FY 2008
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 2, 2008 through July 11, 2008

PROGRAM ELEMENT EVALUATED: Growing Area Classification

A. Status of Previous Program Evaluation

The FY 2007 evaluation of the Maine Department of Marine Resources (DMR) Growing Area Program found that the DMR was in non-compliance with one item found in the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). The Growing Area Program was also provided with three (3) recommendations cited to help the state strengthen its program. The non-conformity was addressed in the state's response to the Program Element Evaluation Report (PEER) dated March 12, 2008.

The non-conformity and recommendations noted in the FY 2007 evaluation followed by the states response to each item are listed below:

Non-conformities:

1. *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*

   The DMR drafted new relay regulations over the winter of 2007/2008 which went to public hearing in March 2008. The updated rules went into effect on May 26, 2008. The new rules require strict oversight on all relay projects to ensure that moderately polluted shellfish are not inadvertently diverted to market prior to purging in an approved growing area. The new rules were added to DMR regulation Chapter 21 and are now fully enforceable by marine law enforcement.

Recommendations:

1. *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.*

   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.

2. *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.*

   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).

3. *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.*

   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.

The DMR fell behind in growing area classification work during 2007 due to the loss of a staff member. The Boothbay Harbor water quality supervisor left state employment at the end of November 2007. The supervisor provided direction and guidance from Kittery to the Penobscot River region. The new supervisor for this region of the state did not begin work until April 2008. Assessment work in several growing areas fell behind placing growing areas in jeopardy of being closed due to the inability to complete the work required by the NSSP.

In 2007 the shellfish industry was the primary financier of an independent audit of the growing area classification program. The audit identified a number of areas where the program could be improved if additional staff were added to the water quality group. The audit also provided specific recommendations for the DMR to review and determine if such recommendations would work well with the program. The state legislature passed a requirement that all recommendations be summarily adopted without due process of review and assessment by the DMR or the FDA. The legislature did not provide any additional money for the number one cited problem with the program, lack of personnel. The DMR now has additional responsibilities with even less resources.

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 reviewed in the past three years. The selected growing areas are listed below.

Shellfish Management Areas

West - Boothbay Harbor Office	East - Lamoine State Park Office
WB - York River	EA - Bagaduce River
WI - Casco Bay	EE - Swans Island
WJ - Maquoit Bay	EH - SE Mount Desert Island
WQ - Damariscotta River	EI - Frenchman Bay
WV - Spruce Head	ER - Machias Bay
WW - Western Penobscot Bay	EU - St. Croix River

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.

As part of the 2007 independent audit findings a Shellfish Advisory Council (ShAC) was created to make recommendations to the commissioner and the legislature on shellfish issues. The ShAC recommends how to best utilize state agencies, municipal governments, the shellfish industry and citizen groups to make improvements to and maintain the quality of the state's coastal waters. The ShAC is acting as a liaison between the multiple groups. The ShAC in part is also charged with assisting the DMR with prioritizing the existing workload. Based on the outcome of the audit the legislature agreed to allow towns and harvesters to submit special study and proposal ideas on how to better determine shellfish and water quality cleansing rates. The special studies and proposals are submitted to the ShAC for review and ranking. The ShAC will collectively decide which studies should have municipal funds used to collect the proposed information. The DMR is responsible for helping develop the study plan, analyzing the data and writing reports at the end of the project. The additional workload, without additional staffing resources, will put an added strain on the program.

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 except for one, Area WJ. 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. Eleven of the reports have sections which were very detailed; and included charts, graphs and pictures to further illustrate findings. 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.

During the file review portion of the evaluation it was noted that the 2007 Sanitary Survey for Area WJ was lacking detailed information in most of the sections of the

report. The report was presented during the evaluation as a final copy ready for management review and concurrence. The review revealed that almost no impact assessment was made regarding water quality data and pollution source information. Upon further scrutiny it was found that major pollution sources were omitted from the report. When questioned about the lack of information in the sanitary survey the specialist responsible for writing the report simply stated that there was not enough time to complete all of the required work. The specialist did not alert anyone regarding the deficient work which could result in the entire area being placed in the closed status.

