I. CALL TO ORDER

Chairman Keith Skiles called the meeting to order at 1:35 PM on May 27, 2014.

II. THE PASSING OF THE GAVEL

Keith Skiles thanked the Board for their support during his term and then passed the gavel to Maryanne Guichard, Chair Elect.

III. ROLL CALL

Ken Moore conducted roll call. The following members were present:

Board Members Present:	Representing:
Maryanne Guichard	Chair
Keith Skiles	Past Chair / VMC Chair
Patti Fowler	Vice Chair / Region 4 Regulatory / Task Force I Chair
Ken Moore	ISSC Executive Director
William Eisele	Program Chair / Conference Office Manager
Mike Hickey	Region 1 Regulatory
Lori Howell	Region 1 Industry / Task Force II Chair
Dave Carey	Region 2 Regulatory
Steve Fleetwood	Region 2 Industry
Julie Henderson	Region 3 Regulatory / AFDO Representative
Tommy Ward	Region 4 Industry
Jerrod Davis	Region 6 Regulatory
Margaret Barrette	Region 6 Industry
Terri Gerhardt	Non-Producing State
Quincy Boyce	Non-Producing State
Bruce Flippens	Non-Producing State
Paul DiStefano	FDA
Calvin Walker	NOAA
Bill Kramer	EPA
David Fyfe	Northwest Indian Fisheries Commission
Kirk Wiles	Task Force III Chair

Board Members Absent:	
A.J. Erskine	Region 3 Industry
Joe Jewell	Region 5 Regulatory
Chris Nelson	Region 5 Industry
Mike Pearson	Patrol Advisor
Greg Pallaske	Conference for Food Protection Representative

ISSC staff was also present.

IV. MINUTES

Maryanne Guichard advised Board members that a copy of the draft minutes for the March 6-7, 2013, January 27, 2014, and January 31, 2014, meetings had been provided in the Board materials. In response to an inquiry by Margaret Barrette, Ken Moore advised the Board that the Executive Office will re-distribute the Conflict of Interest Statement to Board members and ask for any comments within thirty (30) days of distribution. Paul DiStefano asked that his introductory comments in the January 31, 2014, minutes be corrected to state that the EU and FDA are working to recognize Spain, the Netherlands and the UK for US shipment and nothing is being

shipped at this time. Following comments on editorial corrections which will be made by the Executive Office, a motion (Lori Howell) was made that the minutes be approved. A second (Bruce Flippens) was made and the motion carried with a voice vote by the Board.

V. INTRODUCTORY COMMENTS

A. ISSC EXECUTIVE BOARD CHAIRPERSON

Maryanne Guichard said she is honored to be the new Chair and expressed her appreciation to Keith Skiles for his service as Chairman.

B. FDA

Paul DiStefano provided the following information to the Board:

1. Thanked Keith Skiles for his service as Chairman;
2. Bill Watkins will be retiring this year; and
3. The China ban on west coast product has been lifted.

C. NOAA

Calvin Walker provided the following updates to the Board:

1. Geoff Scott (Charleston Lab) will be leaving NOAA on June 1st to assume Chairmanship of the Department of Environmental Health Sciences at the University of SC in Columbia;
2. The suspension of receiving geoduck in China had been lifted; and
3. NOAA will be providing support for Vibrio research and forecasting models at the Seattle Research Center.

D. EPA

Bill Kramer did not have any additional comments since the last Board meeting.

V. PROGRAM CHAIRMAN'S REPORT

A. 2015 Meeting

Bill Eisele reported that the 2015 Biennial Meeting would be held in a non-producing State. He said Cleveland or Cincinnati, Ohio; Nashville or Memphis, Tennessee; and Salt Lake City, Utah would be considered. He will provide a follow-up at the October 2014 Board meeting.

B. Executive Board Meeting Schedule

Bill Eisele reported that the next Executive Board meeting would be held either October 6 & 7 or October 14 & 15 in Atlanta or Charlotte. Ken Moore asked Board members to send an email to the ISSC Executive Office stating their preference.

