

**MODULAR FILTRATION SYSTEM**  
**USER REQUIREMENT SPECIFICATIONS**

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**U.S. DEPARTMENT OF COMMERCE**  
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## **2 SCOPE**

The project will include a modular tangential flow filtration system mounted on a portable skid. This document defines the requirements and deliverables for this system. It describes overall requirements that must be met to produce the specific equipment requested. This document covers the procurement and delivery of the systems, with no required installation.

This URS is the input document for the:

- Equipment procurement purposes.
- Equipment sizing
- Functional and technical specifications.

## **3 BACKGROUND**

The Dakota Bioproducts Innovation Institute is a research facility for the development of high-quality bioproducts. A modular filtration system has been identified as one of the separation technologies that will be available for customer use.

## **4 PROCESS DESCRIPTION**

The modular filtration system will provide a membrane filtration process that can support a wide range of volumes and applications. The system is designed to enable a client to rearrange the hardware to run varying batch sizes and membranes. It will support the use of several membrane sizes and types. Membrane types will include polymeric, tubular, hollow fiber, and ceramic. The system may or may not include recipe-based, fully automated control.

## **5 BASIS OF DESIGN**

### **5.1 Capacities**

The filtration system should be capable of handling batch volumes up to 2400 L. The membrane feed pump shall be capable of, but not limited to, supplying 30-100 GPM at 25-100 psig.

### **5.2 Skidded Construction**

The filtration system shall be mounted on a portable, steel frame skid. Any control system, electrical panel, and all associated wiring shall be included.

### **5.3 Health, Safety and Environment (HSE)**

The filtration system will satisfy appropriate conformity assessment procedures and the controls shall carry the UL marking. The selected unit shall be constructed per the current ASME BPE standard. It will be designed to protect users from hot surfaces. Pressure relief safety valves or rupture disks shall be vented to a safe location.

### **5.4 Operation, personnel and automation**

The filtration skid may or may not be fully automated as a standalone unit such that operations personnel will not need to attend to it once it is started and operating. The level of automation will be determined after the equipment proposals for this unit operation have been carefully considered.

### **5.5 Materials of Construction**

All materials of construction must be compatible with ambient and hot water for injection (WFI), and typical chemical cleanings agents such as phosphoric acid, potassium hydroxide, and sodium hydroxide up to 3%. Piping specifications, including all gasket and valve seat material must align with current ASME BPE standards, where applicable.

### **5.6 Reliability & maintenance**

The filtration system will be designed to operate routinely during operations and rated for continuous use. All wear parts shall be easily accessible and replaced on a regular maintenance schedule. Wear parts like gaskets shall be stock items that can be ordered and delivered in a timely manner.

## **6 ABBREVIATIONS, ACRONYMS & DEFINITIONS**

<b>Acronyms</b>	<b>Description</b>
ASME-BPE	American Society of Mechanical Engineers Bio-Processing Equipment
CIP	Clean In Place
GPM	Gallons per Minute
HMI	Human Machine Interface
LMH	Liters per Square Meter Hour
OPT	Optional Attribute
P&ID	Piping & Instrumentation Diagram
PLC	Programable Logic Controller
NEMA	National Electrical Manufacturers Association
REQ	Required Attribute
SCADA	Supervisory Control and Data Acquisition
UL	Underwriters Laboratories
URS	User Requirements Specification
WFI	Water for Injection

## 7 USER REQUIREMENT SPECIFICATIONS

<b>URS TABLE – Modular Filtration System</b>		
<b>Designation</b>	<b>Description</b>	<b>Type</b>
URS-F1	The system shall be capable of feeding 30-100 GPM to the membrane.	REQ
URS-F2	The filtration skid shall be designed to operate multiple membrane formats such as polymeric, hollow fibers, and ceramics.	REQ
URS-F3	The filtration skid shall support the use of several membrane sizes and types. Membrane materials and pore sizes will be available for microfiltration, ultrafiltration, nanofiltration, and diafiltration.	REQ
URS-F4	The system shall be configured to accept 3rd party filters such as, but not limited to, Cytiva, Repligen, or Millipore.	REQ
URS-F5	Piping shall be 304 or 316 stainless steel, of a sanitary design, and include tri-clamp connections.	REQ
URS-F6	Gaskets shall be EPDM or better.	REQ
URS-F7	The system shall be self-draining.	REQ
URS-F8	The estimated flux rate shall be approximately 5 to 200 LMH.	REQ
URS-F9	The skid will be CIP cleanable and sterilizable.	REQ
URS-F10	Any pumps on the skid shall be controlled by variable frequency drives.	REQ
URS-F11	All electrical panels/enclosures shall carry a NEMA 4 rating.	REQ
URS-F12	Power shall be provided to the skid via a single point 480V, 3-phase/ 60Hz connection.	REQ
URS-F13	The skid needs to be instrumented such that pertinent data can be collected and sent to a SCADA system for recording purposes.	REQ
URS-F14	A feed tank will be supplied as part of the skid.	OPT
URS-F15	The controller shall be an Allen Bradley PLC with an HMI interface.	OPT
URS-F16	The control system shall have robust recipe building capabilities for complete walk away functionality.	OPT
URS-F17	The control system shall have an external ethernet connection for integration into a SCADA system.	OPT
URS-F18	Full system documentation shall be provided, including instruction and maintenance manuals, safety instructions, P&IDs, recommended spare parts list, and dimensional drawings.	REQ
URS-F19	Control system documentation shall be provided, including specifications, wiring overview, circuit diagram, arrangement drawing, and terminal connection diagram.	REQ
URS-F20	Startup support shall be provided. Details to be determined.	REQ