On June 2, 2008 the FDA accompanied the DMR on sampling run #3. On this run samples were collected from permanent sampling sites from Biddeford to Kennebunkport. A total of 23 samples were collected over the course of the day. While in the field, we were provided with an opportunity to compare actual field observations with the items listed in the most recent water quality reports. It was noted that information regarding animal farms in the area was lacking from the reports. The specialist assigned this area being sampled was unable to answer basic questions regarding pollution source location or their impact on the nearby shellfish beds.

On June 3, 2008 the FDA accompanied the DMR and the municipal shellfish warden Claire Ross for the Town of Great Chebeague Island on sampling boat run #5. On this run samples were collected from permanent boat sampling stations around Great Chebeague, Bates, Long and Cliff Islands. A total of 22 samples were collected over the course of the day. While collecting samples we reviewed the island coastlines and compared visual observations to what was documented in the latest growing area report. Two noteworthy discrepancies were observed. First, multiple pipes traveling overland and heading into the water on Great Chebeague Island were observed yet not identified in the written reports. According the maps these pipes were found in approved harvesting areas.

Secondly, the report did not contain an assessment of Hope Island which is part of growing area WI. During the boat sampling run it was noted that privately owned Hope Island has undergone extensive modifications to include multiple horse paddocks directly along the shore. The land itself slopes considerably down to approved waters. A triennial was reviewed as part of this evaluation. The triennial evaluation lacked overall assessment of most major pollution sources. The animals observed on Hope Island were not mentioned in the triennial report. Upon further investigation of the 2003 Sanitary Survey of the area the only reference to animals was a statement that *"There are no large agriculture activities near the coast."*

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.

In past years the FDA has found growing area reports not completed within the specified timeframes of the NSSP. The DMR neglected to close the affected growing areas and only formally addressed the situation when challenged by the FDA.

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 final 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 except for one report.

Growing Area WI (Casco Bay) has a Triennial Evaluation due in 2008. This report was reviewed as part of the FY 2008 PEER. The report was presented during the evaluation as a final copy ready for management review and concurrence. The evaluation was found to be deficient in multiple areas. Three of the six waste water treatment plants in this growing area did not have an evaluation completed to determine potential impact to neighboring growing waters. The Triennial Evaluation also reports that the Yarmouth and Sea Meadows Community waste water treatment plants both had effluent pipe modifications recently. The report states that *"This change may alter the hydrographic impact on the (clam) flats"* and recommends further assessment. According to documents submitted to the DMR the changes occurred in 2007 and early 2008. No attempt appears to have been made to perform any assessment work once the modifications were complete.

The DMR has established many stream sample sites to collect water periodically after heavy rainfall to determine any impact on shellfish. The report omits the amount of rainfall and date of rainfall, but does include a table which states that bacteria scores were greater than 1,700 CFU/100ml at seven of the ten sites collected on September 11, 2007. The assessment of the data ceases and no bacteria loading information is present. It is unclear what impact these streams have on the surrounding shellfish beds. The Storm Water section also includes the following reference, *"In 2007, Friends of Casco Bay and the Town of Cumberland collaborated on a storm water runoff project and concluded that non-point sources <u>are a threat</u> to the shellfish resources in Cumberland. See Appendix F for more information."* This statement was absent of any further explanation or assessment. The brief one page appendix stated that after a rain event on July 6, 2007 (no rain amount provided) pesticide 2,4-D was detected (no pesticide level provided) and that fecal coliform bacteria counts were reported at 10,000 CFU/100ml. The significance of these concentrations was not discussed

and the full extent of the impact the shellfish growing waters was not determined. The information provided makes it is unclear if the shellfish around the Town of Cumberland is safe for human consumption following a rain event.

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. The Boothbay Harbor Laboratory documented when there was a schedule change along with the new sampling date in the sample calendar master file. A review of the Lamoine Laboratory sample calendar revealed multiple schedule changes; however there was no documentation readily available as to why the sample dates were changed or when the make-up sample runs were completed.

The review of growing area reports found that the DMR collected the minimum number of samples required to be collected. A minimum of six samples were collected at all active stations in 2007. In those growing areas with conditionally managed shellfish beds the minimum number of samples appear to have been collected whether the condition was rainfall (six samples in the open status), marina/seasonal (three samples in the open status) or WWTP (monthly samples in the open status.)

