

Maine Peer Team Review Summary (October 29, 2007- November 2, 2007)

Submitted to: Paul Anderson, Director Maine Sea Grant

Submitted by: Joe Migliore, Rhode Island State Shellfish Program
Tom Herrington, Retired FDA Shellfish Specialist
Lori Romick, Retired CT Shellfish Program Specialist

Date submitted: November 29, 2007

This is a summary report of a peer review of part of the Maine Department of Marine Resources (DMR) Shellfish Sanitation Program, conducted between October and November of 2007 in response to a request from Maine state officials. A more thorough discussion of specific findings, conclusions and recommendations follows this summary.

The review was conducted by Joe Migliore, Rhode Island Shellfish Program; Lori Romick, formerly of the Connecticut Shellfish Program; and, Tom Herrington, retired Food and Drug Administration (FDA) shellfish specialist; under a Maine state contract. The team was contracted to consider; 1) whether the Maine DMR exceeded the minimum requirements of the National Shellfish Sanitation Program (NSSP), 2) if sampling protocols are appropriate, 3) if standard operating procedures are appropriate, and 4) whether facilities and the program are adequate and appropriate. The review consisted of meetings and interviews with industry and various state officials, field site visits, and a review of various state reports. Specific industry concerns were addressed. The Review Team conclusions and findings were in agreement with FDA's previous findings.

Substantial paper review was conducted the week before the team visit to Maine and during the week following the field visits. Initial meetings, first with industry, and then with Maine DMR personnel were held in DMR's Boothbay Harbor Lab on October 29, 2007, giving opportunity for both parties to convey information and concerns. Under the field visit itinerary, site reviews were made along Maine's coastline of the following shellfish growing areas: Haraseeket River, George River, and Machias Bay. The team further requested a brief field review of a relaying area within the Weskeag River and Timber Cove in Whiting Bay (Cobscook Bay) in Lubec. A final meeting was held with both industry and Maine DMR personnel on November 2, 2007.

Maine's shellfish program and industry offer many unique opportunities and challenges. It was concluded that:

- Several of industry's specific concerns regarding DMR's use of salinity, data information, and pollution source sampling were a matter of misunderstanding and much of that concern was ameliorated or mitigated with the meetings that were held.

DMR agrees with this assessment.

- There was apparent mistrust and some hostility between industry and Maine DMR that can only be addressed through openness and honesty.

DMR agrees with this assessment and that communication needs to be improved. Efforts to date include: The Division Director and Volunteer Coordinator conducted presentations on NSSP basic criteria and how it is implemented in Maine last fall, winter and early spring at 9 shellfish committee meetings. These presentations were conducted as an

educational outreach component of the program. Staff members also routinely participate at Clam Day at the Fishermen's Forum and do presentations on whichever topic we are asked to cover by the Maine Soft-Shelled Clam Advisory Council. Additionally, field staff and Area Biologists attend shellfish committee meetings and other meetings as their schedules allow. The limiting factor on education and outreach is that staff members are conducting training and outreach on top of their existing scheduled workloads.

- Growing area classification boundaries are not all necessarily made in coordination with marine patrol authorities.

DMR makes most of its classification boundary lines with input from DMR Marine Patrol. DMR staff members do not routinely coordinate with municipal shellfish wardens because they are not the statutory authority for enforcement. Public Health Division staff members and MPOs sometimes coordinate with municipal shellfish officers on closure boundary lines when it is appropriate.

- Sampling protocols and standard operating procedures (SOPs) can be improved.

No recommendations were made in this report regarding what sections of the SOP need improvement.

- Specific legislative actions may be required to protect Maine's shellfish resources from future impairment.

DMR agrees with this assessment and will continue to work with other state, local and federal agencies that have statutory authority to make changes.

- Maine DMR does not exceed the minimum requirements of the NSSP requirements and additional sampling does not necessarily mean there will be any additional openings.

DMR agrees with this assessment.

Final Peer Review Team recommendations:

1. Additional Staff is required in order for the Maine Shellfish Growing Area Program to be able to comply with the NSSP-Model Ordinance requirements. Additional staffing will allow for: timely assessment of data, additional sample collection and studies, and timely preparation of reports.

DMR agrees with this recommendation

2. Biannual meetings should be held between industry and DMR representatives, the structure of which should be initial presentations followed by discussion. An independent moderator should also be considered. The meetings should also be staged to coincide with the biennial Interstate Shellfish Sanitation Conference (ISSC) to enable joint DMR/shellfish industry request for change to the NSSP Model Ordinance prior to the ISSC.

DMR agrees that biennial meetings should be held to coincide with the biennial Interstate Shellfish Sanitation Conference and that they should have a mutually agreed upon agenda.

3. A Shellfish Advisory Council should be established to act as mediator for DMR and industry.

DMR supports the formation of a Shellfish Advisory Council with members appointed by the Commissioner. The purpose of the council would be to investigate issues affecting the shellfish industry and provide advice to the Commissioner.

4. The Standard Operating Procedures (SOPs) should be finalized.

The SOP document that is currently in use is a final draft that has been in place since April 26, 2007 as noted on the cover page. Some sections are noted as being “under construction” in the shoreline survey section; i.e. WWTP evaluation, agricultural evaluation, etc. DMR staff members are working on finalizing those sections and will have them completed by April 1, 2008. It is a dynamic document that will continue to be refined and updated as needed.

5. Sampling protocol should continue to be standardized and should address subsurface sampling when the sampler is at a minimum knee deep water depth, and the sample is collected up-current, and away from floating objects such as seaweed. Samplers should be further evaluated to ensure that sediments are not disturbed in the collection area.

DMR realizes the challenges of quality control and standardization in sampling practices. DMR held mandatory field staff training on the new sampling protocol in April 2007. It included a line-by-line review of the written SOP and then a field component. DMR will be holding a winter sampling SOP staff member training in mid-January 2008. Each staff member must sign that they had training, understand and will follow the SOP. The field staff supervisory position also carries a workload of field work which precludes a lot of supervisory field time with subordinates. DMR will continue efforts to improve standardization and consistency among staff members. The Volunteer SOP has been updated and mailed to all volunteers and annual mandatory training (similar to staff member training) will be held in early 2008.

6. Water samples should not be collected at periods of “no water,” in rivulets or stagnant pools.

It is not a practice of DMR staff members or DMR certified volunteers to collect water samples when there is “no water” at the sample station or in rivulets or stagnant pools. It is clearly stated in the SOP on page 39 the following:

d. Locate the Sample Station

Every attempt should be made to collect the water sample as close as possible to the GPS mapped sample site position. Many sample stations cannot be collected during the lower tides simply because there is no water there at that time. Some samples can be collected if the sampler walks a short distance from the GPS mapped location, however, the sampler has to use his/her best judgment to determine if the water collected is still a representation of the typical water quality at the mapped location. Other important cautions include:

- i) DO NOT collect the sample from a channel or stream which may be flowing across the flat from the upland area. These streams are predominately fresh water and not representative of the water that the shellfish was exposed to at the higher tide stages;***
- ii) DO NOT collect your sample from puddles or pools that may have been stranded in depressions on the flat as the tide receded. Samples taken from pools or puddles at low tide are essentially a pollution source sample and are not representative of the water that the shellfish are exposed to at higher tide stages.***

There has been some confusion by the public about the difference between growing area samples and pollution source samples. DMR staff members collect samples from streams,

rivulets and seeps when conducting pollution source investigations. The pollution source samples are NOT used for classification purposes and these data are housed in a completely different database.

7. Sampling should be scheduled using the Systematic Random Sampling (SRS) method but should be timed during the day with respect to tidal conditions that allow for sample collection at the minimum water depth of 18”.

The DMR SOP stipulates that samples should be collected in water depths of 12 to 18 inches. Additionally, the Low Water SOP allows sample collection in water depths of at least 6 inches. The review team did not specifically address this part of the SOP and did not provide any reason to support their recommendation of sampling at 18 inches. Many tidal flats in Maine have depths of water much less than 18 inches during the lower tidal stages but are immersed in water. Shellfish are still siphoning at water depths of less than 18 inches on ebbing and flooding tides. Collecting only at 18 inches would severely restrict the tidal stages that samples could be collected at these stations. This would be in direct conflict with previous FDA guidance and the Model Ordinance.

The DMR will also begin assessing sample station placement in all growing areas this winter (2008). The Division Director has already scheduled time to begin the process.

8. Samples should be collected during various tidal conditions especially in areas where times of tidal impacts have not yet been adequately determined. Collection during both ebb and flood tides is acceptable.

DMR does collect samples during various tidal stages following the specifications in the SOP. This item appears to be in conflict with the previous recommendation. Collecting samples at only at 18 inches would severely restrict the tidal stages at which samples can be collected.

9. DMR should continue to collect salinity data.

DMR agrees with this recommendation.

10. Pollution source sampling should continue.

DMR agrees with this recommendation.

11. DMR should utilize volunteer industry or shellfish warden boats where possible for growing area classification sampling.

