13076 and F1927 will be reviewed for reapproval. E398 on water vapor measurement was originally developed for the old Honeywell apparatus and needs to be expanded to others via a new WVTR ILS. A collaborative ILS study involving the comparison of E96, E398 and F1249 on WVTR was started in March with 27 laboratories, and results will be discussed in Barcelona. Negatives were addressed on the new method for impermeability to the passage of air using a Gurley densometer and will be reballoated. The term non-porous was deemed better than impermeability. Additionally, the Scope will address exceptions such as diffusion and pinholes.

**F02.15 Chemical & Safety**  
Marilyn Baker  
Subcommittee Chair

F2638, aerosol filtration as a surrogate for microbial barrier, was approved with the added reproducibility in the P&B statement. (see feature article). Microwave test methods, F1317 and F874 will be reviewed for reapproval. F34, Practice for Liquid Extraction, will also be reviewed for reapproval, particularly since ASTM appears to be a defacto custodian for FDA food regulations in this area.

**F02.20 Physical Properties**  
Marie Tkacik  
Subcommittee Chair

F1921, test method for hot tack, was balloted with new P&B and resulted in one negative which was voted non-persuasive and upheld at main committee. The abrasion resistance test method will be re-energized with a new task group leader, Rick Clark. A new fast rate, sharp puncture test, other than slow rate, blunt puncture in F2132 will be investigated and reported on at the next meeting. Additionally, the need for a cut resistance test, and expanded heat seal ability guidance for other than heat sealers, such as impulse, RF and ultrasound sealers was discussed.

**F02.40 Package Integrity**  
Nick Winters  
Subcommittee Chair

D3078, Leaks by Bubble Emission, will add a Method B to allow vented packages to be tested. Additional edge dip and eye dropper methods for dye penetration, F1929, have completed the ILS and will be balloted in the next main ballot. ILS samples for non-porous dye penetration have been distributed to 8 test labs. Laser pinholes to 10µm and channels to 50µm (2 mil) will be challenged. Mike Grimm will establish a collaboration area to establish an initial draft for Head Space Analysis. Nick Winters will resurrect the airborne ultrasound test method. F2096-11, Internal Bubble Test, will be videotaped for inclusion in the standard.

**F02.50 Package Design & Development**  
Matt Gibney  
Subcommittee Chair

Matt Gibney was appointed new subcommittee chair by Dhuane Dodrill and the Executive Subcommittee. No standards activity occurred; however, F17, Terminology, will be revised to include common definitions in other standards since the last update in 2008. New definitions for conditioning, non-porous materials, impermeability and sterile barrier systems were particularly noted.

---

**Recently Added or Updated FDA Medical Device Recognized Standards in ASTM**

- D903-98(2010) Peel Strength of Adhesive Bonds
- F2391-05(2111) Helium Leak Testing
- F2475-11 Biocompatibility Guide
- F2825-10 Climatic Stress Practice
**NEXT MEETING**

**PLACE:** HOTEL REY JUAN CARLOS, BARCELONA, SPAIN  
**DATE:** 26-27 SEPTEMBER 2012  
**MEETING FEES:** $40 MEMBERS  
$115 NON-MEMBERS  
(WHICH INCLUDES A ONE YEAR ASTM MEMBERSHIP AND FREE VOLUME)

As most of you know Committee F02 will be meeting in Barcelona, Spain this September. Each of the Subcommittees will have a topical presentation as part of their agendas. Attendees will not only have an informative presentation but also participate in the standards process within each subcommittee. We are particularly interested in attracting new members to F02. Please let clients, customers or affiliates know about this upcoming meeting and steer them to the Barcelona meeting site at the end of this article.

Hotel Rey Juan Carlos has a separate reservation form that must be submitted to them either by fax or scanned email no later than 18 June 2012. We recommend booking your hotel reservation as soon as possible. Room rates: 170€ for a single / 185€ for a double.

Click here for a PDF of the Registration form.

