



FY 2007
PROGRAM ELEMENT EVALUATION REPORT
OF THE
GROWING AREA CLASSIFICATION ELEMENT
SHELLFISH SANITATION PROGRAM
DEPARTMENT OF MARINE RESOURCES
STATE OF MAINE

PREPARED BY

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ON

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PROGRAM ELEMENT EVALUATION REPORT

STATE: Maine

DATES OF EVALUATION: June 18 - 22, 2007 and July 9 - 13, 2007

PROGRAM ELEMENT EVALUATED: Growing Area Classification

A. Status of Previous Program Evaluation

The FY 2006 evaluation of the Maine Department of Marine Resources (DMR) Growing Area Program found that the DMR was in non-compliance with six (6) items found in the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). The Growing Area Program was also provided with two (2) recommendations cited to help the state strengthen its program. The non-conformities and recommendations were addressed in the state's response to the PEER dated December 22, 2006.

The non-conformities and recommendations noted in the FY 2006 evaluation followed by the states response to each item are listed below:

Non-conformities:

1. *During the review of the Shellfish Management Area files it was noted that two Triennial Reports scheduled for completion in calendar year 2005 had yet to be completed by the time of this audit. Although the field work had been completed the final version of the report had not been submitted to management for review and approval. The DMR did not follow the NSSP-MO and place the growing area in the closed status at the end of 2005 when the report was not completed. Chapter IV@.01.C.3.(a)(b)*

The reports which were to be completed by the end of 2005 were not. The Division was granted a two week extension at the end of the FY 2006 FDA field evaluation to complete the writing of the reports. All field work and data collection in growing areas WA and WS had been completed in 2005. Due to the volume of work to be completed and low staffing levels, the time table has been adjusted from reports being completed by February 28th to reports being completed by April 1st. The director has started an internal audit of the reports on file for the program.

2. *During the review of the Shellfish Management Area files it was noted that water quality sampling runs were being adjusted to accommodate conditional area sampling. The samples were collected during a specific timeframe and were not collected year-round. This approach left Approved sample stations which were open year-round without the year-round data to support the classification. Chapter IV@.02.F.6.b.ii*

The adjustment for sampling all systematic random samples year-round was identified by staff and fixed for the 2006 sampling schedule. The SRS was set up in 2006 year round as weather permitted without regard to conditional area sampling needs. After the schedule was made, the DMR identified the months when additional sampling would be needed for conditional areas to meet the requirements of the MO and scheduled additional conditional area sampling in those months.

3. *During the review of the Shellfish Management Area files it was noted that 25% of the growing waters did not have the minimum number of samples collected per the Systematic Random Sampling regime. Chapter IV@.02.F.6.b.iii*

The DMR does not have enough staff to continue random sampling runs during flood closure events. We also do not have enough laboratory resources to simultaneously run both flood sampling and random samples. Staff is activated to pull flood samples from previously identified stations within the closure areas, daily until the areas meet approved or are at/below background levels. In 2005 we collected and analyzed ~1000 seawater samples during flood closures. All the random sample runs during the ten/eleven week closure periods had to be rescheduled to collect samples while they were in their open status.

The problem of missed sample stations was identified by staff and fixed for the 2006 sampling schedule. We keep a missed station or missed sample run log in the laboratory that is filled out by the collector when the samples are submitted to the lab. We have set up a query in MARVIN for identifying any stations that may have been missed during a random run. Missed stations/runs are rescheduled as field staff is available and laboratory capacity allows. The query is carried out on a monthly basis and will continue with the 2007 sample season and beyond.

4. *During the review of the Shellfish Management Area files it was noted that multiple conditional areas have been created which do not correlate the water quality scores to the environmental condition which would adversely affect the area. Chapter IV@.02.@.03.C.1.c*

The Director has issued a directive that reports should be thoroughly reviewed and is committed to making sure that all reports are complete and accurate. We are also working on specifying how many data points are needed so that we can specify that in the standard operating procedures. Additionally, we will use ANOVA to determine the best months to include in seasonal conditional areas. We are committed to using a more statistical approach to perform data analysis.

5. *During the review of the Shellfish Management Area files it was noted that not all conditional area management plans contained procedures for immediate notification to the DMR when performance standards or criteria are not met. This was specifically noticed in some marina conditional area management plans with regards to the actual presence of boats verse the opening and closing dates (change in status) of the conditional area. Chapter IV@.03.C.2.f*

The growing area supervisors have developed field sheets [corrective action form style] to use when reviewing the reopening criteria for marina and seasonal conditional areas. Marina areas will be sampled 2 weeks prior to opening dates and at that time confirmation of boat numbers will be documented. Seasonal Conditional Areas will also be sampled prior to reopening. Any samples which do not pass in order for non-point source seasonal areas to open will have legal notices promulgated in order to keep the areas in the closed status until water quality meets approved standards. These details are being added to all Conditional Area Management Plans.