**END OF SPECIFICATION**

## 8 SELECTION CRITERIA

Vendors will be evaluated based on the following criteria:

<b>Evaluation Criteria</b>		
<b>Description</b>	<b>Ranking</b>	<b>Weight</b>
<b>Mandatory Technical Requirements</b> A review of your proposal to determine adherence with the REQ specifications and technical requirements.	1-10	30%
<b>Proposal Pricing</b> Review of your proposal in relation to the services offered in the proposal. Proposals will be evaluated against competing proposals for cost effectiveness. Proposals will be evaluated to be reasonable and appropriate.	1-10	20%
<b>Technical Response</b> The technical response in your proposal portrays knowledge, experience, and professionalism. Relevant product features and/or specifications are available with your equipment other than those mandatory specifications allotted above.	1-10	10%
<b>Lead Time</b> A review of your product's lead time to meet business objectives.	1-10	15%
<b>Product Warranty</b> The available warranty, in scope, duration, and value, proposed with your product.	1-10	5%
<b>Experience and Demonstrated Results</b> Our evaluation will include a review of your history, your experience as it relates to the requirements within this RFP, evidence of past performance, quality and relevance of past work, references, and related items.	1-10	20%

## 9 RETURN BIDS TO

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## **10 OTHER PROVISIONS**

Must meet 200 CFR buy America Provision • Title 49 Subtitle B Chapter VI [Part 661](#)

Federal Participation Disclosure – “This project will be partially funded with Federal funds from the United States Department of Commerce, Economic Development Administration and therefore is subject to the Federal laws and regulations associated with that program.”

Must meet Federal Contract provision 200 CFR Title 2 subtitle A Chapter II [Part 200](#)

### **Certification Relating to Prohibited Entity**

For contractors, vendors, suppliers, or subcontractors who enter into a contract with the State of South Dakota by submitting a response to this solicitation or agreeing to contract with the State, the bidder or offeror certifies and agrees that the following information is correct:

The bidder or offeror, in preparing its response or offer or in considering proposals submitted from qualified, potential vendors, suppliers, and subcontractors, or in the solicitation, selection, or commercial treatment of any vendor, supplier, or subcontractor, is not an entity, regardless of its principal place of business, that is ultimately owned or controlled, directly or indirectly, by a foreign national, a foreign parent entity, or foreign government from China, Iran, North Korea, Russia, Cuba, or Venezuela, as defined by South Dakota Executive Order 2023-02. It is understood and agreed that, if this certification is false, such false certification will constitute grounds for the State to reject the bid or response submitted by the bidder or offeror on this project and terminate any contract awarded based on the bid or response. The successful bidder or offeror further agrees to provide immediate written notice to the contracting executive branch agency if during the term of the contract it no longer complies with this certification and agrees such noncompliance may be grounds for contract termination.

### ***RESTRICTION OF BOYCOTT OF ISRAEL***

For contractors, vendors, suppliers, or subcontractors with five (5) or more employees who enter into a contract with the State of South Dakota that involves the expenditure of one hundred thousand dollars (\$100,000) or more, by submitting a response to this solicitation or agreeing to contract with the State, the bidder or offeror certifies and agrees that the following information is correct:

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The bidder or offeror, in preparing its response or offer or in considering proposals submitted from qualified, potential vendors, suppliers, and subcontractors, or in the solicitation, selection, or commercial treatment of any vendor, supplier, or subcontractor, has not refused to transact business activities, has not terminated business activities, and has not taken other similar actions intended to limit its commercial relations, related to the subject matter of the bid or offer, with a person or entity on the basis of Israeli national origin, or residence or incorporation in Israel or its territories, with the specific intent to accomplish a boycott or divestment of Israel in a discriminatory manner. It is understood and agreed that, if this certification is false, such false certification will constitute grounds for the State to reject the bid or response submitted by the bidder or offeror on this project and terminate any contract awarded based on the bid or response. The successful bidder or offeror further agrees to provide immediate written notice to the contracting executive branch agency if during the term of the contract it no longer complies with this certification and agrees such noncompliance may be grounds for contract termination.