**F02 MEETING AGENDA**

**Wednesday, September 26, 2012**

7:30-8:30 AM Coffee  
8:30-10:00 AM F02.90 Executive Subcommittee  
**Presentation:** Diane Trinsey, ASTM International - Developing Industry Solutions with ASTM International Standards

10:00-10:30 AM Break  
10:30-12:00 PM F02.10 Permeation SC  
**Presentation:** Franz Sturm, Lippke - Future Trends in Permeation Measurements

12:00-1:30 PM Lunch  
1:30-3:00 PM F02.15 Chemical & Safety SC  
**Presentation:** Thierry Wagner, DuPont Medical & Pharmaceutical Protection - Microbial Barrier Test Methods for Porous Sterile Barrier Materials

3:00-3:30 PM Break  
3:30-5:00 PM F02.20 Physical Properties SC  
**Presentation:** Henk Blom, Rollprint Packaging Products – Predicting Package Performance Testing With Physical Material Properties

6:00-7:00 PM Welcome Reception

**Thursday, September 27, 2012**

8:00-8:30 AM Coffee  
8:30-10:00 AM F02.40 Package Integrity SC  
**Presentation:** Wendy Mach, Nelson Laboratories – Package Integrity: Methods of Detection

10:00-10:30 AM Break  
10:30-12:00PM F02.50 Package Design & Development SC  
**Presentation:** Hal Miller, PACE Solutions - Use of Design Guide F2097

12:00-1:00 PM Lunch  
1:00-2:30 PM F02 Main Committee  
**Presentation:** Pat Weixel, U.S. FDA – U.S. FDA Perspective: The use of standards in premarket submissions and auditing the medical device packaging process  
**Presentation:** Pat Nolan, DDL – Sterile Medical Device Package Performance Testing and the Nebulous Effect of Vibration in Transit

The meeting announcement and agenda with presentation abstracts may be found at [http://www.astm.org/COMMIT/F02/Barcelona_Meeting_info.html](http://www.astm.org/COMMIT/F02/Barcelona_Meeting_info.html)

For further information contact  
*Diane Trinsey, Committee F02 Staff Manager*  
*Phone: 610-832-9661*  
*Email: dtrinsey@astm.org*

Committee F02 would like to thank the following sponsors who have committed to make the Barcelona meeting possible:

- Medtronic
- Cardinal Health
- Rollprint Packaging
- Systech Illinois
- Amcor Flexibles (Europe)
- Oliver-Tolas Healthcare
- Coca Cola
- Lippke/Mocon
- DuPont
- Spartan Design
- Anecto

*We haven’t met our goal, so additional sponsors are greatly appreciated!*
**COMMITTEE LIASONs**

**ASTM Committee D10 on Packaging**

Newly elected Chairman, Larry Anderson, presided over his first meeting with flying colors. Of particular note was the honoring of Pat Nolan with a well-deserved ASTM Award of Merit. Congratulations to Pat who happens to be an active F02 member as well.


---

**MEMBERSHIP REPORT (4/18/2012)**

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Producer</td>
<td>40</td>
</tr>
<tr>
<td>User</td>
<td>66</td>
</tr>
<tr>
<td>Consumer</td>
<td>0</td>
</tr>
<tr>
<td>General Interest</td>
<td>77</td>
</tr>
<tr>
<td>Unclassified</td>
<td>4</td>
</tr>
<tr>
<td>Totals</td>
<td>187</td>
</tr>
</tbody>
</table>

---

**Welcome New Members (10/23/2011-4/18/2012)**

- Rod Alire            Fp International
- Broc Couling        Medtronic
- Patty Curran        US AMC LOGSA PSCC
- Dorian Dixon        University of Ulster
- Jiajian Gu           Mocon, Inc.
- Christine Kasmar     JM Smucker Co
- Ondrea Kassaerjuan   Stryker Instruments
- Jacob Kowalski       Medtronic
- Minda McDorman       Sangart, Inc
- Rick Merical         Sealed Air Corp
- Eric Pearson         Boston Scientific
- Matthew Pilley       Mangar Industries
- Khalid Sheikh        A123 Systems
- Oliver Stauffer      PTI
- Michelle Stevens     Mocon, Inc.