The 2007 independent audit suggested that the DMR should collect all samples in a minimum depth of 18 inches of water from six to nine inches below the surface whenever possible to limit the amount of surface contamination from being collected as a representative sample of the surrounding water quality. Prior to the audit the DMR was collecting routine water samples in a range of 12 to 18 inches of water with a minimum depth of four inches from the surface. The DMR also had a low tide sampling guideline suggesting water be collected in no less than six inches of water. A review of the data set did find that fewer samples are now being collected at lower tides due to the need for more water at each station. Since this sampling approach has been used for less than one year it is unclear what effect this will have on the overall dataset. The NSSP requires that sampling take place across all tide stages unless a particular tide stage has been identified through science to be impacted by elevated bacteria levels. In order to ensure that the dataset continues to meet the minimum requirements of the NSSP the DMR has been reassessing all sample stations for need and accurate placement. As a result of this assessment the DMR has both created new stations and deactivated others.

While on various sampling runs during the field portion of this evaluation it was noted that not all sample data was collected in a timely manner. Two samplers were noted not entering wind direction information at each sample station and one sample collector was noted not entering the exact water temperature observed at each sample station. At each sample station location the sample collector ***should*** enter the exact environmental conditions observed at the time and place the sample is collected.

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; including that they are predictable and manageable. 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.

The Ash Point Cove Seasonal Conditional Area in Growing Area WJ was found to no longer meet approved criteria in the open status. Based on the unpredictable data results observed by the FDA the DMR reclassified the cove. The cove now has both restricted and prohibited classifications due to the water quality scores and actual/potential pollution sources identified in the shoreline survey, respectively. Due to the lack of staff the DMR has been unable to perform much needed pollution identification and abatement in order to keep the area open. As with all seasonal conditional areas the FDA recommends that the authority verify the season by sorting the data appropriately to prove that there are actual seasonal trends in the water quality scores.

Marina Conditional Areas are managed on the presence or absence of boats in a particular area of any shellfish growing area. During this evaluation it was noted that Marina Conditional Areas were being closed based on a calendar date without actually verifying whether or not the number of boats present would require a modification to when the closures were initiated. The annual conditional area management plan review stated that no reporting was needed; however it was pointed out that it is appropriate to generate a brief report to list the number of boats supporting the decision to open or close the area.

The upper Medomak River rainfall conditional area has a rainfall threshold of one inch. During 2007 the area was closed a total of 216 days. This area has proven to be very resource and labor intensive. Starting with a closure in October 2007 the area was sampled four times over a span of six weeks before the water quality returned to acceptable levels.

b) Shoreline Survey Requirements

The DMR is required to evaluate and document 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. The shoreline survey database review found entries which were either incomplete or had no data field sheets available for review to verify the accuracy of the information. One specialist, when asked for the field data sheets for review as part of the evaluation, replied that all past sheets were destroyed to save file space leaving no official record of actual work completed in each of the growing areas.

Throughout 2007 and into 2008 the Public Health Division worked to identify growing areas with deficient shoreline survey assessments. DMR management reviewed growing area files and mapped the coastline to reflect where immediate field survey work was needed. The mapped color coded the coast to reflect activities needed in less than two years (red), two years to five years (yellow) and greater than five years (green). Through the internal review of the shoreline activities many growing areas had portions of coastline which exceeded the 12 year minimum timeframe for review. As a result of the overdue field work in Growing Areas WN

and WR a total of 5,677 acres were reclassified "prohibited" closing vast productive shellfish harvesting areas.

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 (WWTP) 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. Some of the treatment plant outfalls have completed hydrographic studies. Outfalls waiting for these studies are required to have established buffer zones based on mathematical calculations using worst case situations for untreated or partially treated sewage. A review of Growing Area EI found that the WWTP buffer zones were based on assumed fecal concentration numbers and not actual data collected from the plant.

The DMR completed the field data collection portion of the hydrographic studies on two WWTPs. The Royal River and the Town of Wiscasset plants have had final reports pending for more than two years because the shellfish program does not have access to an engineer able to analyze the available data and generate a complete assessment of the impact from the plants to the shellfish growing areas.