The Review team recommendation is a general recommendation and does not address DMRs concern about the exclusive use of boat sampling in some areas. The DMR does utilize volunteer industry and warden boats. However, in our SOP 4.0.3.3.2 Boat sampling there are restrictions on the exclusive use of boats in areas where access within 300 ft of the station would be difficult at all tides. Further clarification from the Review team with regard to this recommendation and with respect to our SOP would be helpful.

12. A simplified version of the NSSP statistical information should be presented for the local community.

A request for technical assistance to develop a simplified version of the NSSP statistical information has been submitted to our Regional Shellfish Specialist.

13. Additional sample stations should be added further out in bays and across growing areas that may be used to more specifically define classification lines such as in the Timber Cove area.

DMR does not understand the justification for this recommendation. The DMR has identified through shoreline surveys and sampling that pollution impacting shellfish growing areas comes from land. DMR does not have the resources (staff time or equipment) to conduct sampling offshore and across growing areas that are only accessible by boat. It is presently DMR policy when making classifications or reclassifications to extend the boundary to the next approved station. When this appears excessive for the pollution source new stations are established to reduce the size of the restricted or prohibited area. The coast of Maine is so extensive that even with the most well financed program it would not be possible to establish stations close enough together to minimize areas to be closed or restricted for harvest. Accelerated sampling may be conducted to establish enough data points to justify a smaller area.

14. The boundary line separating the conditional from the approved classification in growing area ER may be moved, thereby opening an additional harvest beach without compromising public health. (Station 8.0 to Station 45.0). This should be further reviewed by DMR.

The Machias WWTP discharges untreated sewage when it goes overboard. A hydrographic study was completed by FDA in 1976 to specifically answer the question of Randall Flats and Sanborn Cove. DMR does not think the Review team was aware of the existence of the Study when they made the above recommendation. The scientist responsible for the area will take the hydrographic study recommendations into consideration when reviewing this request.

15. DMR should consider the viability of remote area classifications.

Remote Status is defined under Chapter IV. @ (03)(A)(5)(e) and (f):

(e) Remote Status. A growing area may be placed in the remote status if:

- (i) A sanitary survey determines that the area has no human habitation, and is not impacted by any actual or potential pollution sources; and
- (ii) The area is in the approved classification.

(f) Seasonally Remote/Approved Status. A growing area may be placed in a seasonally remote/approved status requiring two water samples per year if the following criteria are met:

- (i) The area is initially classified as approved;
- (ii) The closure time period is defined; and
- (iii) At least one sample be taken upon reopening the area.

There is no place in Maine that is "not impacted by human habitation" and "not impacted by actual or potential pollution". DMR has asked FDA about this several times in some island areas but the requests have been denied because there is human habitation there and there is failing water quality due to fecal pollution.

16. A river gauge should be added below the confluence of the Kennebec and Androscoggin Rivers so DMR can more accurately assess impacts of river stage on those affected growing areas.

DMR agrees with this recommendation. The placement of river gauges is the responsibility of the U. S. Geological Survey. DMR requested that a river gauge be added to the Kennebec River below the confluence of the Androscoggin River back in 2000/2001; however, this request was not approved

17. “No Discharge Zones” should be established in critical shellfish growing areas.

DMR agrees with this recommendation. Currently, Casco Bay is a “No Discharge Zone”. Some towns have also designated their harbors as “No Discharge Areas (NDZ)”. The DMR currently is participating on an interagency panel of stakeholders on the education, outreach and enforcement of the Casco Bay NDZ. The Maine Dept. of Environmental Protection is the agency with statutory authority to implement NDZs.

18. Specific legislation should be enacted prohibiting overboard discharge into critical shellfish habitat.

DMR agrees with this recommendation but does not have statutory authority to implement the prohibition.

19. Dye dilution studies should continue to be conducted by trained parties but may be made a local requirement of WPCFs and NPDES permittees and at their expense.

DMR does not have statutory authority to require this but makes this recommendation to DEP when reviewing permit renewals. DEP has the statutory authority to require this.

We wish to thank all who made our visit possible and accompanied us, and the hospitality displayed by all parties throughout this evaluation.

Lori Romick, Joe Migliore, and Tom Herington

Maine Peer Review Report of Findings

Date of Review Site Visit: October 29, 2007- November 2, 2007

Review Team Members:

Joe Migliore, State of Rhode Island Growing Area Specialist

Tom Herrington, Retired FDA Shellfish Specialist

Lori Romick, Retired State of CT Shellfish Specialist

Introduction: The Maine Shellfish Industry campaigned for assistance from the Maine State Legislature requesting a review of the State Shellfish Program as administered by the Maine Department of Marine Resources (DMR). Maine Sea Grant advertised for shellfish growing area experts and developed a review process and plan for program component evaluations. A contract was developed and awarded to the chosen contractors by DMR requesting a review of the following:

A. Specifications of Work to be Performed

Contract item 1. Review DMR Public Health Division operations to determine if Maine exceeds the United States Food and Drug Administration Northeast Region minimum requirements for its Shellfish Sanitation Program. This is primarily in the context of how other state programs in the region are complying with the NSSP. If the review determines that the State does exceed these requirements then it should make specific recommendations for any areas where it feels the State is unnecessarily impacting the shellfish industry.

- **Review Team findings:**

- The classification line in Growing Area ER may be able to be reevaluated and moved if coordination is agreed with the shellfish warden and additional acceptable sample results.

The Machias WWTP discharges untreated sewage when it goes overboard. A hydrographic study was completed by FDA in 1976 to specifically answer the question of Randall Flats and Sanborn Cove. DMR does not think the Review team was aware of the existence of the Study when they made the above recommendation. The scientist responsible for the area will take the hydrographic study recommendations into consideration when reviewing this request.

- There were no inefficient exceedences with staff and time in sampling, except for the collection of samples at low tide when timing for sampling may be expended without the ability to collect a sample due to insufficient water depth. Determining the dates for sampling as required when using Systematic Random Sampling (SRS) and subsequently identifying the time of sampling for those dates with regards to tides would be more effective instead of predetermining a timeframe with no regard to tidal stage.

The DMR was found in non-compliance by FDA in the past when the practice of scheduling sampling based on the time of tide was in place resulting in mainly high tide sampling.

DMR staff members are assigned sample runs and that is all that is on their schedule for the day. It is more efficient to go back to stations a second time during the day when they are already in the area than to spend time and resources for multiple staff members to re-schedule the missed stations.

- The addition of offshore stations as sentinel samples with collection at various tidal stages is recommended in order to adequately monitor the entire growing area.

The DMR does not understand what the reviewers mean by “sentinel” samples. Most sampling stations are located near shore in proximity to potential pollution sources. DMR has areas where mid-channel samples had been added in river systems in order to monitor and assess what is coming downstream. DMR also has offshore sample stations in areas where monitoring the water quality around island systems and aquaculture lease sites is necessary. Current staffing levels prohibit DMR from fully implementing this recommendation.

- Boat sampling would be more efficient in some cases, if boats were made available by towns (when available) or assistance by governmental or agency professionals for sampling.

The DMR utilizes boats in some areas, primarily for offshore islands. DMR also allows volunteer groups, towns, municipal shellfish groups and concerned citizens to use boats. Some of the issues encountered with the use of boats for sampling are:

- Difficulty in obtaining the required number of samples per year to meet the NSSP requirements due to inhospitable weather conditions, the limited staff and boat resources and high maintenance and breakdowns associated with boat usage.
- Ability to sample by boat at all tide stages where there are long flat areas

With diligent effort DMR has managed to remain in compliance with sampling minimums for boat only accessible stations collected by DMR. Every effort is made to not increase the number of sample stations that are accessible only by boat. This is a challenge with respect to offshore islands. In order to resolve the noncompliance issue with volunteer collected samples, over the past two years DMR has reviewed sample stations with respect to land access. For onshore stations, sample stations only accessible by boat have been replaced with stations that are accessible by land or boat. Only a few boat only accessible stations remain. Some volunteers have a preference for collecting by boat. In order to stay in compliance with the systematic random sampling regime and to insure that the required number of samples will be collected, DMR has instituted a policy that if a volunteer cannot accomplish the sample run by boat (for whatever reason, weather conditions, boat problems, etc.) the volunteer will complete the run by land. If the volunteer chooses to not complete the run by land, they must notify DMR so that DMR staff can be scheduled to complete the scheduled run.

- The State needs to supply necessary/additional staffing and equipment to improve efficiency and effectiveness. This would allow for refining of the growing area classification. One example as observed during the field trips would be in Timber Cove. Additional sampling could possibly allow for a more timely management of the openings of that area. Additional staffing of the laboratories, especially the Lamoine Lab, would ease the burden with regards to collection times and possibly expand the number of days during the week for sample analyses. Currently there is only one full-time laboratory Staff member assisted by three full-time growing area specialists, who primarily conduct field work and assist with lab sample preparation, and one part-time seasonal summer hire.