6. *During the review of the Shellfish Management Area files it was noted that in some of the growing areas there were closed area boundaries around failing water quality stations which were established in an arbitrary fashion. The closure lines need to be based on scientific principals such as analytical data from other water quality stations or dilution calculations when sample stations are not possible due to overland topography or basic accessibility. Chapter IV@.01.C.(5)(6)*

A document has been developed that lists the present prohibited, restricted or conditional classified areas in Maine. Presently the staff is populating the file. Under each closure title is a map of the closure and accompanying discussion as to the reason the area is classified, the acreage of the closure, the water quality sample sites within or on the margins of the closure and, if margin sample sites are inaccessible, a calculation of the pollution impact zone and statement as to its comparison to the regulation closure size.

Recommendations:

1. *The FDA recommends that whenever a change to the original master systematic sampling calendar occurs that along with the new date of sampling the reason for the change be added to the calendar master file in order to justify the date change.*

The DMR realized that this was problem at the end of the 2005 sampling season. We have developed a mechanism in the laboratory sample schedule calendar which is kept in MS Outlook to track any changes to the systematic random sampling schedule; why it changed or got cancelled, re-sample date, etc. It has been a very successful tracking mechanism for us and we will continue to use it in the future.

2. *The FDA recommends that the conditional area management plans be reviewed to ensure that the pollution upon which the conditions are set is truly predictable.*

The Director will utilize the expertise of more scientists on staff to review reports. Specialists will not be reviewing each others work, reports will be reviewed by Scientist I (and peer colleagues of different disciplines) and above.

As a result of the first deficiency list above, noted in the FY 2006 PEER, the Public Health Division Director launched an internal audit of all shellfish growing areas statewide. The internal audit revealed that two triennial reports (growing areas WQ and WR) and one

sanitary survey (growing area WN) were overdue, thus requiring the growing areas to be closed until the assessment and written report could be complete. The DMR Commissioner proposed a different course of action for the three affected growing areas.

The DMR was unwilling to close the three growing areas in their entirety due to the adverse impact to the shellfish industry. The Department performed abbreviated risk assessments of the areas by reviewing pollution source information and water quality data through December 2006. The Department in a memo dated January 23, 2007 proposed specific timelines for each area and the specific work to be completed by staff members to ensure a thorough assessment of all pollution sources which may be impacting the shellfish growing areas.

In a letter to the DMR Commissioner dated January 25, 2007, the FDA concurred with the proposed course of action outlined by the DMR. The FDA agreed that based on the information available the public would remain protected as the DMR performed the remaining assessments in each of the growing areas and completed the written report detailing the findings of the in-field assessment. The DMR briefed the FDA on a weekly basis as to the progress of the work in the three growing areas. The work was completed per the timelines proposed by the DMR.

B. Status of Current Evaluation

1. Total Number of Growing Areas Evaluated

The Maine Department of Marine Resources monitors 45 separate Shellfish Management Areas. Twelve of the shellfish areas were selected to be evaluated. The number of evaluations is based upon a representative sampling plan designed to provide a 95 percent probability of detecting a 20 percent or greater defect level. The selection of the 12 growing areas was performed by Peter Koufopoulos, the Northeast Regional Shellfish Specialist. Mr. Koufopoulos chose 12 shellfish growing areas which had not been previously reviewed as part of a prior audit or had not been reviewed during the past three audits. The selected growing areas are listed below.

Shellfish Management Areas

West - Boothbay Harbor Office

- WA - Piscataqua River
- WD - Wells
- WG - Saco Bay
- WS - Muscongus Bay
- WT - Meduncook River
- WZ - Fox Islands

East - Lamoine State Park Office

- EC - Deer Isle
- ED - Isle au Haut
- EG - Eastern Blue Hill Bay
- EK - Dyer Bay
- EN - Jonesport – Beals Island
- ES - Cutler

2. Program Area Level of Compliance

a) Sanitary Survey

General

The Maine DMR follows the NSSP Model Ordinance regarding the completion timeframes for all required reports. Currently the staff is required to complete the Sanitary Surveys every 12 years, the Triennial Reports every 3 years and the Annual Updates every year. Internal DMR policy states that all reports are to be formatted to meet the requirements of the MO. All Annual Updates are scheduled to be completed the first quarter of each year for the previous calendar year. Conditional area management plans are re-evaluated on an annual basis. Information gathered from the management plan review is included in the Annual Update and used to support any changes in classification. All conditionally managed areas that were reviewed during this evaluation period were closed according to the criteria established in the Conditional Area Management Plan.

DMR also closes approved waters during emergency conditions, typically after heavy rainfall events. The DMR staff receives great pressure from the commercial shellfish harvesters to reopen closed areas as soon as possible. In lieu of shellfish tissue sampling, areas closed due to management plan violations are normally closed for a minimum of fourteen days after the event. In order to be more responsive to the harvesters demand, the DMR has decided to incur the additional expense of sampling both shellfish growing waters and shellfish tissues in an attempt to open the shellfish harvesting areas more quickly whenever possible and appropriate. A closed area will reopen only after acceptable water samples and/or shellfish tissue results are received and evaluated. This sampling also supplements ongoing studies to document relationships between fecal coliform bacteria levels in the water and fecal coliform bacteria levels in the surrounding shellfish. Any correlation made could reduce the effort of future sampling and also allow the fourteen-day cleansing period to be shortened.

