

## State of Maine Procurement Justification Form

This form must accompany all contract requests and sole source requisitions (RQS) over \$5,000 submitted to the Division of Procurement Services.

INSTRUCTIONS: Please provide the requested information in the white spaces below. All responses (except signatures) must be typed; no hand-written forms will be accepted. See the guidance document posted with this form on the Division of Procurement Services website (Forms page) for additional instructions.

PART I: OVERVIEW				
Department Office/Division/Program:	Department of Marine Resources, Bureau of Public Health			
Department Contract Administrator or Grant Coordinator:	Kohl Kanwit			
(If applicable) Department Reference #:				
Amount: (Contract/Amendment/Grant)	\$309,033.00	Advantage CT / RQS #:	13A 20201210000000001828	
<b>CONTRACT</b>	Proposed Start Date:	1/1/2021	Proposed End Date:	12/31/2025
<b>AMENDMENT</b>	Original Start Date:		Effective Date:	
	Previous End Date:		New End Date:	
<b>GRANT</b>	Project Start Date:		Grant Start Date:	
	Project End Date:		Grant End Date:	
Vendor/Provider/Grantee Name, City, State:	Bigelow Laboratory for Ocean Sciences 60 Bigelow Dr East Boothbay, ME 04544			
Brief Description of Goods/Services/Grant:	Contract shellfish biotoxin sample processing using National Shellfish Sanitation Program approved HPLC PCOX, HPLC UV and LCMS/MS methods in a FDA certified laboratory.			

PART II: JUSTIFICATION FOR VENDOR SELECTION			
Mark an "X" before the justification(s) that applies to this request. (Check all that apply.)			
	A. Competitive Process		G. Grant
	B. Amendment		H. State Statute/Agency Directed
<b>X</b>	C. Single Source/Unique Vendor		I. Federal Agency Directed
	D. Proprietary/Copyright/Patents		J. Willing and Qualified
	E. Emergency		K. Client Choice
	F. University Cooperative Project		L. Other Authorization

PART III: SUPPLEMENTAL INFORMATION
Please respond to ALL of the following:
<b>1. Provide a more detailed description and explain the need for the goods, services or grant to supplement the response in Part I.</b>

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### PART III: SUPPLEMENTAL INFORMATION

The Department of Marine Resources, Bureau of Public Health is tasked with monitoring the bivalve shellfish resources of the state of Maine for biotoxin threats. This monitoring program is mandated by the National Shellfish Sanitation Program Model Ordinance, compliance with which allows Maine shellfish to be exported out of the state. Testing must be done using an approved method in a US Food and Drug Administration certified laboratory. DMR has transitioned from the mouse bioassay (MBA) method of saxitoxin detection to the High-Performance Liquid Chromatography (HPLC) method. This provides a more accurate result with increased sensitivity and eliminates the need for animal testing. DMR also requires HPLC UV testing for domoic acid which first appeared at quarantine levels in the Gulf of Maine in 2016. Finally, DMR requires access to LCMS/MS testing for okadaic acid which also first appeared at potential quarantine levels in 2016. All of these toxins require routine monitoring to ensure public safety.

#### 2. Provide a brief justification for the selected vendor to supplement the response in Part II.

The biotoxin monitoring program is time sensitive and results must be disseminated daily through the height of the biotoxin season (March-October) as well as on an as needed basis year-round. Bigelow Laboratory for Ocean Sciences has the staff expertise to run the approved HPLC PCOX, HPLC UV and LCMS/MS methods and has conducted single lab validation work and obtained FDA certification. No other governmental or non-governmental labs are certified by the FDA to conduct these testing methods. The Department of Marine Resources lacks the staff, equipment and expertise required to run these methods.

#### 3. Explain how the negotiated costs or rates are fair and reasonable; or how the funding was allocated to grantee.

DMR has traditionally spent between \$40,000 and \$80,000 on materials to conduct biotoxin testing annually. The majority of these funds were historically spent on mice that were injected with shellfish extract. The cost of mice has increased dramatically from about \$3/mouse in 2012 to \$5.62/mouse in 2017 with an increase to \$6.41/mouse in 2019. A standard biotoxin sample requires 3 mice/sample and when shellfish are toxic, often requires an additional 3 to 6 mouse/dilution. DMR processed about 3,000 MBA samples per year, at a cost of \$38.46-57.69/sample for just the mice, resulting in a budget of between \$57,690 and \$115,380. This contract would result in a per sample cost of \$18.33 (\$55,000 annually) and requires limited staff time for processing. The savings in staff time allows DMR to focus more on early warning phytoplankton monitoring which is becoming increasingly important. Further this contract incorporates testing for three distinct toxins while MBA can only accommodate one toxin. Finally, the contract incorporates consulting on emerging biotoxin threats and new lab method development (\$5,000).

#### 4. Describe the plan for future competition for the goods or services.


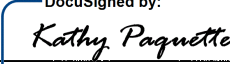
There is one other FDA certified biotoxin laboratory in Maine (Resource Access International) and if they were to develop the capability to test biotoxin samples with HPLC PCOX, HPLC UV and LCMS/MS a competitive process could be implemented. However, as it stands now, RAI only provides MBA analysis and charges \$150/sample.

### PART IV: APPROVALS

**Signature of requesting**

*By signing below, I signify that I approve of this procurement request.*

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<b>Department's Commissioner (or designee):</b>			
<b>Printed Name:</b>	Patricia C. Kelher	<b>Date:</b>	1/14/21
<b>Signature of DAFS Procurement Official:</b>	DocuSigned by: 		
<b>Printed Name:</b>	41C2BA36FAF44CD... Kathy Paquette	<b>Date:</b>	1/22/2021