There are very few industrial discharges along the coast of Maine. The ones that exist are located in heavily populated areas which have an existing closure due to other influences. The field component of this evaluation found a few industrial areas not assessed in the sanitary survey reports. The largest area of concern was the old Navy Fuel Depot located in lower Middle Bay. The Federal Government has referred the site to the Army Corps of Engineers to monitor the site as a formally utilized defense (FUD) site. The FUD listing gives the property a categorical exclusion from remediation if the site is to be used for such things as a cemetery; other uses would require remediation by the developer. The ME DEP performed shellfish tissue samples in the area of the FUD site and the information was found on the agency website. Most of the impact assessment information readily available was omitted from the most recent sanitary survey.

Agricultural runoff is not a problem for many growing areas along the coast. The bold rocky coast of downeast 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.

Agricultural runoff along the western part of the state has a more pronounced and immediate impact to local shellfish beds after rainfall. A wide range of animal farms from just a couple horses all the way up to several hundred head of cattle

can be found in and around the bays and coves stretching from the Town of Kittery east to the Saint George River. During the review at the Boothbay Harbor Laboratory basic agricultural information was found in the reports, however details regarding waste management, buffer zones and exact number and type of animals were lacking. While conducting the field survey portion of this evaluation animal farms were noted along the shore but were not found described in the written reports.

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.

During the evaluation it was determined that a field specialist was not completing shoreline surveys in areas where sewer lines had been installed. The staff member was reminded that not all home owners freely tie into the municipal sewer systems merely based on their proximity to the home. The staff member began surveying the sewered areas in hopes of verifying which coastal properties actually were hooked up to the public waste system. The results of the survey revealed that multiple malfunctioning private septic systems were observed among the homes relying on public sewage collection. Closures along the coast

zone were immediately created near the malfunctioning septic systems and the failures were reported to the local towns for follow-up and enforcement.

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.

During this evaluation it was determined that storm water impacts were not accessed in most growing areas from Portland Harbor east through the town of Harpswell. The sanitary survey of the Freeport, Brunswick and Harpswell area stated there was no storm water collection in the area; however a basic internet search revealed multiple impact studies completed by the local town and ME DEP showing outfall locations and analytical results. The reports determined that storm water outfalls in the area significantly contributed to the degraded water quality in the area. Vital information from these reports was omitted from shellfish sanitary surveys.

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. While accompanying the DMR on sampling run #3 we observed several pet waste bag stations placed along access points to the local beach. Various towns along the coast have created new regulations prohibiting pet fouling near sensitive shellfish growing waters.

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 DMR has worked over the past few years to complete marina surveys in which they will document all know pollution sources associated with the marina including pump out facilities, fuel docks and boat repair operations. The staff has been collecting marina latitude/longitude data and is developing a statewide GIS data layer for mapping purposes.

The marina 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.

It is important to evaluate all boat fueling docks as 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. During this evaluation unreported commercial seafood docks were found to have fuel tanks along the shore. The tanks did not have containment systems to collect any spilled fuel. The staff has been collecting fuel dock latitude/longitude data and is developing a statewide GIS data layer for mapping purposes to share with the ME DEP.

The DMR had been completing marina surveys on at least a triennial level in order to remain in compliance with the NSSP. The evaluation revealed multiple marinas which had not been visited in more that four years. Due to the lack of an assessment it was unclear if the number of boats in the marina had changed possibly resulting in the closure not being large enough to dilute the pollution to safe levels prior to entering the open shellfish beds.

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. The Maine Department of Environmental Protection tests coastal water, sediment and shellfish for metals and provides the analytical data on their website.

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.

Because there have been no *V.p.* illnesses epidemiologically linked to the consumption of oysters harvested in the state, and because water temperatures do not exceed 81 degrees Fahrenheit, a Vp control plan for Maine is not required by the NSSP. State regulation in Maine requires shellstock to be refrigerated within 16 hours of harvest. Although the authority is not required to perform a risk assessment the DMR completed the FDA *V.p.* risk assessment worksheet which found that oysters harvested in July and August should be refrigerated within ten hours of harvest. Under state regulation European oysters can not be harvested June 15 to September 15. Currently American oysters and all oysters harvested by aquaculturists are exempt from the harvesting date restrictions. (see Attachment I)

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. A sample of the remaining cooked mussels revealed toxin levels greater than 16,000 ug/100 g of shellfish tissue (closure threshold is 80 ug/100 g).