Contract item 2. Review DMR Public Health Division Standard Operating Procedure (SOP) for Water Quality Sampling and specifically review all protocols related to following and make specific recommendations for any changes it feels are needed in either the SOP or to sampling site locations, including:

- review sampling stations locations as related to harvest/growing areas, fresh water inputs, access points and tide-related issues

The DMR will also begin assessing sample station placement in all growing areas this winter (2008). The Division Director has already scheduled time to begin the process.

- **Review Team findings:** A lack of additional stations offshore and across the growing areas may impact future FDA Program Element Evaluation Report (PEER) negatively. Additional stations may also allow for reclassifications.

DMR Note: there were no negative statements regarding the location of present stations; the comment was that more are needed – another justification for additional resources since presently DMR does not have the resources (staff or equipment) to conduct offshore and across growing areas (boat only accessible). It is presently DMR policy when classification/reclassification to the next approved station appears excessive for the pollution source to establish new stations to reduce the size of the restricted or prohibited line. The coast of Maine is so extensive that even with the most well financed program would not be able to establish stations close enough together to at times cause larger than needed (by going to the next approved station) areas to be closed or restricted for harvest.

- review appropriate depths for water sample collection
- **Review Team findings:** The current Standard Operating Procedure (SOP) revision requires samplers to carefully wade out to knee deep water and collect the water sample by plunging the Whirl-Pak bag 8”-10” below the surface, opening it and drawing in water up current. The review team observed samples being collected in the western area after the collector had physically moved seaweeds and at another station after significantly disturbing sediments. The current SOP requirements for sample collection are considered to be adequate by the review team, however more quality control and standardized training is needed. The collection of samples should be done as uniformly as possible as this is a procedure that may produce great variability in the data.

DMR realizes the challenges of quality control and standardization in sampling practices. As a result we held mandatory field staff training on the new sampling protocol in April 2007. It included a line-by-line review of the written SOP and then a field component. DMR will be holding a winter sampling SOP staff member training in mid-January 2008. Each staff member must sign that they had training, understand and will follow the SOP. The field staff supervisory position also carries a workload of field work which precludes a lot of supervisory field time with subordinates. DMR will continue efforts to improve standardization and consistency among staff members. The Volunteer SOP has been updated and mailed to all volunteers and mandatory training (similar to staff member training) will be held in early 2008.

- review whether (and how) salinity should be a factor in determining the utility of a water sample for growing area classification
 - **Review Team findings:** Salinity is not used to determine classifications but may be utilized as additional data and may be used to assess and track potential pollution transport into a growing area. DMR data indicates no significant differences in fecal results on either side of the tide. This information is very important with regards to environmental conditions for Vibrio species and should continue to be collected.
- review timing of sample in relationship to tidal stages
 - **Review Team findings:** The DMR should continue to add data in order to predetermine if and which tidal stages affect the growing area(s). The DMR uses Systematic Random Sampling (SRS) and currently predetermines dates and times of sampling for staff without considering the tidal stages during those times. It would be a more efficient use of time to determine sampling times for the SRS dates after reviewing the tidal conditions. The review team observed collectors having to go back to stations a second time during the day in order for there to be sufficient water depth to collect the samples. This is more time consuming than a predetermined time for samples when it is known that sufficient water will be available.

There appears to be a misunderstanding on the part of the review team regarding our sampling protocol. The DMR was found in non-compliance in the past when the practice of scheduling sampling based on the time of tide was in place. At that time, a review of the database indicated that the majority of samples at all stations had been collected at high tide. DMR is required by the Model Ordinance to determine if tidal stage increases fecal coliform concentration. ISSC charged FDA with investigating our program with regard to tidal stages and sampling. FDA found us in non compliance. Our present sampling regime was developed to correct this non compliance with this three part objective:

- To collect samples at all tidal stages at stations where water is present
- To document which stations samples cannot be collected at all tidal stages and for those stations determine the tidal stages that samples can be collected at

- To accumulate enough data points to be able to determine if a tidal stage increases fecal coiliform concentration

DMR staff members are assigned sample runs and that is all that is on their schedule for the day. It is more efficient to go back to stations a second time during the day when they are already in the area than to spend time and resources for multiple staff members to re-schedule the missed stations.

The field component of the review was scheduled to occur at low tide in order for the review team to see Maine shellfish flats at this particular tidal stage. This is the worse case scenario for collecting water samples and DMR's Low water sampling protocol is one of the points of concern with the industry.

- review mode of sampling (land-based vs. boat)
 - **Review Team findings:** It would be more efficient to utilize boats when available and in partnership with the industry and/or local enforcement agencies. The development of partnerships between local municipalities and/or industry representatives for boat transportation to collect samples has the additional value of community outreach and involvement. Land-based sampling is extremely time-consuming due to the overall logistics of driving the coastline, the distance a sampler has to walk out to collect a sample, and the general terrain. The weather is the main restricting force for boat sampling. The review team suggests that the DMR maintain land stations and add stations away from shore, striving to collect all, yet realizing that each type of sampling has its own set of constraints.
 - **Note:** Additional samples will burden the existing laboratory staff. The review team understands that the current laboratories capacity is adequate at this time for additional sampling but not the current level of staffing.

DMR agrees that in some cases it would be more efficient to use boats such as when there is sufficient water to sample within 300 feet of the sample stations. DMR is willing to work more closely with industry and/or local enforcement agencies that may be able to provide boat transportation to collect samples. In fact, boat sampling is routinely utilized by some volunteers.

- review appropriate time frame for utilizing historical water sampling data and potential for expediting review and possibly the reclassification of existing areas.
 - **Review Team findings:** The review of the DMR reports and the FDA PEER is consistent with other states operation and a function of staffing limitations. Reclassifications are currently being done with the Triennial Reevaluations. Again, additional staffing may provide for real-time review and expedited reclassifications.

The statement that DMR only does reclassifications during the Triennial Reevaluation is not correct. DMR does reclassify areas during periodic reviews of data when stations are no longer meeting approved standards to protect public health; classification changes are also made with annual reviews and during the year with addendums to sanitary surveys as resources and time allow.

- review the role of hydrographic studies in determination of sampling locations and in growing area classification.

- **Review Team findings:** The review team has read the presented materials with regards to dye-dilution studies and has taken all concerns into consideration. The studies have been thoroughly reviewed by past FDA shellfish personnel and it has been determined that sampling locations are adequately located, except for the addition of some stations in the middle of the growing areas, overlying shellfish waters.

Contract item 3. Review of the DMR Public Health Division should consider standard operating procedures from other states in the region to determine if there are other approaches that nearby states are using that would be appropriate for use in Maine and whether Maine's industry has been placed at a competitive disadvantage by any of the current procedures.

- **Review Team findings:** The two state reviewers feel that the Maine program is very similar to the procedures and management that is currently conducted in other nearby New England states. Again, the FDA PEERs have not identified any major significant procedural inconsistencies with regards to the National Shellfish Sanitation Program – Model Ordinance (NSSP-MO) and progress of the program areas has been made since the 2000 reports.

Contract item 4. Review DMR Public Health Division operations to determine whether the facilities and the program are both staffed and equipped adequately and appropriately to address the current and future needs of the shellfish industry and the general public. The reviewers will evaluate laboratory and field personnel workloads, laboratory space and capacity, and the role of non-DMR personnel (volunteers) in the program. If the review determines that deficiencies exist then it should make specific recommendations for any changes it feels are needed.

- **Review Team findings:**
 - The DMR is understaffed with regards to the growing area portion of the program. Additional staff is needed in order to conduct surveys and collect water samples in accordance with the frequencies specified by the NSSP-MO.
 - The review team commends the DMR for the work that is being accomplished and the difficulties due to the uniqueness of your coastline and environment is appreciated. Additional water sampling will impose additional burden to the already overworked and understaffed laboratories. It was stated to the team that the current laboratory space and equipment was sufficient.
 - Due to the lack of DMR boats, sample collection using the assistance of municipal employees or industry to provide boat transportation would also

promote stewardship and improve communication and trust between the DMR and industry. The review team does not recommend the use of industry for the actual collection of the water samples due to conflict of interest. The industry can volunteer transportation to the growing areas for the sample collectors.

While the DMR agrees with the statement about using industry members to sample as a conflict of interest, current law requires: “A commercial shellfish license holder who complies with the shellfish sanitation program’s quality assurance and quality control training and certification requirements as administered by the department may serve as a volunteer water quality sampler for the department.”.

- The use of municipal or local enforcement volunteers may provide the additional staffing needed, but this also requires a great deal of communication, quality control and program coordination.

We do not have the staff and resources to expand our volunteer program. The current Volunteer Coordinator is managing >200 volunteers that are geographically spread from Kittery to Calais. The coordinator also is responsible for managing volunteers for the water quality, phytoplankton monitoring and annual horseshoe crab count all of which run concurrently making it impossible for her to take on additional responsibilities at this time. The Department relies on volunteers for quality data which is assured through the coordinator’s ability to provide assistance, training and resources. Any more volunteers added to this stressed program would compromise quality assurance.

