



MFRPA Board of Directors
Minutes
December 12, 2013

The meeting was called to order by Steve Mandernach at 12:30PM (Eastern).

Next Meeting

Thursday, January 9th at 2:00PM (EST) until 3:30PM (EST); 877-221-0336; 885-3585

In attendance

- Board Members
 - Kimberly Stryker (Alaska), Chair
 - Steven Mandernach (Iowa), Co-Chair
 - Natalie Adan (Georgia)
 - Adam Inman (Kansas)
 - Benjamin Miller (Minnesota)
- Advisors
 - Ellen Buchanan (FDA)
 - Ron Klein (AFDO)
 - Jim Melvin (North Carolina)
 - David Read (Minnesota/AFDO President)
 - Steven Sobek (Wisconsin)
 - Tim Weigner (FDA)

Absent

- Hitelia Castellanos (FDA)
- Matt Ettinger (Virginia)
- Tressa Madden (FDA)
- Michael Moore (Massachusetts)
- Steven Sobek (Wisconsin)

Minutes

The previous meeting minutes were approved by the board.

MFRPA 2014 Meeting Planning Process and Agenda (Ron Klein & Tressa Madden)

Ron and Tressa are continuing to develop the agenda. Ron received a new item from Pat Kennelly regarding standard number one. Ron is also working with Dan Rice and Yvonne Salfinger to finalize the Sampling Workshop. Ron and Tressa will take all feedback into consideration and modify the agenda accordingly. Board members and advisors can send additional comments to Ron (rklein@afdo.org) and Tressa (tressa.madden@fda.hhs.gov).

Inspector Training Prerequisites and Course Frequency (Kimberly Stryker & Dave Read)

Kimberly and Dave are continuing their work on this subject. They have a conference call scheduled with FDA to discuss.

Request for State Opinion on Standard Three Variance Process (Ellen Buchanan)

FDA's Audit Director, Ellen Buchanan is seeking feedback from MFRPA State Programs on the Standard Three, Risk Based Frequency. An email was sent to all Alliance members on 11/21/13 asking them to review and provide feedback to their respective MFRPA Regional Board Member. The deadline for comments was December 4, 2013.

Kimberly Stryker, Natalie Adan, and Benjamin Miller received feedback. Kimberly and Natalie sent their information to Ellen Buchanan. Benjamin will send his feedback to Ellen as soon as possible. Randy Young will post the various comments in one location that is accessible to the Alliance Board. The documents are available to the Alliance Board at <http://ti.afdo.org/standard3>.

The Board Members and Technical Advisors continued to discuss the language of standard 3. After each member had an opportunity to comment the Board asked Tim Weigner and his group to interpret and vet the standard 3 process.

Standard 10 (Ron Klein)

Prior to today's conference call, Ron Klein and Steve Sobeck discussed how to address standard 10 issues. Ron and Steve recommend using the Laboratory Steering Committee as they group to receive comments and report back to the Alliance Board.

OP/SIS Update (Tim Weigner)

On December 29, 2013 Michelle Motsinger will join the OP/SIS.

Action Items

- (12/12/2013) Tim Weigner and his group will interpret and vet Standard 3
- (11/21/2013) Kimberly Stryker will form a Training Prerequisites Workgroup
- (11/06/2013) Present provisional by-laws to entire Alliance for ratification at the March meeting (Alliance)
- (11/06/2013) Complete 1st Draft of Agenda by December 1st (R. Klein & T. Madden)
- (11/06/2013) Report room needs to AFDO office (Board)
- (11/06/2013) Draft CFP issue regarding standards harmonization (S. Mandernach)

Recently Completed

- ~~(11/21/2013) MFRPA Regional Board Members will submit Standard 3/Risk Based Frequency comments to Ellen Buchanan by COB December 4, 2013~~
- (11/21/2013) Tressa, Adam, and Randy will develop a method to collect recommendations for changes to the standards
- ~~(11/06/2013) Ellen Buchanan, Audit Director, submit questions for feedback to Kim for distribution to Board (E. Buchanan)~~
- (11/06/2013) Ron Klein will contact Steve Sobeck regarding standards 5 and 10 and the FSMA recommendations (R. Klein)