Required

Sanitary Surveys are completed on all Shellfish Management Areas prior to the harvest of shellstock for human consumption. A Sanitary Survey along with its associated shoreline survey is used to determine the proper classification of an area as Approved, Conditionally Approved, Restricted, Conditionally Restricted or Prohibited.

Written Sanitary Survey reports were present and complete for all 12 management areas reviewed. DMR follows the format described in the NSSP MO Guidance Document Growing Area @.03. The reviewed survey reports had all of the required sections and subsections. The various sections within the report have very detailed information; including charts, graphs and pictures to further enhance the discussion.

Once the shoreline survey results are reviewed and the water quality data is analyzed the DMR completes the written sanitary survey report. The report details the findings of the staff in the specific Shellfish Management Area. All failing water quality stations are placed within classifications (other than approved) which would prevent direct market harvest except under certain circumstances.

While conducting the in-field portion of the FY 2007 Patrol Evaluation in the northern most portion of Maple Juice Cove (Growing Area WU) a commercial boat fuel dock was noted outside of any existing closure. Through the course of the day, two additional fueling dock areas (both areas found with Growing Area WT) were found in areas Approved for shellfish harvesting in the open status. One area, in Friendship Harbor, had two adjacent fueling docks on Bradford Point, off of Young's Drive. The second area had a fuel dock in Hatchet Cove along the northwest border of the cove. The lack of a closure is of concern due to the unpredictable nature of fuel spilling in small amounts of varying sizes into the shellfish growing areas. Once the patrol in-field evaluation was complete on July 24, 2007 the information was forwarded to the growing area program staff for assessment.

Performance

The DMR schedules Sanitary Surveys to be completed once every 12 years for each Shellfish Management Area. The water quality staff recognizes that if a Sanitary Survey (or a Triennial Review) is not completed within the specified time frames then the Shellfish Management Area shall be placed in the closed status pending completion of the report.

Triennial Report --

The DMR Shellfish Program completes Triennial Reports every three years in order to supplement and update information found within the Sanitary Survey. The triennials are more comprehensive than the Annual Updates. The triennials are intended to be a thorough review of all known pollution sources; an actual reassessment of their impact on the shellfish growing waters.

The reports were submitted by the DMR to the Shellfish Specialist and reviewed while they were in draft form prior to the actual in-field audit. The reports were reviewed for completeness and accuracy based on field observations to be conducted during the audit. Comments generated by the report review were forwarded to the appropriate growing area staff member for concurrence and inclusion within the report when necessary. The in-field file review conducted as part of this evaluation found that the Triennial Reports which were due to be completed by the end of this calendar year were either completed or in draft form waiting for management review.

Annual Update --

Annual Updates are designed to review important performance standards, sampling data and pollution source information to determine if a downward trend in water quality is occurring. The Annual Updates were reviewed as part of this evaluation and found to be complete; thus they are in compliance with the minimum requirements of the NSSP MO.

The review of the annual reports revealed greater detail in the narrative sections of the updates which is an improvement over past years. The growing area staff members, with direct oversight from management, continue to review and improve upon the reports outline (template) to help ensure consistent reporting by all staff members.

Sampling requirement --

The DMR Shellfish Program operates under the Systematic Random Sampling Scheme and creates the sampling schedule in December of each year for the next calendar year. The schedule is completed far enough in advance to ensure sufficient variation with respect to environmental conditions. A master sampling schedule file is maintained for each of the two Division offices. The water quality staff is required to document any changes to the sampling calendar and obtain management approval prior to any change.

While reviewing the sampling calendar several instances were noted where the original sampling date was changed. As an improvement over past years the reason for any schedule change has been added to the file such as: hazardous weather conditions, equipment failure, other high priority public health incidents, etc. When there was a schedule change a new sampling date was also noted in the sample calendar master file.

The review of growing area WD found that the minimum number of samples required to be collected in the open status within the Webhannet River conditional area were not collected during calendar year 2006. The area is only open to shellfish harvesting January 1st through April 30th. Under these circumstances the conditional area sampling stations must be sampled a minimum of five times per year while in the open status. The seven sample stations located within the conditional area were only sampled four times when the area was in the open status.

Conditional Area Management Plans --

The DMR Shellfish Program uses the conditionally approved and conditionally restricted classifications in order to allow Maine shellfish harvesters a greater opportunity to harvest shellfish otherwise not accessible under the traditional classification process. The program uses the conditional area classification for the

following conditions when the water quality variations are predictable: wastewater treatment plant, marina, rainfall and season. The conditional areas are placed in the open status when the area meets approved water quality, thus allowing more opportunity to harvest shellfish.

The conditional area management plans are being reviewed annually for compliance with NSSP requirements. The DMR has increased sampling efforts in order to obtain information needed to fully assess the predictable nature of the conditional areas. The creation of new conditional areas have slowed in recent years as the department spends more time reviewing the appropriateness of existing areas as well dealing with the fact that these areas are very resource and labor intensive to manage.

b) Shoreline Survey Requirements

DMR evaluated and documented all potential and actual pollution sources in the initial Sanitary Survey report for each growing area. Throughout the year, staff constantly updates pollution source information by monitoring by boat and vehicle. The pollution source information gathered throughout the year is then incorporated into the next appropriate report. Specific pollution concerns are individually discussed below as they are found in the reports along with noted details from the shoreline survey database:

Domestic/Industrial/Agriculture Wastes

Many of the 45 Shellfish Management Areas are negatively impacted by Wastewater Treatment Plants that discharge either directly into the surrounding shellfish waters or indirectly by discharging into rivers which drain into the growing areas. DMR has placed buffer zones around all of the discharges located in the coastal zone. Many of the treatment plant outfalls have completed hydrographic studies. Outfalls waiting for these studies to be completed have buffer zones based on mathematical calculations using worst case situations for untreated or partially treated sewage.