---

**ISO TC122/SC 4 Packaging and Environment**

Subcommittee 4 has several new works in process, NWIP, to be discussed. One is to develop a “packaging and the environment” vocabulary. SC 4 will meet in Seoul on 24 May 2012. Committee D10 liaison will keep us abreast of happenings.

Comments from the DIS ballots on general requirements, optimization, reuse, material recovery, energy recovery, and organic recycling should also be reviewed at the Seoul meeting. These standards will then be balloted as a FDIS (Final Draft International Standard) which require only a yea or nay vote.

---

**Administrative Deadlines**

- Subcommittee Ballot #1 20 June 2012
- Main Committee Ballot 1 August 2012
- Meeting Minutes 1 August 2012
- Subcommittee Ballot #2 7 August 2012
- Meeting Agendas 14 August 2012

---

**Future Meetings**

- **17-18 APR 2013**
  - JW Marriott Indianapolis
  - Indianapolis, IN, USA

- **23-24 OCT 2013**
  - Hyatt Regency Jacksonville Waterfront
  - Jacksonville, FL, USA

---

**Headquarters Staff Support**

- Diane Trinsey (Staff Manager) 610-832-9661 dtrinsey@astm.org
- Jamie Huffnagle (Administrative Assistant) 610-832-9712 jhuffnag@astm.org
- Todd Sandler (Editor) 610-832-9731 tsandler@astm.org

---

What's Happening 5
Picture Gallery from Phoenix

Photos by Curt Larsen

Andy D’Esposito, Joel Fischer & Karen Green

VP Technical Committee Ops. – Kathie Morgan & Chairman of the Board – Ken Yarosh

Kent Hevenor, Marie Tkacik & Jan Gates

Nick Winters & Roger Allen

John Spitzley & Diane Trinsey

Hal Miller & Ken Yarosh

-- Members enjoying our F02 dinner social we have at every meeting. Why not join us next time? --
## Hotel Booking Form

### F02 ON FLEXIBLE BARRIER MATERIALS
25\textsuperscript{th} – 27\textsuperscript{th} September 2012, Barcelona, Spain

Please use one form per delegate. Please send fax this form back to the Hotel Rey Juan Carlos I: +34 93 364 42 32 or to reservas@hrjuancarlos.com, before the 25\textsuperscript{th} August 2012.

By sending this booking form, the Hotel cannot guarantee availability in case that all the allotment reserved for this event has been booked by other attendees. In that case reservations will be made on space availability basis.

### Delegate Information (please fill in)

I would like to make the following reservation at the special F02 ON FLEXIBLE BARRIER MATERIALS rate for the Hotel ReyJuan Carlos I:

- Double room for single use: 170 € per night
- Double room: 185 € per night

* Buffet Breakfast and VAT are included in the room rate

### Hotel Cancellation Policy

The reservation can only be confirmed with a credit card number + expiry date. All cancellations should be cancelled in writing.

- The indemnity will not be incurred if the cancellations are received 21 days prior to the date of arrival.
- Any cancellations received between 20 and 3 days prior to the date of arrival, will incur an indemnity equal to 1 night’s accommodation, included, in this case, any taxes and/or expenses that they could have earned, and it will be imputed as cost of opportunity.
- Any cancellation received between 2 days prior to arrival date as well as no-shows or early departures will incur cancellation charges equal to the entire stay, included, in this case, any taxes and/or expenses that they could have earned, and it will be imputed as cost of opportunity.

### Payment

Reservations can only be confirmed with a credit card number with valid expiry date.

- Visa
- Mastercard
- American Express
- Diners Club

Credit Card: ____________________________________

Card Number: ________________________________

Expiration Date (MM/YY): __________________________

Cardholder Name: ________________________________

Signature of Card Holder: __________________ Date: ___________

**Hotel Use Only**

Confirmed By: __________________

Confirmation Nr.: __________________

Signature: __________________