VI. EXECUTIVE COMMITTEE REPORT

A. Executive Committee

Ken Moore updated the Board on the following items:

1. Our FDA Cooperative Agreement will end August 31st. FDA has advised that our 2015 funding should be available September 1st.
2. The FDA Small Conference Grant will be closed out as soon as the remaining paperwork is received for the final two travel expense reimbursements.
3. The 2014 draft budget was shared with the Board in San Antonio but due to time constraints approval was carried over to this meeting. Minor adjustments have been made to accommodate the permanent status of Cathy Mantooth. A motion (Lori Howell) was made and seconded (Mike Hickey) to approve the budget as submitted. The motion passed with a voice vote by the Board.

VII. OLD BUSINESS

NOTE: Paul DiStefano asked for an update on the status of posting the State Vibrio Plans on the ISSC website. Ken Moore will check on this and report back to the Board.

A. 2013 Work Plan Evaluation
B. 2014 Work Plan Approval

Maryanne Guichard asked Board members to provide any comments on the 2013 Work Plan Evaluation and/or the 2014 Work Plan Draft to the Executive Office within the next (30) days.

C. *V.v.* Illness Review Committee Database

Ken Moore reported that the Committee had held a conference call and discussed the development of a database. He said there have been discussions with FDA on who will assume responsibility for the data base when Marc Glatzer retires. Ken said it has not been determined what type of database is needed to be able to look at fields and sort the data. Lori Howell said the Committee is moving forward and there are no current cases that need review.

D. Harvester and Dealer Training Programs
E. MSC Informational Meeting

Ken Moore informed Board members that the Executive Office has received notification of contract approval from NoreCORE for the award of monies which included funding for the harvester and dealer training programs and the MSC Informational Meeting.

Ken also reported that the MSC Oversight Committee had a conference call on Thursday to discuss the MSC Informational Meeting. He said that FDA will be providing travel expense support to the meeting attendees and NoreCORE will be providing funding for other activities and reviewing data. Ken said Geoff Scott is now with the University of SC School of Public Health and has offered the services of a graduate student to help with the MSC data call, project activities and project review.

F. FDA State Evaluations

Julie Henderson asked for a follow-up on the status of a report from FDA which was requested at the January 31, 2014, Board meeting. The request was that FDA report their compliance schedule and whether or not the frequency of that schedule is being met by FDA. Ken Moore said a report had been received from FDA and due to time limits this item was not on the agenda for today's conference call meeting. Paul DiStefano asked that Julie furnish written clarification of this request.

VIII. NEW BUSINESS

A. FDA Response to 2013 Summary of Actions

Ken Moore said that items needing Board action had been identified and reported the following:

1. Proposal 13-200 Reducing the risk of Vibrio illnesses

FDA concurred with ISSC referral of Proposal 13-200 to Committee. As appropriate, FDA will provide support to the Committee via participation of Agency *Vibrio* research and risk assessment experts to assist in addressing Committee charges as set forth in Proposal 13-200. The Agency will look to the Conference to advance recommendations made by the Committee for purposes of implementing appropriate controls to reduce the *Vibrio* risk. Results of ISSC actions in response to Proposal 13-204 will be integral to answering key questions associated with the Committee's charges.

2. Proposal 13-202 Requirements for Outbreaks of Shellfish Related Illnesses
    - A national conference call was held to discuss Vibrio illness reporting.
    - ISSC and FDA will coordinate and prepare for a national conference call with State Shellfish Control Authorities to talk about 2014 implementation of 13-202.

   Proposal 13-202 was adopted without a specific implementation date. Given its significance and intended public health benefits, FDA recommends Conference action to establish immediate implementation.
    - Recommended establishing an official implementation date of June 1, 2014. A motion was made and seconded that the Board approve the implementation date of June 1, 2014. The motion carried with a voice vote by the Board.
    - Recommended remaining issues are included in VMC charge for discussion.