A second documented PSP intoxication occurred July 4, 2008. A local family from Washington County was aware of the existing PSP closure in the area; however did not heed the warnings. A family member harvested blue mussels in Cutler Harbor from abandoned fish pens for personal consumption. Three family members consumed the shellfish that same day and were subsequently hospitalized for PSP related symptoms. All three individuals were released from the hospital the following day. Mussels were collected from the fish pens and analyzed by the DMR. The PSP scores were greater than 6,000 ug/100 g of shellfish tissue (closure threshold is 80 ug/100 g).

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) Water Quality Laboratory Evaluation

The FDA Laboratory Evaluation Officer Linda Chandler evaluated both the micro and biotoxin laboratories in both the West Boothbay Harbor and Lamoine State Park facilities. All four components were found to be conforming to good laboratory practices. The actual laboratory evaluation reports are on file with the FDA and the DMR.

f) 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 an 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.

g) 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 restricted areas to waters classified as approved.

The DMR relay regulations which went into effect on May 2008 now require strict oversight by an unbiased and vetted individual to ensure that shellfish harvested in moderately polluted waters is not inadvertently diverted to market. The new regulation also requires additional record keeping on the part of both the harvester and person performing the oversight for the relay project. The new regulation details how the site where the shellstock are relayed to will be properly marked on all corners and that the normally approved waters will be closed until the required testing is performed.

During this evaluation the aquaculture requirements outlined in Chapter VI of the NSSP-MO were reviewed. The DMR currently issues aquaculture permits, reviews operational plans, approves sources of seed. Currently there are no land-based aquaculture facilities in Maine which require inspections every six months.

3. Current Findings

a) State Program Deficiencies

i. During the review of the general program files it was noted that the DMR did not complete all required portions of the sanitary survey outlined in Chapter IV@.01.A.1.

ii. During the review of the general program files and based on the field review of the growing areas it was noted that the DMR did not identify and evaluate all actual and potential sources of pollution which may affect the growing area. Chapter IV@.01.D.1.a

iii. During the review of the general program files it was noted that the DMR did not reevaluate all pollution sources necessary to fully evaluate any changes in the sanitary conditions of previously classified growing areas. Chapter IV@.01.C.3.a.iii

iv. During the review of the general program files it was noted that the DMR did not assess the reliability and effectiveness of sewage or other waste treatment systems to determine the size of the prohibited area adjacent to each outfall. Chapter IV@.03.E.5.b

v. During the review of the general program files it was noted that the DMR did not verify each year that existing conditional areas had data which continued to support the conditional classification or verify that the conditions for each area were reasonable to manage.
Chapter IV@.03.C.1

b) Recommendations

i. The FDA recommends that any changes made to the systematic random sampling schedule described in Chapter IV@.02.F.6.b.ii be formally documented describing the reason for the schedule change and the revised date of sampling.

ii. The FDA recommends that all environmental data observed at the time and place of sample collection be entered into the official record on the authority approved sample data collection form. Required to satisfy Chapter IV@.01.A.1.d.

4. Corrective Actions taken by the State

On June 9, 2008, the supervisory Scientist for western Maine instituted a mechanism to list and track all marinas in western Maine. The spreadsheet that was created includes the growing area, marina name, location, classification, last interview completed date, the opening and closing dates of the conditionally approved area and the GPS coordinates of the marina or mooring field. The supervisor also added the opening and closing dates to the sample schedule calendar with a one month and a two week prior to opening/closing alert date to notify staff members that field reconnaissance is required. The staff member must turn in the necessary documentation to demonstrate that the area meets the requirements for opening/closing. When all of the GPS coordinates have been entered into the form, the supervisor will develop a GIS layer for use in report writing and shared with other agencies.

The Lamoine staff members have developed a schedule for monitoring and inspecting their marinas as well. It is documented on the public board and information is filled in on the form as it is gathered.

On June 10, 2008, the supervisory scientist for the western Maine group developed a tracking and reporting mechanism for all the wastewater treatment plants that require evaluation. The spreadsheet includes the following information: growing area, town, treatment plant, owner/operator name/number, and date of last review, date of new review request, DEP comments, DEP inspector, and management plan last reviewed and updated and date last MOU signed.