Contract item 5. Review of the DMR Public Health Division will likely involve at least 5 days in Maine with some time dedicated to visiting at least 3 shellfish growing areas. These areas will be selected by the DMR staff and industry to represent a variety of water bodies that will provide the reviewers the opportunity to see the situation from the field. The balance of time will be spent on file review in the two DMR laboratories in Boothbay Harbor and Lamoine, and also in interviews with Industry and DMR staff.

- **Review Team findings:** Monday, October 29, 2007 through Friday, November 2, 2007 were scheduled for the team visit, with Monday and Friday scheduled as meetings days before and after the three scheduled field days during the middle of the week.

B. Review Process:

A large volume of related materials including growing area reports, water quality data, maps, FDA evaluations, and a historical summary of program information were sent to the review team two weeks before the planned visit. A total of five days were scheduled for the review team to allow for meetings with all parties and for specific coastal site visits as related to the issues of concern. Days one and five were meeting days scheduled to allow for the exchange of information and question and answer sessions. The review team was in the field for three days in between, and escorted by representatives from the industry, DMR and the state legislature. Additional industry, enforcement and DMR representatives met the team at various locations to expand upon information, address specific growing area concerns, and point out site specific

efforts. The team observed commercial shellfishing activities, gathered information on the growing areas, pollution sources, and sampling locations. DMR representatives collected water samples and discussed pollution sources and surveys. Industry representatives relayed information of resource utilization and classification concerns. Local enforcement officials provided specific information with regards to activities of the areas and the local residents.

Discussions, questions and observations were recorded during the entire review. Additional informational material that was presented was reviewed by the team at the end of each day. The review team applied findings to the NSSP-MO requirements as well as discussed differences and similarities between the State of Maine Shellfish Program and other states. The team assessed the importance of observations and reported information and determined the need for change, if any.

C. Review Team Site Visit Summary:

Industry Concerns

What follows is a list of the areas that Industry would like the reviewers to evaluate and comment on. Suggestions should be made primarily in the context of how other state programs in the region are complying with the NSSP:

1. Location of growing area classification (GAC) stations as related to harvest/growing areas, fresh water inputs, access points and tide-related issues.
 - **Review Team findings:** The review team suggests that the DMR continue to finalize the SOPs implementing sample collection at a minimum water depth of “knee-deep,” or approximately 18” with the sample collected 8”-10” below the surface. Sampling routine growing area stations from stagnant or minimal water is not recommended as it creates unacceptable variability in the dataset and is not representative of the overlying waters with regards to the shellfish. The DMR SOP clearly states that water samples should not be collected from streams crossing a mud flat or from stagnant pools of water. Pollution source sampling may and should continue to be collected during low tide stages. The NSSP-MO requires sampling during tidal stages that, through data assessment, have shown to negatively impact the area(s).
2. Distinction between GAC stations vs. pollution monitoring stations.
 - **Review Team findings:** The pollution source samples may be collected during the routine sampling runs for the growing areas as a means of being more efficient as logistically returning to the same areas a day or two later for just the pollution source samples would waste a great deal of time. The data however is stored in separate databases. Collection of pollution source samples is required but a statistical review of a representative number of pollution source samples may allow for the deactivation of such stations and allow for better time management.
3. Random Sampling method versus Adverse Sampling method for different types of areas.

- **Review Team findings:** A validation of data indicating acceptable fecal levels is required to determine predictability with regards to automatic reopenings. First the trigger for closure must be identified. Then the recovery period has to be defined. This is done by storm tracking and intensive sampling. A large database of sample results collected continuously daily after non-point pollution events would be utilized to verify the time for growing waters to return to acceptable levels of fecal coliforms. Once the recovery period is defined and is consistent and predictable, a management plan can be written. Such verification studies are extremely time-consuming and labor intensive. The NSSP-MO requires that the areas must meet the “Approved” area classification criteria when open and defines the requirements for the operation of “Conditionally Approved” growing areas.

This is a good explanation of a conditional area; currently we do not have the staff or resources to implement any more conditional areas due to the explanation outlined. It should be noted that the data presented to the review team in the opening presentation (St. George River rainfall conditionally approved area) was of concern to the review team as not appearing to be “predictable” or “manageable”. Additionally, many of our seasonal conditional areas in the past 2 years have not been meeting the NSSP requirements to maintain their classification and so have been reclassified as restricted.

4. Rainfall conditional areas: their role in ME's Growing Area Classification Program; Guidelines on how to manage them.

- **Review Team findings:** A shellfish resource study should be performed in areas that sampling results and shoreline survey reports indicate there is a good chance of being managed as a conditionally approved area. If the resource appears to be productive and abundant it should be prioritized as a candidate for conditionally approved management. If and when the DMR obtains additional resources they may be able to include this in their work plan.

The Division is frequently asked by other agencies, non-governmental organizations and environmental groups about shellfish resources in areas. We currently do not have any comprehensive GIS data layer that has information on the location of shellfish beds. This winter, we are embarking on the process of mapping shellfish resources. The data will be systematically collected and added to data layers and will eventually be available on the Maine GIS website for public and other agencies accessibility. As a starter project, a staff member will be working on one small watershed. We will be sending out copies of NOAA charts to town shellfish committees in the near future. We are hoping that the committee members will draw circles on the charts where known shellfish beds are for American oysters, European oysters, surf clams, soft-shelled clams, razor clams, mussels and quahogs. The finished product should be mailed back to the assigned staff member where a GIS data layer will be created.

5. Standard Operating Procedure (SOP) for Water Quality Sampling: Depth for water sample collection, and distance from GAC station at which samples may be collected.

- **Review Team findings:** Most other states rely on boats sampling for the vast majority of their growing area stations. The review team also notes that Maine has a very extreme environment as compared to most other states making the utilization of boats possible. Most states follow the EPA guidance for the collection of bathing beach waters having a minimum of 36” of water depth and plunging the collection bottle rapidly below the surface to an approximate depth of 12”-18”. The Review team suggests that the DMR continue to finalize the SOPs implementing sample collection at a minimum water depth of “knee-deep,” or approximately 18” with the sample collected 8”-10” below the surface.

We believe the comment above should be stated as it is on page 10 of the Final Report 12-13-07 which states: “Most other states rely on boat sampling for the vast majority of their growing area stations. The review team notes that Maine has a very extreme environment, as compared to most other states, making the full year-round utilization of boats *impossible*.”

- **Review Team findings:** Evaluating a distance of 300’ may be difficult. Noting that the sample may have been collected away from the GPS location on the collection form is important. If the stations are significantly greater than 300’ from each other then 300’ feet of “leeway” would be acceptable.

6. Role of salinity to determine the utility of a sample for GAC.

- **Review Team findings:** The Review team was repeatedly told by the DMR that salinities are not used to determine growing area classifications. No collected data should be discarded. Salinity data collected at pollution source sampling location is kept in a separate database from the growing area data. Salinity data is a valuable tool and the usefulness was thoroughly discussed during the final meeting day of 11/02/07.

7. Access to GAC stations: Land vs. boat, AND

8. Use of municipal resources and volunteers: Role of DMR-trained personnel, municipal boats and vehicles etc.

For items 7 and 8:

- **Review Team findings:**
 - Most other states rely on boat sampling for the vast majority of their growing area stations. The review team notes that Maine has a very extreme environment, as compared to most other states, making the full year-round utilization of boats impossible.
 - Due to the lack of DMR boats, sample collection using the assistance of municipal employees or industry to provide boat transportation would also promote stewardship and improve communication and trust between the DMR and industry. The review team does not recommend the use of industry for the actual collection of the water samples as the interest may be conflicting. The industry can volunteer transportation to the growing areas for the sample collectors.

While the DMR agrees with the statement about using industry members to sample as a conflict of interest, current law requires: “A commercial shellfish license holder who complies with the shellfish sanitation program's quality assurance and quality control training and certification requirements as administered by the department may serve as a volunteer water quality sampler for the department.”.

- The use of municipal or local enforcement volunteers may provide the additional staffing needed, but this also requires a great deal of communication, quality control and program coordination. The use or expansion of a volunteer program does have its own inherent concerns with regards to quality control and dependability.

We do not have the staff and resources to expand our volunteer program. The current Volunteer Coordinator is managing >200 volunteers that are geographically spread from Kittery to Calais. The coordinator also is responsible for managing volunteers for the water quality, phytoplankton monitoring and annual horseshoe crab count all of which run concurrently making it impossible for her to take on additional responsibilities at this time. The Department relies on volunteers for quality data which is assured through the coordinator's ability to provide assistance, training and resources. Any more volunteers added to this stressed program would compromise quality assurance.

9. Threshold for initiating a state-wide flood closure.

- **Review Team findings:** It is up to the DMR to determine, via extensive post-rainfall sampling, the conditions that areas become impacted under and subsequently “clean-up” to acceptable levels of fecal coliforms. Most states do initiate state-wide closure at between 2.0”-3.0” and the areas remain closed for a minimum of two weeks. The DMR SOP initiates flood sampling on or after day three. DMR also conducts subset sampling to determine lingering impacts prior to reopening.