There are very few industrial discharges along the coast of Maine. Most of them are located in heavily populated areas which have an existing closure due to other influences. Agricultural runoff is not a problem for many growing areas along the coast. The bold rocky coast of Maine is not conducive to large amounts of livestock. There are vast blueberry fields near the coastal waters; however stream sampling has not shown their overland runoff to pose a problem to the surrounding water.

Domestic Waste - Individual Sewage Disposal Systems

As is often the case in coastal Maine, the subsurface soil composition is not always adequate for establishing proper leach fields. Consequently the majority

of the recently installed septic systems are designed to have raised bed leach fields. Prior to the use of this more modern sewage disposal system, the coastal area of Maine relied on a system known as an Overboard Discharge (OBD). The Maine Department of Environmental Protection (DEP) currently licenses, regulates, and inspects these OBDs which are approved sewage treatment systems consisting of a sand filter or mechanical treatment system and a chlorine disinfection unit used to treat discharges of sanitary waste from residential and commercial facilities. If the system is designed properly the chlorinated waste is discharged through a pipe extending to below the low tide mark. OBDs have been regulated in Maine since the late 1970s when direct discharges of untreated wastes were banned. New OBDs are prohibited by law however, existing systems that remain licensed and inspected may continue to be used until the owner is offered a grant from the Maine Overboard Discharge Program administered by the DEP. The program offers money to replace the OBD with a traditional septic system; or find and/or design an alternative system that can be installed. The Maine Overboard Discharge Program awards grants based upon a priority system. OBDs located in the most productive shellfish habitats are the highest priority for removal. If any of the OBDs are found not to be working properly then that system is given priority for replacement.

Existing OBD outfalls have a prohibited closure zone placed around the end of the pipe. The size of the closure zone is based on calculations generated from the permit information. The water depth (for dilution, including viral), permitted flow rate and the average fecal coliform concentration for a chlorinated system of this type are all factors used to establish a buffer zone to protect public health.

Drainage Ditches - Stormwater Runoff

Stormwater runoff from drainage ditches, creeks and streams are considered to have the largest impact on water quality in the growing areas of Maine. Stormwater transports pollutants, including fecal coliform bacteria, from many of the indirect pollution sources in the drainage basin, to the growing area. The impact of these outfalls is evaluated by strategically placing sampling stations in these ditches, creeks and streams and also at their confluence with the growing area.

As with many indirect sources of pollution, the overall impact from these specified drainage-ways on the growing area is only known through the review of long-term historical data. Most of the data centers on heavy rainfall events. This is due to the fact that these drainage-ways, which may be dry most of the year, will begin to flow, becoming a conduit for potential pollution to reach the viable shellfish areas. Actual flow rates are now being collected and are used to generate fecal loading calculations.

Wildlife/Domestic Animals

General descriptions of migratory waterfowl and typical populations of other regional wildlife are included in the shoreline survey reports. Regional wildlife populations are considered significant contributors to the fecal coliform levels in the growing areas during rain events within the local drainage basin. Migratory waterfowl are contributors also; however, the overall impact of wildlife, in general, is ultimately unknown.

Domestic animals within the management areas are typically dogs and cats. Few homes have horses and fewer still have other barnyard type animals as domesticated pets.

Marinas

All marinas within close proximity to approved shellfish harvesting waters were evaluated as the focus of the FY 2002 Growing Area Program Evaluation. The evaluation noted that the marina community within Maine will only operate part of the year due to adverse regional weather. The operating procedures the marinas have in place provide an excellent opportunity for the shellfish growing waters to be accessible, at least part of the year, to direct market harvest through the use of conditional management plans.

The closure zones were created by the state using volumetric calculations and re-verified during the evaluation. The basic formulas used were found in FDA guidance issued in June 1989, which describes the proper procedure when establishing a precautionary closure zone around a marina for the purpose of protecting public health.

Although the boat fueling docks noted in the Sanitary Survey section above were not affiliated with a formal marina, it is important to evaluation all possible pollution sources which may have an affect on the shellfish growing waters. Fuel spillage reporting criteria should be reviewed for all boat fueling stations including any available response plan which would be used in the event of a spill.

Radionuclides/Metals

There were no known sources of radionuclides or heavy metals impacting any of the growing areas evaluated. There is some metals data in the central files for those growing areas near industrial or more heavily populated areas. General statements to this effect are made in each of the growing area reports.

c) Illnesses

The State of Maine has not been the original source of shellfish associated with any *Vibrio vulnificus* (*V.v.*) illness in the past three years. Maine was the possible source of two *Vibrio parahaemolyticus* (*V.p.*) illnesses in the past three years.