      Attribution of cases to a state and harvest area:
      - How will multi-source illnesses be handled?
      - What are the public health rationale and criteria for case exclusion?

      1/100,000 risk per serving:
      - What is the process/criteria for determining risk/serving and compliance?

      How can retrospective annual risk/serving determinations be used to evaluate performance of state V.p. control plans?
      - Illness reporting:
      - Timeliness of reporting to state shellfish authorities
      - Engaging state epidemiologists and local health agencies to improve reporting of State notification of illnesses to ISSC and FDA

      Performance criteria for evaluating state compliance

      A motion to adopt this recommendation was made and seconded. The motion carried with a voice vote by the Board.

3. Proposal 13-203 Annual Assessment of Shellfish Production & Utilization
   Although not required by Proposal 13-203 as adopted, reporting landings by product category (half shell, post-harvest processing, shucked, etc.) would enable greater refinement to risk per serving calculations associated with shellfish intended for the half shell market.
    - Recommended the Executive Office communicate with States asking, when available, to provide this information. A motion was made and seconded to approve the recommendation. The motion carried with a voice vote by the Board.

4. Proposal 13-204 Vibrio Control Plans
   FDA has secured initial funds in the amount of $75,000 for the ISSC to begin implementation of Proposal 13-204. These funds will serve to assist States with

studies that support the intent of the substitute proposal. FDA is also looking at ways to provide resources and expertise from its Gulf Coast Seafood Laboratory to assist States with additional studies.

- Recommended appointing a committee to identify the type of studies that support the intent of 13-204 and the criteria for that should be used by ISSC in awarding funding. A motion was made and seconded to approve the recommendation. The motion carried with a voice vote by the Board.

5. Proposal 13-205 V.v. Control Plan Evaluations
   FDA continues to encourage States required to implement a *V.p.* or *V.v.* Control Plan to develop analytical capability and capacity to monitor total and pathogenic Vibrio levels. States are further encouraged to link Vibrio levels to corresponding environmental data, including air temperature, water temperature and salinity.
   - No Recommendation for action by the Board.

6. Proposal 13-206 Analytical Capability & Capacity for Vibrio Testing
   Most shellfish producing States experience environmental conditions within their shellfish growing areas at certain times that present a greater Vibrio risk. Development of the analytical capability and capacity to test for Vibrio within each state will greatly facilitate the characterization and control of this risk with regard to season, location, environmental conditions and industry practices. While Proposal 13-206 was not adopted by the Conference, FDA continues to encourage States required to implement a V.p. or V.v. Control Plan to develop analytical capability and capacity to monitor total and pathogenic Vibrio levels. States are further encouraged to link Vibrio levels to corresponding environmental data, including air temperature, water temperature and salinity. This will help establish baseline data that can be used to assess the effectiveness of Vibrio Control Plans and to make Vibrio management and control decisions. FDA has assisted a number of States with enhancing their Vibrio analytical capability and capacity by providing guidance, training and performance assessment. It is the intent of the Agency to continue to make this assistance available to ISSC stakeholders.
   - Recommended the Executive Office communicate with States to encourage them to gather this data where they can. A motion was made and seconded to approve the recommendation. The motion carried with a voice vote by the Board.

7. Proposal 13-209 Re-submerging of Shellstock
   FDA concurs with Conference action to refer Proposal 13-209 to committee. Proposal 13- 209 requires that a study be conducted to ensure that shellstock transplanted or re-submerged, for purposes of mitigating levels of naturally occurring pathogens, are allowed sufficient time to reduce levels to background. While the intended purpose of re-submerging is to reduce naturally occurring pathogens such as Vibrio spp. to pre-harvest levels, re-submerging also has the potential to greatly increase Vibrio levels, especially if shellstock purging is limited as a result of environmental conditions, handling practices, over-stacking, etc. If shellstock cannot effectively pump, Vibrio levels will remain the same or possibly increase, depending on water temperature. While re-submerging can effectively reduce Vibrio levels, as demonstrated by FDA-ISSC studies conducted in 2013, effective application needs to be scientifically demonstrated.