The DMR SOP states that post flood event sampling starts (with a subset of sample stations, not full sample runs) on the third day after the event has ended. DMR staff members often start sampling 24 hours after the event has ended due to industry pressure. DMR does not close on flood conditions for a minimum of 14 days. The 14 day minimum closure in Maine is utilized only for conditional areas.

DMR does not have the staff or resources to continue the random sample schedule for days after a flood closure event. DMR currently has no way to determine the conditions that impact areas or how long those areas take to return to background levels. DMR has a subset of “flood stations” that are sampled within a flood closed area in order to determine if those sample stations have returned to normal so that the area can be opened again for harvest.

10. Method for establishing boundary lines between open and closed areas.

- **Review Team findings:** Logistically, the distances between samples are a direct condition of the expansive linear miles of coastline. In order for the reclassification and upgrading of areas, there must be representative sampling station locations to create a classification delineation line. The current level of DMR staff is insufficient to accomplish additional sampling or area reclassifications.

11. Accelerated sampling for expediting review and possibly the reclassification of existing growing areas. Role of independent laboratories in ME's Program.

- **Review Team findings:** State programs that have regulatory duties are often cautious to allow for analyses to be conducted outside of their control. Strict regulatory criteria and minimal variability directly affect the areas available for market harvest. The DMR laboratory staff expressed concerns with regards to a loss of quality control if the utilization of commercial laboratories is allowed. Additional laboratories will also cause an increased workload on the Laboratory Evaluation Officer (LEO) as conducting additional quality control verifications and inspections at each approved laboratory. A more reasonable request may be for additional DMR laboratory staff.

The DMR currently allows for accelerated sampling in areas that meet the following criteria:

1.) it is well documented that identified pollution sources have been ameliorated and there is an updated shoreline survey,

2.) in the absence of identified pollution sources and the presence of an updated shoreline survey, new sample stations may be added to try and refine a smaller closure boundary line,

3.) during triennial report or sanitary survey report years.

12. Real-time closing and opening of growing areas based on P90 calculations.

- **Review Team findings:**
 - This issue was not addressed in the most recent FDA PEER. The DMR has stated that it normally reclassifies areas based on the Triennial Evaluations. This concern is a legitimate one as areas that may be impacted by fecal coliforms need to be closed. However, it is "normal" for states to reclassify during annual data assessments as one elevated result may not be just cause for the reclassification of an area. Elevated results must be addressed and both temporary closures and/or additional sample collection may be useful in identifying the predictability of the impacts.

The statement that DMR only does reclassifications during the Triennial Reevaluation is not correct. DMR does reclassify areas during periodic reviews of data when stations are no longer meeting approved standards to protect public health; classification changes are also made with annual reviews and during the year with addendums to sanitary surveys as resources and time allow.

Changes in classifications are detailed and justified in reports that area vetted and posted on the DMR website and we have been doing this since January 2006. Additionally, the SOP has been posted on the website since April 2007.

- Additional DMR staff would be extremely useful in this area as statistically sound assessments may be able to be conducted routinely in a more time-critical manner.

13. Hydrographic studies: their role in determination of sampling locations and in growing area classification.

- **Review Team findings:** The review team has read the presented materials with regards to dye-dilution studies and has taken all concerns into consideration. The studies have been thoroughly reviewed by past FDA shellfish personnel and it has been determined that sampling locations are adequately located, except for the addition of some sampling stations in the middle of the growing areas, overlying shellfish waters. The studies were conducted by trained recognized agencies even though there may have been differences in the methods or presentation. Utilizing local or state study requirements by outside contractors may be useful in the future especially with the permitting of wastewater treatment facilities, their renovations, and or pre-treated industrial discharges. The financial burden is then placed on the facility discharging instead of the state or municipality.

14. Cross-check method(s) for ensuring that only samples collected under the Random protocol get used for growing area P90 calculations.

- **Review Team findings:** The DMR has addressed this issue through its' SOPs and there have been evident improvements in the way that data is entered, checked, queried and analyzed. The review team advises DMR to continue with their quality control (Q/C) checks and improvements with their databases. Also note that additional Q/C of data involved additional staff time.

Industry Advisory Panel/ Review Team Meeting October 29, 2007, Boothbay, 9:30 am

Summary of Industry Meeting Discussions:

The industry was assisted by State Representative David Webster. Representatives from the industry included commercial diggers, clammers, aquaculturists, shellfish commissions, the Maine Seafood Alliance, Maine Clam Association and local law enforcement officers. Valy Steverlynck, a shellfish grower from the Town of Freeport was the organizer and a spokesperson. (See attached list of participants.)

The meeting began with a review of the Interstate Shellfish Sanitation Conference (ISSC) and the National Shellfish Sanitation Program (NSSP) as voiced by Team Specialist Tom Herrington.

The discussion progressed to a review of the shellfish industry including types of shellfish (species) and harvesting methods and gear types. Much of the shoreline is hand dug by commercial diggers for soft-shelled clams during periods of low tide when the extensive flats are exposed. The soft-shell clam resource is extremely important to the industry across the coastal towns. The mahogany clam fishery is primarily located offshore in deeper waters and is

primarily affected by phytoplankton blooms that may cause paralytic shellfish poisoning. *Mercenaria* (hard clam) and surf clams (*Spisula*) are harvested to a lesser degree both intertidally. Mussels are often cultured, hand picked, and harvested by dredges dragged over the bottom. Oysters are extensively cultured with almost no natural setting. Maine also has a limited scallop and razor clam fishery.

Discussion continued regarding the growing areas and classifications. The industry indicated that the Maine DMR was working on a Standard Operating Procedures Manual (SOP) and that much progress has already started but that the industry wished for this to continue until completed. There had been recent area closures and the industry feels that Maine's sampling restrictions are tougher than those in other states.

The industry was concerned about the techniques used to collect samples and the standardization between different collectors. There were concerns raised with regards to samples being collected during low tide which along most of the shoreline meant no water. The DMR collects samples using Systematic Random Sampling (SRS) methodology instead of Adverse Pollution Collection (APC).

The industry was concerned with regards to the samples being collected with no water present. Such samples would not be representative of condition shellfish are being exposed. Some growing areas only have water for six (6) hours, two times per day. Tides can change substantially from 12 feet to up 30 feet along the coast. The industry also raised concerns about testing in streams and not necessarily over the shellfish growing area. There were concerns raised of past samples that were collected on foot from land of water in stagnant depressions.

The NSSP MO requires that sampling be collected during conditions that may negatively impact the growing areas, or the waters that the shellfish are subject to. A lengthy discussion took place regarding the location of stations vs. changes in pollution sources since the original station location. Questions regarding the distance between stations and the classification lines were debated. The industry wanted to know how the DMR determined the pollution sources and the classifications. Questions regarding pollution sampling vs. routine growing area sampling were raised.

The industry stated that there are only three growing areas that area classified as "Conditionally Approved" and closed based on specified rainfall amounts. The Industry wanted more "Conditionally Approved" areas. The flood closure conditions including the statewide 3.0" closure trigger were also discussed.

The industry felt that more labs are needed to analyze the samples. Questions regarding the collections of samples during ice conditions were also addressed.

The timing of reclassifications was a concern as the industry felt that too much time passes before reclassifications are made.

Overall the industry expressed a genuine desire and need to improve communication and build trust with DMR.

A letter was presented regarding competency and uniformity concerns with hydrographic studies and their significance. The response was that FDA is fully qualified and considered as experts.

Each of the review team members have worked with the FDA groups, support them and consider them fully competent in these studies and their formal training.

Question regarding the need for diggers to have a dealers permit and to have a refrigerated vehicle or whether they can sell shellfish at their home was discussed, if they do not have a reefer truck they cannot sell to retail directly.

Summary of Discussions: DMR Meeting, October 29, 2007

Maine DMR representatives:

Amy Fitzpatrick, DMR Public Health Director
Mercuria Cumbo, DMR Water Quality Laboratory
Jan Barter, DMR Boothbay Lab
Robert Goodwin, DMR Lamoine Lab

Industry Representatives:

Valy Steverlynck
Dan Devereaux

Note: DMR was not present during the industry meeting earlier that morning but industry was present during the DMR meeting.

Amy Fitzpatrick presented a PowerPoint slide show. In summary, there are more than 5,300 miles of coastline with 800-1,200 miles assigned per growing area staff person, totaling six. These people also help with the lab. There are 14 seasonal program people and 86 volunteers covering 33,000 sq miles of growing areas, including more than 60,000 acres of mud flats. There are two labs that analyze samples from 1,463 stations a minimum of five (5) runs per week with 20-25 samples per run three days a week annually. The Laboratory also analyzes dealer well water samples. The work load for the PSP program is great. Volunteers will have to sign an agreement regarding sampling protocols as part of the revised SOP and attend an annual standardized retraining.