- A 67 year old male, consumed boiled/steamed clams as a meal on August 27, 2005 with illness onset the next morning. No other seafood was reportedly consumed. The victim died on August 30, 2005. The clams were purchased by the victim from a truck located at one of the Portland, Maine fishing piers. The clams had no identification; therefore the harvest area is unknown.
- A 21 year old male, consumed lobster along with steamed mussels and clams on July 29, 2006 at two different restaurants (lunch and dinner) with illness onset the next day. Six different shellfish dealers provided the clams and mussels within two days prior to consumption to the two dealers. All shellfish tags reviewed showed the product was harvested only from Maine state waters.

No additional *V.p.* illnesses have been reported since the July 29, 2006 illness. The two illnesses above were isolated cases with no other individuals outside their party becoming ill. The DMR recently updated their state regulations and require harvesters to deliver shellstock to dealers within 16 hours of harvest. This is currently more restrictive than the previous requirement which allowed harvesters to follow Time-Temperature Matrix Option 3 - Level 2.

The DMR was alerted to a possible *Vibrio fluvialis* (*V.f.*) illness from mahogany clams harvested from Area 2 in Addison, Maine. A 56 year old white male, and resident of Delaware, consumed both raw oysters (harvested in Delaware) and raw clams (harvested in Maine) at a restaurant in Maryland in July 2007. No other illnesses were reported associated with this shellfish and no other individuals became ill with *V.f.* who ate at the Maryland restaurant in July 2007.

The state of Maine experienced their first paralytic shellfish poisoning case in nearly 30 years. A lobsterman from the Downeast area of the state found a floating 55-gallon poly drum offshore while tending to his lobster pots. The drum was covered with blue mussels of varying sizes. The lobsterman retrieved the drum from the open ocean and took it home that same day. He proceeded to remove the mussels, cook them and serve them to three of his family members in addition to himself. . The mussels contained high levels of saxitoxin which resulted in immediate respiratory distress among the family members. Three of the four individuals were admitted to the hospital with symptoms ranging from tingling and numbness to complete paralysis. All four individuals fully recovered.

d) Marine Biotoxin Evaluation

The DMR has developed a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas. The blue mussel, *Mytilus edulis*, is used as the indicator species when monitoring for paralytic shellfish poisoning (PSP). PSP levels in mussels usually become toxic two weeks before soft-shelled clams, *Mya arenaria*. Mussels are sampled weekly from April through October along the entire coast. Additional samples are collected as conditions dictate whether to further delineate a closure or simply assess an area that has experienced a slight rise in PSP concentrations.

Maine adheres to the PSP international toxic level standard of 80 micrograms/ 100g of whole shellfish tissue. Current state law allows the DMR to immediately close any area that contains toxins or contaminants known to be a public threat. This type of emergency closure effectively revokes all shellfish licenses; it also grants authority to embargo, confiscate and destroy contaminated or potentially contaminated shellfish.

When a closure is deemed necessary, the director of the biotoxin monitoring program will draft a legal notice and a map and notify the state's shellfish program director. The director of the biotoxin monitoring program will then submit the legal notice to the Commissioner's office. Once the legal notice has been signed by the Commissioner or his/her designee, the director of the biotoxin monitoring program will update the Shellfish Sanitation Hotline with the new information and send out an e-mail version to the distribution lists, while the shellfish program coordinator works on sending out copies of the legal notice by fax to all affected towns, marine patrol offices, and municipal shellfish wardens. The shellfish program coordinator also forwards the notice in local newspapers. The municipal shellfish wardens will post notifications in highly visible public places, and marine patrol officers will then conduct intense patrols of the affected harvesting areas by water and from land.

The DMR has established policy to assist in the coordination of a contaminated shellfish product recall. DMR requires the certified dealer to contact the receiving state's control authority and provide all pertinent recall and tagging information. The dealer will request the suspect product to be destroyed or returned to the state of origin for further assessment.

The DMR is in close contact with the Canadian shellfish authorities and other state officials along the eastern seaboard. Information regarding increased toxicity in a growing area and changes in phytoplankton populations is shared and analyzed. Collaboration by the DMR, USFDA and the University of Maine Cooperative Extension resulted in the creation of a volunteer-based phytoplankton monitoring program in 1996. There are currently 62 active volunteers sampling 46 sites statewide who report weekly to the DMR on their findings from plankton tows performed at stations assigned by the DMR.

e) Shoreline Survey Database

The Shellfish Management Areas within Maine are quite large. The water quality staff members have been forced to break areas into smaller, more manageable sized areas when conducting any shoreline survey reconnaissance. As a result, it may take several years for the pollution source assessment along the entire growing area shoreline to be completed.

The shoreline survey database is set up to be very comprehensive. The eastern-half of the state routinely updates the shoreline database from their field data sheets; however not all fields are routinely filled in with information. It was noted that only a portion of the western half of the state's shoreline survey information has even been entered into the computer. Currently hardcopies of their shoreline data must be reviewed to determine if correlations exist between water quality and identified pollution source locations. It was noted during the last evaluation that the database was not up to date. Although it appears that the DMR has made some progress in this area, the process of updating the database is not yet complete.

f) Aquaculture/Relay Activities

The DMR has seen an increase in shellfish aquaculture and relay activities. Until recently, shellstock relay from prohibited or restricted areas has not been a routine commercial endeavor. Due to the depletion of shellstock in some coastal towns and to the change in classification of shellfish harvest areas where there are pre-existing shellfish aquaculture leases the harvesters and aquaculturists have been diversifying their interests by requesting permits to move shellstock from prohibited and restricted areas. The harvesters are moving the shellstock from prohibited and restricted waters to waters classified as approved.