On June 12, 2008, the supervisory Scientist for western Maine instituted a new policy for the Boothbay Harbor staff members for quality assurance and accuracy in reporting for shoreline survey work. After returning from the field, all staff members now must go over the data sheets and write a summary of the day's work. The daily summary should include, at a minimum, information such as location of survey, number of properties visited, what was found, and any follow up work required. An electronic copy must be

saved in the survey activity files for the growing area for the current year. A hard copy of the summary must be printed and filed in the appropriate folder in the growing area file. The summaries are to be used in the final reports at the end of the year. The summaries are required to be shared via email with the supervisor and division director. Once the daily summary report is completed, the **original** data sheets must be submitted to the supervisor. Each staff member will not be responsible for entering the data into the database. Data entry will be done by laboratory staff members or other DMR staff members who area trained in shoreline survey data entry. The division director has been entering the shoreline surveyed areas in the newly established GIS shoreline survey layer. All original data sheets will be kept in the division director's office in files for each growing area. This new SOP will be an expectation for the eastern portion of the state as well.

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 complete all required portions of the sanitary survey.

   b) 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 identify and evaluate all actual and potential sources of pollution which may affect the growing area.

   c) 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 reevaluate all pollution sources necessary to fully evaluate any changes in the sanitary conditions of previously classified growing areas.

   d) 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 assess the reliability and effectiveness of sewage or other waste treatment systems to determine the size of the prohibited area adjacent to each outfall.

   e) 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 verify each year that existing conditional areas had data which continued to support the conditional classification or verify that the conditions for each area were reasonable to manage.

6. Accomplishments

General

- Program Coordinator, Michelle Mason is working with shellfish committees throughout the state in order to develop a comprehensive GIS map layer of shellfish areas. Many agencies, non government organizations (NGOs) and

industry often request this information which is not available. The data layer will contain all shellfish species, not just soft-shelled clams.

- Don Card, Area Biologist in Southern Maine has been working with coastal towns in Casco Bay to deploy the 10 automatic, internet connected, rain gauges rain gauges that the Casco Bay Estuary Partnership supplied to the department. The towns of West Bath, Yarmouth and Harpswell have already signed agreements with the DMR and the rain gauges are reporting live on www.wunderground.com. Don is working to launch more gauges in Brunswick and Chebeague Island. The hope is that these gauges will allow us to more accurately determine rainfall impacts on shellfish areas.

- Alison Sirois, Volunteer Coordinator with the assistance of Cathy Vining, Microbiologist II and Mercuria Cumbo, Microbiologist III held mandatory annual volunteer training events. New equipment was provided, instruction on the standard operating procedures, new applications and volunteer agreements were signed. The training included a field component to check for proper aseptic technique and also to go over winter sampling protocols in the field. Specific attention was paid to the actual labeling of sample container and sample collection due to identified problems in the past year.

- The 2008 Growing Area Standard Operating Procedures manual was completed. It incorporates the appropriate recommendations from the 2007 Review Team Summary Report (October 29 – November 2, 2007). The document can be found on the website at:
  http://www.maine.gov/dmr/rm/public_health/shellfishgrowingarea.htm

- The Casco Bay Estuary Partnership sponsored a Municipal Shoreline Survey training course which was developed and presented by an interagency cadre from DMR, DEP, DHHS and U.S. FDA. The course was held in Portland on Tuesday, March 25th and Wednesday, March 26th. There were 30 people in attendance including many shellfish committee chairs, municipal shellfish wardens, harbormasters, codes enforcement officers and licensed plumbing inspectors. DMR and DEP staff members attended for cross-training purposes. As a result of the successful training, expired shoreline survey work has already been scheduled to be completed. An agreement between DMR and FDA was reached for areas that can be surveyed prior to April 4th; if the areas can be surveyed they will not need to be placed in the prohibited status. The DMR sponsored a second two day training April 30th and May 1st.

- The DMR updated Shellfish Relay Chapter 21 and added a shellfish seed definition to Chapter 2.95 that went into effect May 26, 2008. This brings the DMR into compliance with the National Shellfish Sanitation Program on these issues which were identified in the FDA audit of 2007.

- John Fendl, water quality specialist in the Lamoine Laboratory has been working with GIS experts from DEP on a Google Earth project and DMR is ready to go

live on the Public Health web page. John collaborated on developing a program that takes the most recent copy of the bacterial closures from the office of GIS server, converts it to a file that is read by Google Earth, and places it on an FTP site that is easily accessible by the DMR webmaster. The next step is for Maggie Hunter (webmaster) to create a link on the DMR webpage to the file.