DMR uses SRS and has three (3) rainfall “Conditionally Approved” areas. The DMR has not adequately determined all tidal impacts to the sampling stations yet. Closure is initiated in areas after more than 2.0” of rain and statewide closures are enacted after ≥ 3.0 ” of rain. Subsets of runs are sampled after heavy rain conditions to assess lingering impacts prior to reopening. The DMR has both routine growing area classification sampling stations and pollution source monitoring stations. River stage was also addressed. The cost of press releases was discussed.

The vast majority of samples are collected by land due to several factors; pollution sources are from the land, the subtidal areas are extensive, the drop in tide is extreme and can leave vessels stranded, times of sample with sufficient water depth is short, and travel time by boat or with a trailer is restricted due to distances and weather (ice, waves, wind, fog). Sampling by boat requires two people while only one is required by car. All stations have global positioning system (GPS) coordinates.

Pollution source samples, such as pipes or ditches, in growing areas not open are not used for growing area classification. The DMR collects both routine samples that are used to classify growing areas and pollution source monitoring stations at the same time as a means of efficiently monitoring both. Pollution source monitoring is an important tool in determining the level of

bacterial contamination entering a growing area and the predictability. A chronically, extremely elevated station (pipe, culvert, ditch) is one that must be studied further and abated. A source that occasionally is flowing with elevated bacterial levels will not impact the shellfish growing areas constantly.

Sampling procedures (SOPs) have been redefined to allow for land sample to be collected with water depths of 18" and a plunge depth of 8"-10".

DMR has reclassified areas with downgrades from 2003-2007. The majority of upgraded classifications were from "Prohibited" to "Restricted-Relay."

Salinity data is collected but DMR does not use salinity for any area classifications. The salinity data is used to determine if there is a freshwater pollution source for traceback and follow-up action and for use with temperature data to monitor environmental conditions with regards to *Vibrio* species.

Field Site Visit: October 30, 2007 Harraseket River Area (Shellfish Growing Area J)

Macquoit Bay, Whistler's Cove (low) and Sandy Beach were visited and included pollution source sampling and growing area classification station discussions. The review team was accompanied by DMR (Amy Fitzpatrick and Laura Livingston), Dan Devereaux for the industry, Tom Kay a local enforcement officer and Legislator David Webster.

The team discussed land sampling, station locations and sampling techniques. The team observed samples being collected with little or no water after moving seaweeds and after disturbance of sediments. Samples were attempted to be collected at preset times irregardless of tides. The team felt that this was a waste of time especially when attempts are later made to collect the sample again at a later tide.

The team observed maps with no closure lines for areas with undetermined water quality. It was noted that the river gauging station on the Kennebec River was not located at the confluence of the Kennebec and the Androscoggin Rivers and should be moved or an additional river stage monitoring station should be installed.

Field Site Visit: October 31, 2007 Saint George's River Area (Shellfish Growing Areas U and V)

Participants: DMR (Amy Fitzpatrick and Fran Pierce), Dan Devereaux for industry, Neil Pollis representing local enforcement and Butch Taylor from the Saint Georges River Shellfish Committee.

The team reviewed land sampling in Prohibited, Conditionally Restricted, Restricted-Relay, and Conditionally Approved growing areas. The conditions and survey for the identification of pollution sources was discussed. The need for straight visible delineation lines for area classifications is important to law enforcement.

On 10/31/07, after the field work, a late afternoon meeting between the review team, DMR and industry representative Dan Devereaux took place at the Holiday Inn.

The concern regarding the use of salinity data had been discussed each day with several representatives and was clearly a point of contention. Mercuria Cumbo prepared and presented salinity data analyses. Results showed no significant difference of fecal levels between the different stages of tide. A general trend showed lower fecal levels at higher salinities. Since 2000, an effort has been made to collect samples under all tidal conditions. During dry weather conditions, fecal levels were higher in samples collected with lower salinities. Fecal levels were elevated significantly after rain and with lower salinities indicative of non-point pollution (runoff).

This meeting was scheduled on the agenda indicating “DMR” and industry to be present. Dan did voice objection, stating that Mercuria was not actually listed to speak. Dan was present for the entire meeting and suggested that Mercuria present the same information at the industry meeting scheduled for the last day of the visit.

Eastern Maine Field Site Visit: November 1, 2007 Machias Bay, Buck’s Harbor, and Timber Cove.

Participants included: DMR (Amy Fitzpatrick and Rob Goodwin), and industry represented by Dan Devereaux, Ginny Olsen, Jeremy Wood (Machiasport Shellfish Commission), and Julie Keene from the Lubeic area.

Impacts from farm animals were observed. All samples were collected from land with no offshore sample locations designated.

One area was classified as “Conditionally Approved” based on Wastewater Pollution Control Facility (WPCF) performance, and combined sewer outflow (CSO) and pump station bypassing. The areas along the rivers had registered overboard discharges (OBDs) constituting a point source. These systems collect sewage waste from several area homes and are not inspected or evaluated for performance. Maine currently does not have a “No Discharge Zone.”

This entire area is extremely important to independent diggers for soft-shelled clams. It was noted that the report for this area did not reflect the current classifications even though it was finalized after a reclassification of the area. An updated summary reclassification report and justifying data is needed.

The amount of current staff to adequately monitor this area is clearly insufficient.

A discussion regarding a classification delineation that may be moved between the Conditionally Approved and Approved area at a point from Station 8.0 to Station 45.0 to open the clam flat that is currently closed.

Additional stations offshore should be added to this area as there is resource that is harvested.

Misunderstandings were resolved regarding the interpretation by the industry of the statistics, specifically the 90th percentile (P90). DMR needs to develop a clearer explanation so that the industry can understand. A simplified version of the statistics may be helpful.

The team met with Julie Keene and her sister (soft-shell clammers) to review a Timber Cove site in Lubeic. There were concerns over a stream flowing from two ponds above surrounded by homes. The industry concern was for unnecessary closures due to lack of information. The DMR staff assigned to this area has been addressing this concern and conducting follow-up work with regards to shoreline survey working the entire area.

Summary of Discussions - Final Meeting Day with Industry and DMR: November 2, 2007

Mercuria Cumbo (Laboratory Supervisor) presented the salinity information. Sample data was statistically analyzed for trends in salinity and tides from 188 coastal stations located within 300 feet of a freshwater source and collected using Systematic Random Sampling. The fewest number of samples were collected at low tide representative of the lack of available water. Results showed no significant difference of fecal levels between the different stages of tide. General trend showed lower fecal levels at higher salinities. Since 2000, an effort has been made to collect samples under all tidal conditions. During dry weather conditions fecals levels were higher in samples collected with lower salinities. Fecal levels were elevated significantly after rain and with lower salinities indicative of non-point pollution (runoff).

It was made clear that salinity is an important tool for addressing impacts from freshwater sources with regards to follow-up remediation actions. Salinity is also an important data set with regards to monitoring environmental conditions with regards to *Vibrio* bacteria. This issue was answered satisfactorily to the industry and put to rest as a concern. The Maine DMR does not use salinity to classify growing areas. The DMR collects routine growing area classification stations as well as pollution source monitoring stations sometimes at the same time but maintains two separate databases for the sample results.

A review of the laboratories capabilities with regards to space and equipment currently allows for less than 350 samples per day for no more than three days a week between the two labs. They currently run up to 12,000 samples a year could be increased to 15,000 samples a year with a sampling coordinator.

The importance of sampling properly by opening the bag under water at depth and collecting the sample at the correct locations was thoroughly discussed. The current SOP requires walking out to knee-deep water and collected the sample at a depth of 8"-10" of depth. Although the SOP is not finished it is moving slowly toward completion. Annual retraining is being conducted as a means of standardizing sample collectors and volunteers will have to sign an agreement.

Emphasis was placed on the economic importance of the shellfish industry in eastern Maine and the industry's request for the DMR to continue to consider the hardship incurred with closures.

There is a need for industry involvement with local committees and commissions to plan for future area development and impacts. The need for a Shellfish Advisory Council was also addressed. Annual forums were suggested as a means of continuing communication with presentations and dialogue that is developed in an understandable way. The value of statistics, including the P90 (90th percentile) calculations was reviewed. Industry, DMR and FDA are a team that needs to utilize each others capabilities and experience.

It was suggested that DMR consider the possibility of remote area classifications.

Conclusions:

The NSSP through the ISSC is meant to be a cooperative program. All parties must be actively involved, familiar with the program and willing to learn from their involvement to achieve success. The ISSC is an avenue to propose change. Each entity has a primary charge that defines the areas of their concern. The DMR has the primary charge of protecting public health through regulation by remaining in compliance with the NSSP-MO. The industry has a responsibility to work with the DMR in assuring that a safe wholesome product is harvested and offered to the consumer while working to enhance and maintain production of the economic resource. The FDA provides reviews, oversight, interpretations and training.

The shellfish industry is not alone in being regulated. All food production in the United States is regulated to some degree. Shellfish are eaten raw, whole and alive and thus are a potentially hazardous food with a greater risk of illness than many other protein food items.