The DMR has followed most of the requirement detailed in Chapter V of the NSSP-MO. During this review it was noted that the harvesters and aquaculturists were allowed to move shellstock from restricted waters without continuous and direct oversight to ensure that the shellstock was properly placed in a permitted area where the shellstock could cleanse.

3. Current Findings

a) State Program Deficiencies

- i During the review of the general program files it was noted that the DMR does not have policies and procedures in place to effectively control the harvest of shellstock from restricted waters as part of licensed relay activities. Chapter IV@.03.D.1.(b) and Chapter V@.04.A-E

b) Recommendations

- i The FDA recommends that the Division update the sample station identification notebooks to reflect an up-to-date sample station description of location. The notebooks should contain sample station maps, GPS coordinates and driving instructions to help ensure that the sample is collected at the same location during each sampling run.
- ii The FDA recommends that the shoreline survey database continue to be populated with updated field information. Many of the entries examined in the database revealed that items such as distance of pollution source to water were missing.
- iii The FDA recommends that the master sampling calendar be reviewed monthly to ensure that all required sampling events are completed. If sampling is cancelled due to inclement weather, employee safety or other appropriate reasons the sampling event must be rescheduled as soon as practical.

4. Corrective Actions taken by the State

- a) Recent collaboration between the DMR aquaculture staff and some members of the water quality staff has initially resulted in a system to effectively meet the requirements described in Chapter IV@.03.D.1.(b) and Chapter V@.04.A-E of the MO. Specific guidelines have been developed to insure that the relay procedure meets the needs of the industry, is within the staffing capacity of the DMR and adequately controls the relay process from restricted waters per the Model Ordinance. Additionally, the Division Director and the Aquaculture Policy Coordinator will work to develop rules over the winter of 2007-2008 in order to have updated relay rules in place for the 2008 season. The Division Director has meetings already scheduled with the Regulations Officer to begin the process. Until we have the updated rule in place, attached is the new permit language that was developed and implemented on September 21, 2007. We believe that this meets the requirement for a corrective action plan. The Regional Shellfish Specialist will be updated as the process moves forward.
- b) Due to the on-going changes in active sample station directions and maps because of classification changes, reactivated or deactivated stations, sample stations to monitor changes in the conditions impacting harvesting areas and industry requests, it has become apparent that sample station directions and maps change frequently during the year. Changes to state vehicle use within the Department means that field people may be using a variety of different vehicles. It is evident that the challenge is to assure that sample station locations (GPS coordinates and maps) and directions are up-to-date on a day to day basis for samplers. The best solution to sampling the correct stations is to print the current day's run and map on the day the sample run is scheduled. In-vehicle book updates are labor intensive and time consuming especially if there are varied vehicles being used. Printing current directions and maps before each specific run effectively assures that the sample is collected in the

correct location. We are in the process of developing a new performance expectation which will take the place of in-vehicle books. It will be expected for individual samplers (who will be provided with a station run book) to be responsible for keeping their individual station run book up-to-date. The station change process is being streamlined so that notification of station changes will be made via email. The volunteer coordinator will be included in the email notification in order to assure that volunteer samplers are also informed of any changes. Additionally there will be a book kept at each laboratory for use by lab staff, as well as one for use by seasonal staff. All employees will be immediately instructed in this policy/expectation change.

- c) Some of the information in the MARVIN shoreline database is preliminary information obtained from town offices, state agencies or other information sources. Many times these locations have yet to be verified in the field, thus some of the data fields are empty. The database will be populated as the information becomes available. It should be noted that the Boothbay Harbor staff have only been utilizing a database format for the past 2 years while Lamoine has been using a database format for 10+ years. It is expected that the reviewer will find differences in the amount of information available via the MARVIN database. The Division Director has also put in a request to the technical staff to add actual/potential and direct/indirect to the database fields per NSSP MO Chapter IV.@01.(D).
- d) The review and scheduling of missed stations has been corrected. During the 2007 sample year, the review and rescheduling of missed stations has been done on at least a monthly basis and missed stations have been entered into the SRS schedule as soon as environmental conditions allow and staff and laboratory space are available. Due to weather conditions, unexpected emergency closures and the length of time that a conditional area is in the open status, there may always be a few conditional stations that do not have the required number of times in the open status. All conditional stations are sampled 7 to 12 times per year regardless of their status and every effort will be made to sample all conditional area sample stations in the open status.

5. Action Plans Requested

- a) A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the state will comply with the requirement to maintain an effective program to control the harvest, transport, replanting, and security of shellstock until the completion of the relay activity.