- Recommended Executive Office advise States this proposal was sent to Committee but ISSC suggests if a State is going to allow resubmerging that the State be careful to consider that the possibilities of resubmerging in certain ways will increase risk and ask States to give thought to this when permitting such activities. A motion was made and seconded to approve the recommendation. The motion carried with a voice vote by the Board.

B. V.p. Illnesses Data Conference Call (April 23, 2014)
Ken Moore reported ISSC and CDC held a national conference call to present data on Vibrio illness reporting. He said ISSC had received positive feedback from CDC.

C. 2013 NSSP Guide for the Control of Molluscan Shellfish
Ken Moore advised the Board that the process to update the Guide would begin since the Board has taken action on FDA's Response to the Summary of Actions.

D. 2014-2015 Committee Charges and Rosters
Following a discussion a motion was made and seconded to approve the rosters and charges for the 2014-2015 committees listed below with the following changes:

- Add Communications Committee
- Add Lori Howell to the Shellfish Resubmerging Committee
- Change Angela Ruple to NOAA on the Growing Area Classification Committee

1. Aquaculture Facility Inspection
2. Biotoxin
3. Chemical Contamination
4. Education
5. Foreign Relations
6. Growing Area Classification
7. HACCP Review
8. Import Assessment
9. Laboratory Methods Review & Quality Assurance
10. MSC Committee
11. Model Ordinance Effectiveness
12. NSSP Evaluation Criteria
13. Pathogen Review
14. Patrol
15. Plant Standardization Advisory
16. Post-Harvesting Processing
17. Program Review
18. Proposal Review
19. Recall Guidance
20. Research Guidance
21. Resolutions
22. Shellfish Restoration
23. Time/Temperature
24. Traceability
25. Use of Press
26. Vibrio Management
27. V.v. Illness Review
28. Wet Storage Tagging

E. Sanitary Transportation of Human and Animal Food
Ken Moore advised Board members that documentation had been furnished in the Board materials. He explained that FDA had asked for ISSC comments. Ken suggested that Board members read the entire regulation. Paul DiStefano informed the Board that the comment deadline had been extended for sixty (60) days until July 30, 2014. Following further discussion, a motion was made that the Executive Director draft comments in response to the regulation and distribute to the Board for comments. The motion was seconded and approved with a voice vote by the Board.

F. NoreCORE
Ken Moore advised that Board members had previously received a copy of the proposed contract with NoreCORE and that he would provide a final copy at the next meeting.

G. Time-Temperature Questions & Answers
Ken Moore advised the Board that as a result of Proposal 11-201B a workgroup had been formed to answer questions concerning interpretation of the new time/temperature requirements. He said these questions and answers will be posted on a designated page on the ISSC website.

IX. OTHER INFORMATION

A. Conference for Food Protection Issue
Julie Henderson reported on the CSPI issue submitted to the CFP which would require retail and restaurants to provide written warning statements if they serve raw oysters. She said the issue did not pass at the CFP Task Force meeting but will be considered at the CFP Executive Board meeting at CFSAN. Following further discussion, Ken advised the Board that he will distribute the issue and make recommendations to the Board on how to address the CFP issue.

B. Proposal 13-202
Mike Hickey presented a question with regard to Proposal 13-202. He said section F. 5. (a) had dropped the word "or" and asked if this was an oversight. Ken Moore explained that the original proposal was submitted by the Executive Office and a substitute was later distributed. Ken said this was an oversight and that this will be discussed with FDA and he will update the Board. He thinks if there is an agreement between ISSC and FDA the language change can be approved by the Board as interim action.

X. EXECUTIVE DIRECTOR ACTIVITIES

Ken Moore reported recent meetings attended and upcoming meetings.

XI. ADJOURN

A motion to adjourn the meeting was made and seconded. The motion carried and the meeting was adjourned at 3:03 PM.