Maine is unique in the Northeast region as it has by far the most extensive coastline with more than 5,300 miles and more than 60,000 acres of mud flats. The staffing is evidently insufficient to adequately adhere to the requirements or to be able to take on any additional special studies. The location logistics are extreme in the amount of driving time to and from, and the time to walk out to the site to collect a sample. Sampling stations are located along the shore but not across the growing areas. DMR's concern for staff safety is legitimate.

Daily weather and seasonal weather constraints reduce the numbers of days for sampling. Tidal extremes further reduce the sampling ability with some tides changing more than 30 feet. Daylight hours are reduced during much of the year. Although SRS is primarily used the DMR should evaluate for areas where SRS is not the best means of monitoring specific areas effectively.

During the discussions with both industry and DMR it was stated that improvements have been made. Volunteers are retrained and evaluated annually and SOPs are being drafted that will include signed agreements by the sampling volunteers agreeing to follow all sampling protocols and sample at the determined locations. Sampling has become more consistent. Sample locations are designated using a global positioning system (GPS).

Lab staffing to process the samples from the 1,463 stations was summarized. The staff receives no compensatory time but do have flexible work schedules.

A loss of trained qualified staff is a concern of the industry. The replacement of staff and refilling of positions must be given top priority by DMR. Additional staff would be required in order to adequately monitor areas and collect additional samples. Summer hires or interns could be encouraged to return with scholarships.

The DMR closes shellfish growing areas after ≥ 2.0 "-3.0" of rainfall, for a minimum of 14 days, with subset sampling runs to determine when full runs of samples should be collected to reopen. Some areas are resampled repeatedly. The DMR does not have enough staff to conduct sampling studies to determine automatic reopenings.

The overboard discharges (OBDs) in general, are not reliable and must be monitored. They must be considered as a potentially serious public health concern.

The industry indicated that cleaner water is a priority for them. In Connecticut the Nonpoint Education for Municipal Officials (NEMO) program and CT Sea Grant have both been instrumental in educating the local governments on the shellfishing issues.

The review team has reviewed and agrees with both the 2006 and 2007 Program Element Evaluation Report (PEER) completed by FDA Shellfish Specialist Peter Koufopoulos. The DMR continues to be understaffed and thus found unable to be in compliance with the requirements of the NSSP-MO.

The “Chronology of events” has indicated several improvements. A number of closures were made during the Fall of 2006. There was a lack of effective communication between the DMR and the industry. Several key questions were raised by the industry and as a result, DMR began to develop Standard Operating Procedures (SOPs). The SOPs include; adjustments to the minimum depth of sampling, improved communication, the utilization of local enforcement agencies for sampling assistance, the use of boat sampling when possible, and a reevaluation of the sampling station location and area classifications.

A lack of effective communication is a main reason for the lack of confidence by the industry with the DMR. Both parties must be active participants. The DMR are the Shellfish Authority; they are the public health experts. Meetings and workshops educating the industry would be beneficial. The finalization of the SOPs will provide for uniformity. Changes in policy and reclassifications should be explained in writing with detailed justification for the decisions. It was noted that other states have more communication with their state Department of Environmental Protection (DEP), harbor management commissions, shellfish commissions, Sea Grant, and advisory councils. One question placed to the review team was to discuss whether the Maine Shellfish Advisory Council should communicate with DMR or to the legislature. The Shellfish Advisory Council may represent the industry voice to DMR but they should use Maine Sea Grant as their “sounding board.” Together the industry and DMR can develop proposals for ISSC.

Final Peer Review Team recommendations:

1. Additional Staff is required in order for the Maine Shellfish Growing Area Program to be able to comply with the NSSP-Model Ordinance requirements. Additional staffing will allow for: timely assessment of data, additional sample collection and studies, and timely preparation of reports.
2. Biannual meetings should be held between industry and DMR representatives, the structure of which should be initial presentations followed by discussion. An independent moderator should also be considered. The meetings should also be staged to coincide with the biennial Interstate Shellfish Sanitation Conference (ISSC) to enable joint DMR/shellfish industry request for change to the NSSP Model Ordinance prior to the ISSC.
3. A Shellfish Advisory Council should be established to act as mediator for DMR and industry.
4. The Standard Operating Procedures (SOPs) should be finalized.
5. Sampling protocol should continue to be standardized and should address subsurface sampling when the sampler is at a minimum knee deep water depth, and the sample is

- collected up-current, and away from floating objects such as seaweed. Samplers should be further evaluated to ensure that sediments are not disturbed in the collection area.
6. Water samples should not be collected at periods of “no water,” in rivulets or stagnant pools.
 7. Sampling should be scheduled using the Systematic Random Sampling (SRS) method but should be timed during the day with respect to tidal conditions that allow for sample collection at the minimum water depth of 18”.
 8. Samples should be collected during various tidal conditions especially in areas where times of tidal impacts have not yet been adequately determined. Collection during both ebb and flood tides is acceptable.
 9. DMR should continue to collect salinity data.
 10. Pollution source sampling should continue.
 11. DMR should utilize volunteer industry or shellfish warden boats where possible for growing area classification sampling.
 12. A simplified version of the NSSP statistical information should be presented for the local community.
 13. Additional sample stations should be added further out in bays and across growing areas that may be used to more specifically define classification lines such as in the Timber Cove area.
 14. The boundary line separating the conditional from the approved classification in growing area ER may be moved, thereby opening an additional harvest beach without compromising public health. (Station 8.0 to Station 45.0). This should be further reviewed by DMR.
 15. DMR should consider the viability of remote area classifications.
 16. A river gauge should be added below the confluence of the Kennebec and Androscoggin Rivers so DMR can more accurately assess impacts of river stage on those affected growing areas.
 17. “No Discharge Zones” should be established in critical shellfish growing areas.
 18. Specific legislation should be enacted prohibiting overboard discharge into critical shellfish habitat.
 19. Dye dilution studies should continue to be conducted by trained parties but may be made a local requirement of WPCFs and NPDES permittees and at their expense.

Maine Peer Review List of Participants:

Paul Anderson, Director Maine Sea Grant
207-949-4156
panderson@maine.edu

David Webster, Maine State Representative
207-865-4311
dcwebster@suscon-maine.net

David Etnier, DMR Deputy Commissioner
207-624-6553
David.etnier@maine.gov

Linda Mercer, Director DMR
DMR Boothbay Harbor
PO Box 8
West Boothbay Harbor, ME 04575
Linda.mercer@maine.gov

Amy Fitzpatrick, Public Health Division Director
DMR Boothbay Harbor
PO Box 8
West Boothbay Harbor, ME 04575
207-633-9554
207-633-9579
Amy.fitzpatrick@maine.gov

Jan Barter - DMR
Fran Pierce - DMR
John Fendl - DMR
Laura Livingston - DMR

Rob Goodwin – DMR
DMR LaMoine Lab
22 Coaling Station Road
Lamoine, ME 04604
207-667-5654
Robert.goodwin@maine.gov

Mercuria Cumbo
DMR WQ Lab
22 Coaling Station Road
Lamoine, ME 04604
207-667-5654
FAX: 207-664-0592
Mercuria.cumbo@maine.gov

Valy Steverlynck
Shellfish Grower Town of Freeport
207-221-5172
vsteverlynck@hotmail.com

Daniel Devereaux Marine Resources officer / harbormaster
Town of Brunswick
207-725-6631
207-751-2174 cell
ddevereaux@brunswickpd.org

Virginia Olsen
Oceanville Seafood
543 Oceanville Road
Stonington, ME 04681
207-367-5871
oceanvilleseafood@hypernet.com

Tom Kay
Shellfish Warden Town of Freeport
207-865-4800
tkay@freeport.gov

Neil Pollis
Shellfish Warden Thomaston, So. Thomaston
Cushing, Warren, St. George, Friendship
207-785-5404
pollisb@aol.com

Chad Coffin, Commercial Shellfisherman
President Maine Clammers Assn
Chairman Freeport Shellfish Commission
207-865-0298

Ccoffin2@svscom-maine.net

David Corbeau
Town of Scarborough Marine Resources Officer
207-671-2821
dcorbe@ci.scarborough.me.us

Jim Markos, President Maine Seafood Alliance
207-667-5336
jmarkos@meshellfish.com

Julie Keene, Trescott / Edmunds Clam Committee
207-733-2320
Scotland@maineline.net

Richard LeMont, Commercial clammer
Chairman of shellfish commission
207-389-2105
cindik@zwi.net

Jeremy Wood
Machiasport Shellfish Commission
jwood@ptc-me.net

Butch Taylor
Georges River Shellfish Commission

Rod Regier
Town of Freeport former councilman
207-865-6687
samrodfp@aol.com

and
Connie Devenger – DMR Administration
207-633-9525
Connie.devenger@maine.gov

Review Team:

Tom Herrington – bigtom2@bellsouth.net
Joe Migliore – joseph.migliore@dem.ri.gov
Lori Romick – lromick@snet.net or shellfishsister@snet.net

APPENDIX A: Industry Concerns and Perspectives

The following document was prepared by Valy Steverlynck on behalf of the Shellfish Industry in preparation for the review team meeting on Monday, October 29th. It represents industry's understanding of the issues and their perspective as organized into these 14 focus areas.