6. Accomplishments

General

- ◆ In an effort to be more transparent with information, all growing area reports (beginning with 2006 reports) are posted on the DMR website. Additionally, all FDA peer review reports are posted, the Growing Area Program Standard Operating Procedure, hydrographic reports and other pertinent reports that pertain

to growing areas in Maine. All of these can be found at http://www.maine.gov/dmr/rm/public_health/shellfishgrowingarea.htm

- ◆ The program was successful in securing funding from the Casco Bay Estuary Partnership to purchase ten automatic rain gauges to place in Casco Bay. The project is ongoing so no gauges have been placed to date. A memorandum of understanding is being developed and must get approval through the Commissioner's office and the Attorney General's office prior to offering the options to towns and shellfish committees in Casco Bay. We hope to complete this project by early 2008 and should have real time data coming in through www.wunderground.com.
- ◆ The program wrote and published the Growing Area Program Standard Operating Procedures. The shoreline survey section needs added detail and that project will be completed in the winter of 2007/2008 to be ready for the 2008 survey season.
- ◆ A harvester education brochure regarding the dangers of discharging sewage from vessels was developed and published on the website (http://www.maine.gov/dmr/rm/public_health/shellfishgrowingarea.htm) in response to a program deficiency that was noted in the patrol evaluation in 2006. We have printed copies to mail with all harvester licenses in early 2008. Copies will go with each certified dealer application in early 2008 also.
- ◆ The Freeport Wastewater Treatment Plant Facility Dye/Dispersion Study conducted in 2003-2004 Report was completed and posted on the website.
- ◆ On April 25, 2007, we held a staff training event to go over the water sample collection SOP which included meeting time and a field practical exercise. All growing area staff, the Division Director and the Bureau Director were trained and signed an acknowledgement that they were trained in, are familiar with and understand the water sampling protocols described in the current (4/23/07) SOP.
- ◆ On April 30, 2007, Alison Sirois, DMR Volunteer Coordinator held a mandatory volunteer training event to go over the SOP. The DMR has instituted this ½ day formal training for all volunteers involved in the water quality program. Volunteers need to have a more comprehensive understanding of the program and review our current standard operating procedures. The DMR will be hosting this water quality training annually. During this half day event we will cover the basics of the water quality program, get certified in aseptic technique, and go over aspects of shoreline survey training and quality assurance and quality control in the field. This training will fulfill the second requirement in the annual two part certification process: site certification and aseptic technique training.
- ◆ Alison Sirois, DMR Volunteer Coordinator and Amy Fitzpatrick, Public Health Director conducted outreach for all of the western Maine municipal shellfish committees. They delivered a short PowerPoint presentation that covered NSSP Model Ordinance requirements and program basics. They provided growing area

maps with sample stations on them, tabulated data and GM/P90 data, mapped out shoreline survey schedules (if the shoreline survey is going to expire in 5, 2-4, >2 or has expired) and their report schedule for their area. The outreach ended when the season got into full swing and is anticipated to start again in the fall/winter of 2007/2008 continuing up the coast from the eastern side of the Kennebec River.

- ◆ Director Amy Fitzpatrick has been asked by DEP to participate on a group to organize the education and outreach plan, implementation of the E & O plan, and development of enforcement strategy for the Casco Bay No Discharge Area. Casco Bay was designated a federal No Discharge Area last summer, and so, this is the first full boating season after the designation. Further, because of Maine's own cruise ship laws, the discharge of graywater, or the combination of blackwater and graywater from commercial passenger vessels with more than 250 overnight berths is also prohibited. Recreation vessels, fishing vessels, small commercial passenger vessels, and other commercial vessels may continue to discharge graywater only.

Laboratory (testing)

- ◆ The Division was also successful in securing overhead costs as part of the supplemental budget along with one time funding from ME DEP to outfit both WQ laboratories with membrane filtration (MF) equipment. Per instructions of the FDA, Laboratory Manager Mercuria Cumbo has used Model Ordinance FDA Manual of Interpretations, Interpretation Number: 05-IV-@02-101 to calculate weighted 90th percentiles. All reports have been updated to reflect the appropriate P90 standard for the specific MPN/MF combination of fecal coliform scores. It will be 5 years for the DMR to move away from the standard for MPN to the standard for MF. The DMR has developed educational materials which have been emailed to all the email distribution lists and will be posted on our website describing the process and what the "new" numbers will mean as well as describes the timeline. As of Monday, August 21, 2006 the laboratories officially began the membrane filtration method and discontinued the MPN 3 - tube dilution method. The new method does not provide results any faster but allows the DMR to process more samples in less time and saves staff time on clean up and media preparation. The membrane filtration method will also give more precise data.
- ◆ Public Health Director Amy Fitzpatrick just completed notifying all Public Health Division lab (biotoxin and WQ) and field staff (biotoxin and WQ) of a change in work hours and schedules. The change will allow the labs to run 7 days a week from April to November in the event of emergency situations like flood, PSP and rainfall closures within the bounds of the MSEA/State contract agreement restrictions and the available hours remaining in a work week. This change was brought about because over the last several years the fishing industry has voiced a concern that sample collection, lab analyses and the opening and closing of areas was limited to Monday through Friday. The shellfish industry's work is not limited to Monday through Friday. Their previous operating schedule had

delayed the harvesters ability to work when they have to wait a weekend (or longer) for sample collection and lab analyses in order for DMR to reopen an area.

