



What's Happening in Committee F02 Flexible Barrier Packaging

Spring 2012

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

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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.❖

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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

News from Committee F02 Staff Manager



**Diane
Trinsey**

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!

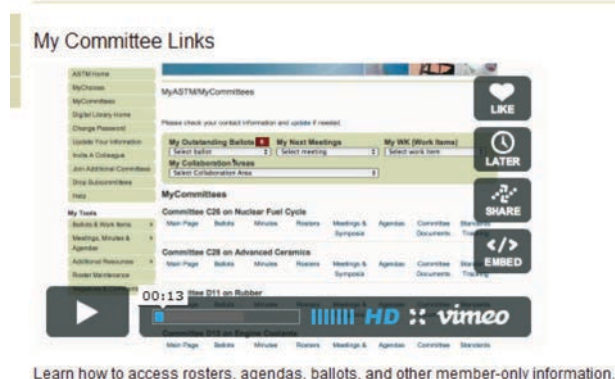
For more details on an upcoming session and to register, please click on the appropriate link(s) below. For a list of all the sessions, please click on this link: http://www.astm.org/MEMBER_TRAINING/

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



Learn how to access rosters, agendas, ballots, and other member-only information.

❖

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 reballoted. 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 Dhuanne 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

For further information contact

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

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

We haven't met our goal, so additional sponsors are greatly appreciated!

COMMITTEE LIAISONS

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.

Task Groups continue to work on updating Elements in D4169, *Standard Practice for Performance Testing of Shipping Containers and Systems*. Schedule J – Concentrated Impacts, Schedule G – Rail Switching, and Schedules D&E – Stacked and Vehicle Vibration will be balloted for revision.

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 ye or nay vote.

MEMBERSHIP REPORT (4/18/2012)

Producer	40
User	66
Consumer	0
General Interest	77
Unclassified	4
Totals	187

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 Merial	Sealed Air Corp
Eric Pearson	Boston Scientific
Matthew Pilley	Mangar Industries
Khalid Sheikh	A123 Systems
Oliver Stauffer	PTI
Michelle Stevens	Mocon, Inc.

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

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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? --



F02 ON FLEXIBLE BARRIER MATERIALS
25th – 27th 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 **25th 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.

Name: _____ Country: _____
 Company: _____ State-Province / Zip-Postal Code: _____
 Address: _____
 e-mail: _____
 Tel: _____ Fax: _____

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

Arrival Date: _____ Departure Date: _____

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

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