Industry Advisory Panel/ Review Team 10/29 Meeting Boothbay, 9:30 am

What follows is a list of the areas that Industry would like the reviewers to evaluate and comment on. Suggestions should be made primarily in the context of how other state programs in the region are complying with the NSSP:

- 1) Location of GAC stations as related to harvest/growing areas, fresh water inputs, access points and tide-related issues.*

Throughout the coast, there is a high percentage of GAC stations that have no water at low tide (e.g. run 6V-Freeport, Maquoit Bay, Kennebec River, etc). For samplers operating under the April 26, 2007 SOP, it is often impossible to collect low tide samples because there simply isn't any water present at that tidal stage- except for runoff streams and puddles of standing water. Does FDA require that stations be sampled specifically at low tide, or is "low water" data (collected on low-to-mid tide) acceptable for compliance with FDA's directive that random samples be collected at "all tidal stages"?

- 2) Distinction between GAC stations vs. pollution monitoring stations.*

ME DMR does not distinguish between GAC stations and pollution monitoring stations. From the Random sampling run station maps, it appears that stations located on streams and high on river banks are used for both purposes (e.g. WJ30 (Bunganuc Creek), WI53 (mouth of Cousin's River)). This leads to sample runs that have a great number of stations and thus require ample time and lab resources to sample.

Please comment on the effectiveness of this approach: Would random runs be more manageable if only stations monitoring overlying waters were sampled fro GAC? Keeping in mind that DMR has limited staff and resources and that on occasion runs don't have the minimum 6 samples/yr required by FDA, having fewer stations per run may make it easier for DMR to comply with FDA regulations.

Is it appropriate to use GAC stations for monitoring both pollution sources and overlying growing waters?

- 3) Random Sampling method versus Adverse Sampling method for different types of areas.*

Maine relies mostly on Random Sampling for GAC. It uses adverse sampling when monitoring pollution, but not for growing area classification. Industry recognizes the need for upfront

investment when using adverse sampling for GAC, yet where there are adversities clearly impacting an area it may be worth considering using this method.

How much data needs to be collected before an area can be on an “automatic” trigger? (by “automatic trigger” we mean that the area can be opened or closed when certain conditions are present without the need for testing). Maine does not have the resources to switch to Adverse sampling, but Industry is committed to helping gather data or help fund studies that will make it possible for key areas to be tested under the Adverse Sampling method and operate on “automatic” triggers.

4) *Rainfall conditional areas: their role in ME's Growing Area Classification Program; Guidelines on how to manage them.*

Despite the length of Maine’s coast, there are only three rainfall conditional areas in the whole state (Medomak River, St. George River and Atkins Bay, Kennebec). There are several areas that have enough data that point to the need for rain gauges, including the Cousin’s River in Freeport/Yarmouth.

Rainfall Conditional areas consume a large share of DMR’s resources: they require extensive testing (to re-open after rainfall events) and expensive notification (newspaper ads to close and re-open the areas). DMR has recently eliminated a number of rainfall conditional areas and is reluctant to instituting any additional ones.

While the financial burden of managing rainfall conditional areas is evident, the productivity of these areas must be taken into account as well. In order to maximize the state’s natural resources, Maine’s shellfish industry and municipalities are committed to doing whatever is necessary to help institute more conditional areas and manage them. Industry contributions would include, but not be limited to, funding studies that would help determine the “triggers” for such areas.

5) *Standard Operating Procedure (SOP) for Water Quality Sampling:*

- *Depth for water sample collection*

ME’s 2007 SOP requires that samplers wade 12-18” and that they plunge the bag 4-10” under the surface. How do these depths compare to those used by other states?

- *Distance from GAC station at which samples may be collected*

ME’s 2007 SOP allows samplers to walk up to 300’ from the GPS location of the GAC station. Is that distance appropriate and most importantly, is it applied consistently by all samplers?

6) *Role of salinity to determine the utility of a sample for GAC.*

Samples with extremely low salinity are routinely used for growing area classification purposes. Do such samples accurately represent the quality of the overlying waters? Are there ways to determine if/when a sample should be discarded?

7) *Access to GAC stations: Land vs. boat.*

8) *Use of municipal resources and volunteers: Role of DMR-trained personnel, municipal boats and vehicles etc.*

For 5) and 6):

Boat sampling is generally considered more accurate than sampling by land: it allows samplers to get to the stations without stirring the bottom and it ensures proper depth when drawing a sample. Nearby states make heavy use of boats when sampling GAC stations.

Sampling a run by boat takes on average ½ the time it takes to do the same run by land.

For safety reasons, ME DMR requires that there always be at least two people when operating a boat. DMR has very few boats and a limited budget. It is therefore unrealistic to expect that the Department will be able to sample by boat.

Many municipalities, however, have access to boats and DMR-trained personnel (wardens) available to aid DMR in collecting samples. In the case of Scarborough, Brunswick, Freeport, Bath and other towns, wardens already sample for DMR. They most often sample by boat (town boats).

Industry members have also offered to provide DMR staff with boat rides when collecting samples.

Could this “volunteer program” be expanded to help alleviate DMR’s lack of resources and available staff? There are many towns and wardens who have expressed an interest in helping out.

9) Threshold for initiating a state-wide flood closure.

The state is currently on a 2”-3”/24 hr rain closure: The flood-closure conversation at DMR starts between two and three inches: it may be initiated after two inches based on ground saturation, recent rainfall events, etc. Once rainfall reaches three inches/24 hrs., a state-wide closure goes immediately into effect.

For areas that are susceptible to rainfall but are not classified as rainfall conditional, it is beneficial to have a low trigger (2”). This prevents random samples from being taken when the area is polluted: these samples have a long-term impact on the area’s P90 and its long-term classification.

Since state-wide closures have a great impact on a business’s bottom line industry members working in areas that are not susceptible to rainfall events prefer a higher trigger (3”).

If productive areas that are prone to water quality deterioration after rainfall events (but clean otherwise) were classified “rainfall conditional” the state-wide closure could be initiated at 3”. Would this be a reasonable and effective approach?.

10) Method for establishing boundary lines between open and closed areas.

Boundary lines are established by ME DMR at the first station that meets the criteria for a different classification. In many cases stations are spread far apart, sometimes a mile or more (eg Scarborough). The area that lies between a “closed” and an “open” station is considered “closed.” Given that this “in-between” expanse is sometimes large and oftentimes productive, Industry would like to ask that the reviewers evaluate this approach and suggest alternative ways for establishing boundary lines, if appropriate.

Areas that are susceptible to rain but are classified using random sampling/P90s have their own set of issues when it comes to drawing boundary lines: In the case of the Cousin’s River, the area that is classified “open” is influenced by rainfall events and should not be permanently open (it is currently open based on P90 calculations). On the other hand, the area that is currently “closed” (restricted) is clean during dry periods and should not be permanently closed.

11) Accelerated sampling for expediting review and possibly the reclassification of existing growing areas. Role of independent laboratories in ME's Program.

ME DMR collects the minimum six samples/year required by FDA for each GAC station. Areas where pollution abatement plans have successfully eradicated the pollution source (eg a failing septic that has been repaired) are good candidates for accelerated sampling (FDA allows up to 24/samples/year). Currently, accelerated sampling is not conducted by ME DMR due to budgetary and staffing shortfalls. Industry would like to make accelerated sampling possible, either helping in data collection (through the use of trained wardens and municipal personnel or by providing boat rides to DMR staff), or by contracting independent laboratories to process the samples (to this date no independent lab has been certified by DMR to process GAC samples)-or both.

12) Real-time closing and opening of growing areas based on P90 calculations.

In Maine, areas are reclassified only at the time of their annual review. If a certain area shows signs of pollution it still remains open for the remainder of the year (Little River/Recompence, Freeport, 2006). Conversely, an area that has P90s that meet the criteria for re-classification to the open status can't be opened until the date of its annual review (Harpowell, 2007). Are there ways to make the closing and opening of areas more accurate and time-sensitive? What does Industry need to do to help DMR achieve the goal of real-time closing and opening?

13) Hydrographic studies: their role in determination of sampling locations and in growing area classification.

Dye studies are complicated and require in-depth knowledge and experience in dealing with hydrographic issues. DMR-generated studies have sometimes been challenged and questioned. Case in point: The Harraseeket River study.

Please comment on the role of such studies and on the qualifications necessary to conduct them. Is there precedent in other states for contracting dye studies to third party experts?

14) Cross-check method(s) for ensuring that only samples collected under the Random protocol get used for growing area P90 calculations.

Adverse samples have been known to get mixed up with Random samples and used to generate P90s (e.g. Brunswick, Scarborough). Are there methods/programs available to eliminate these mistakes?

As far as calculating the P90s themselves, Massachusetts encourages its WQ staff to double-check computer generated P90 calculations by hand (apparently computer programs are sometimes not accurate)

Is this a real concern? Should Maine be doing likewise?