Biotoxin

- ◆ When routine sampling in July 2007 indicated PSP levels >80ug/100g in ocean quahog samples, DMR staff immediately coordinated a recall, performed additional testing on all questionable product that had already been harvested, and was able to determine that there was no product on the market above the quarantine level and it could be released to the markets, protecting public health as well as minimizing any economic impact to the shellfish industry. This entire process was completed in less than 24 hours.
- ◆ When a family in eastern Maine was diagnosed with PSP, the DMR worked closely with several agencies, including Maine CDC and the Poison Control Center to determine the levels of toxicity in the sample, as well as the source of the contaminated shellfish, which was from mussels on a plastic barrel that had been floating offshore in the Gulf of Maine, possibly originating in the Canadian Maritimes. The integrity and thoroughness of the DMR Biotoxin Monitoring program was essential in determining almost immediately that the contaminated mussels did not originate in any Maine growing area, and therefore a catastrophic state-wide shutdown of shellfish harvest was avoided, helping to maintain the public confidence in Maine's shellfish program and its ability to adequately protect public health.
- ◆ Maine agreed to assist FDA CFSAN with the national distribution of STX standard which is vital to the operation of all Biotoxin Monitoring labs in the US. This entailed Maine researching the requirements for becoming a distributing agent, meeting these requirements and identifying qualified personnel to meet this task. As of September, all labs in the US currently have received enough STX from Maine to continue functioning in accordance with NSSP guidelines for the remainder of 2007 and a portion of 2008.
- ◆ Alison Sirois, Volunteer Coordinator, completed her 2006 mission to investigate our phytoplankton program methods and evaluate the data we collect. She spent time with Woods Hole scientists in August 2006 and scientists from the University of Maine and Bigelow Lab from our program advisory committee to discuss how we could: 1) produce more quantitative numbers for managers and research scientist and 2) standardize our data to make it more comparable with other states and institutions that collect like we do. Through these meetings it was decided that this year we would switch over to a more quantitative collection method. The change had several huge implications. For management purposes DMR will be able to, over time, come up with an index or *Alexandrium* count/L that Darcie Couture, Biotoxin Monitoring Manager, can use to better predict when things will go toxic. For scientific purposes we will be able to sync up our data

with Woods Hole Oceanographic Institute, who do these same live counts on their cruises. We will be able provide the inshore counts they are not able to get thus providing them with the “missing” link in their dataset. Alison held mandatory phytoplankton volunteer monitoring training this year which were day long trainings which covered identification and field method training.

- ◆ Biotxin Monitoring Manager Darcie Couture is serving as a steering committee member for the Woods Hole Oceanographic Institute 4th US Harmful Algal Bloom Symposium which will be held in Woods Hole, MA from Oct. 29 - Nov. 1, 2007.
- ◆ Darcie Couture Biotxin Monitoring Manager was invited by the Chair of AOAC Task Force on Marine and Freshwater Toxins, to join the international group, the AOAC Presidential Task Force on Marine and Freshwater Toxins. This is a large group of experts on marine and freshwater toxins, and stakeholders who have a strong and practical interest in the development and validation of these methods. Marine toxins and freshwater toxins require extensive monitoring programs and have a significant economic and human health impact. Although there is a strong and global need for improved testing methods for these toxins, the demand for new, officially validated methods has not been met. This Task Force will address this need by focusing efforts, setting priorities, and identifying economic and intellectual resources. Ms. Couture's background, experience, expertise and recognition will serve the group well. At this time they are also inviting her to join subgroups of interest to her state (saxitoxins, diarrhetic toxins, etc).

7. New or Emerging Problems

No new or emerging problems were noted as part of this evaluation.

8. Technical Assistance and/or Training Requested by the State

In March 2007, the DMR requested technical assistance for more rigorous statistical evaluation of our data, specifically rainfall, seasonal and tide evaluation. The DMR received approval to work with FDA Specialist John Veazey.

DMR has requested the assistance of FDA Engineer Gregory Goblick regarding the development of a guidance document to be used by agencies planning hydrographic or dye/dispersion studies. DMR has the need for this document to describe the type of information needed by the shellfish program to meet the requirements of the NSSP when studies are done by other agencies and we do not have enough staff and resources to participate.

Amy Fitzpatrick, Director, is working with the Maine State Training group to develop a scientific writing class to offer a refresher course to the Public Health Division staff.

9. Summary of the State's response to FDA evaluation

The ME DMR concurs with the findings of this evaluation.

10. Conclusion

The DMR continues to find themselves in non-compliance which stems directly from the lack of resources available to accomplish the work necessary to meet the requirements of the NSSP-MO. The issue of insufficient staff has been noted in formal evaluations since FY 2004. The lack of staff had a direct impact on the internal DMR audit finding three growing area reports which were not completed per the established timeframes.

This evaluation has determined that the Maine DMR Shellfish Growing Area Classification Program has been unable to comply with the requirement to effectively monitor relay activities. The DMR must be able to control the harvest of polluted shellstock which is being moved to approved waters for cleansing purposes. If the agency is unable to provide proper public health controls then the relay activities should cease immediately.

Although the DMR has shown improvement overall since the last evaluation; there is still much work to be done. Additional resources are needed if the program wishes to be in full NSSP compliance.