Biotoxin

- DMR (Darcie Couture) was successful in securing a grant to study lobster tomalley. The National Oceanic and Atmospheric Administration's Center for Sponsored Coaster Research (CSCOR) Event Response Program awarded funds to the states of Maine and New Hampshire to investigate the geographic extent and temporal variability of paralytic shellfish poisoning (PSP) toxins in lobster hepatopancreas (commonly called 'tomalley') and other lobster tissues. In mid-July, preliminary analyses by Maine Department of Marine Resources revealed high levels of PSP toxins in tomalley of some lobsters. These findings prompted the Food and Drug Administration as well as Maine, New Hampshire, and Massachusetts to issue advisory warnings against eating lobster tomalley. CSCOR Event Response-supported research will provide managers with information required for successful management of this fishery, such as the geographic extent of PSP toxins in lobster tomalley, the dietary source of the toxins for lobsters, and toxin retention time in lobster tissues. There are two funding items in the grant; $5,000 for mice, which Woods Hole Oceanographic Institute will send directly to Charles River Laboratory, Inc. as a credit to the Maine DMR account; and $3,500 for the purchase of lobsters, which will be sent as a cash advance for Darcie Couture to administer. Testing will start next week, run for 5 weeks, and results should help to answer some of the questions that are already being asked by other managers and by some industry members.

7. New or Emerging Problems

The FDA has recommended that the state of Maine increase the permanent staff within the DMR Shellfish Water Classification Program since 2004. The state government continues to have limited resources and thus has been unable to provide the necessary funding to ensure that the DMR can adequately protect public health. The DMR is attempting to use volunteers as a stop gap measure to perform essential program tasks. The use of volunteers may sound like a quick and easy way to add more assistance to the shellfish program on the surface; however there is a significant amount of program resources which must be spent training, monitoring and coordinating the volunteers' activities. The volunteers must also attend annual refresher training and be periodically tested for proficiency.

There were two shoreline survey training courses held in 2008 at the request of local towns and the shellfish industry. The course was designed to train municipal employees how to recognize pollution problems so they may be remediated. To date less than half of the trained individuals have assisted the DMR in the field. As expected the trained individuals are only authorized to work within their respective jurisdictions which

requires the state to train countless more town employees requiring three (3) to five (5) additional 2-day shoreline survey training courses which take several days to coordinate and prepare the training materials. The training courses are presented jointly by the ME DMR, ME DEP, ME DHHS and the US FDA.

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

   DMR has requested the assistance of FDA Regional Shellfish Specialist Peter Koufopoulos as part of the training cadre for a Municipal Shoreline Survey training course to be held in March 2009.

   DMR has requested the assistance of FDA Engineer Gregory Goblick in the development of a guidance document to be used by agencies planning hydrographic or dye/dispersion studies. The DMR will use the guidance document to meet the requirements of the NSSP when studies are performed by other agencies. Third party dye/dispersion studies may become more common because the DMR does not have enough staff or resources to conduct the studies.

   Mercuria Cumbo, water quality laboratory manager, has requested that Linda Chandler conduct a laboratory evaluation of the private laboratory which has contracted with the municipality for a pilot project. Linda Chandler is requested to perform the evaluation and prepare the subsequent report. The evaluation will be an "approval" with an MOU for a specific application for the private lab. The Shellfish Advisory Council has chosen one pilot project and so it is necessary to get the MOU process started to proceed with the lab "evaluation" process. The lab evaluation will proceed in relation to the specifics of the testing needed for the project. It will be necessary to have an idea of the number of samples and tests the lab will need to perform which is part of the evaluation process.

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 be in non-compliance which stems directly from the inadequate 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 has had a direct impact on the level of documented incomplete work by the DMR.

    This evaluation has determined that the Maine DMR Shellfish Growing Area Classification Program has been unable to adequately evaluate all known pollution sources in a timely fashion to ensure the safe harvest of shellfish for direct market harvest. The DMR must be able to determine the impact pollution sources have on the shellfish growing areas or the areas shall be closed immediately to direct market harvest (the waters will be classified to something other than approved or conditionally approved in the open status).

The DMR has shown a significant decline in performance since the last evaluation which could impact their ability to ship shellfish in interstate commerce. The program needs additional resources to return to full NSSP compliance.