

**Division of Environmental Health
On-Site Water Protection Section
On-Site Wastewater Branch
Application for Approval Under
Rule 15A NCAC 18A .1969**

PRODUCT NAME: _____ **DATE:** _____

Innovative Experimental Controlled Demonstration Accepted Device Component

Modification If modification, indicate reason for modification: _____

Fast Track Review (For advanced wastewater pretreatment systems only)

APPLICANT INFORMATION

Applicant _____ Address _____ Phone _____

Contact Person _____ Email Address _____ Fax _____

Agent _____ Agent Address _____ Agent Phone _____

Contact Person _____ Agent Email Address _____ Agent Fax _____

SYSTEM INFORMATION

System Description _____

Materials used in Construction _____

Proposed Use _____

ALL APPLICATIONS - The Applicant shall attach the following supporting documentation, as applicable:

- ❶ Summary of pertinent literature, published research, and previous experience & performance with the system.
- ❷ Results of any available testing, research or monitoring of pilot systems or full-scale operational systems. Specify whether the testing, research or monitoring provided was conducted by a third party research or testing organization.
- ❸ Specification of system evaluation protocol.
- ❹ Construction drawings detailing all system components
- ❺ Specifications describing all materials to be used, methods of construction, means for assuring the quality and integrity of the finished product, and installation procedures
- ❻ Copy of Draft new/modified approval document (*provide hard copy and electronic copy on CD or by email attachment*)

The Applicant shall also provide with all applications, if applicable:

- | | | |
|--------------------------|--------------------------|--|
| Done | Not
Applicable | |
| <input type="checkbox"/> | <input type="checkbox"/> | Verification that a system being submitted for approval has been tested and certified in accordance with an approved evaluation protocol |
| <input type="checkbox"/> | <input type="checkbox"/> | For systems with no prior approval in North Carolina, an affidavit certifying that the product submitted for approval is the same as the certified or listed product or any modifications made to the submitted product have been identified |

- Operation, Maintenance and Monitoring procedures for system, system classification, proposed management entity and system operator requirements
- Notification of any proprietary information, system, component, or device (note: any such information shall be clearly marked, on each applicable page or component, ***“Confidential or Trade Secret to not be subject to public distribution as provided for by public records laws and rules”***).

EXPERIMENTAL & CONTROLLED DEMONSTRATION -

For Experimental or Controlled Demonstration System Approval submittals, the applicant shall also provide the following information:

- ❶ Identity and qualifications of any proposed research or testing organization and the principal investigators.
- ❷ Affidavit certifying that the organization and principal investigators have no conflict of interest and do not stand to gain financially from the sale of the system.
- ❸ Description of proposed research or testing program which shall include:
 - Objectives, methodology and duration of any proposed research or testing which are included in research design.
 - Justification that the Research design and testing methodology proposed have reasonable likelihood of meeting the objectives.
 - Substantiation that the research program is such that, if objectives are met, the system would satisfy the standards for approval as a Controlled Demonstration or an Innovative System, as applicable.
- ❹ Specification of the number of systems proposed to be installed, the criteria for site selection, and system monitoring and reporting procedures (**note:** installations are to be under the direct field supervision of the research or testing organization).
- ❺ Procedures specified to address system malfunction and replacement or premature termination of research or testing.

The Applicant shall also provide with all **Experimental System** applications, if applicable:

- | | | |
|--------------------------|--------------------------|---|
| Done | Not
Applicable | |
| <input type="checkbox"/> | <input type="checkbox"/> | When request is to be “Fast-Track” reviewed, prior-approved evaluation protocol has been identified, which proposed research or testing program shall follow. |

The Applicant shall also provide with all **Controlled Demonstration System** applications, if applicable:

- | | | |
|--------------------------|--------------------------|---|
| Done | Not
Applicable | |
| <input type="checkbox"/> | <input type="checkbox"/> | Documentation is provided of at least 50 installation operational for at least 12-months, unless: <ul style="list-style-type: none"> <input type="checkbox"/> Data collected show all other requirements for controlled demonstration approval have been met from a lesser number of North Carolina installations in conjunction with a prior- approved Experimental System research or testing program; or <input type="checkbox"/> Documentation is provided of the system’s design and functional similarity to another approved system and that substantiates performance in a manner equal or superior to the comparable approved system in terms of structural integrity, chemical durability, hydraulic performance and wastewater treatment |
| <input type="checkbox"/> | <input type="checkbox"/> | When request is to be “Fast-Track” reviewed, TS-I or TS-II compliant certification data collected under NSF Standard 40 or another prior-approved evaluation protocol have been provided, and all other available field verification data have been provided and are consistent with TS-I or TS-II performance standards, as applicable. |

INNOVATIVE SYSTEM

For Innovative System Approval submittals, the applicant shall also provide the following information:

- ❶ Proof that the System has been demonstrated to perform equal or superior to a system which is described in Rules .1955, .1956, .1957, or .1958. Indicate whether the basis for the above claim is:
 - A controlled pilot-scale research studies (described fully), and/or
 - A statistically-valid monitoring of full-scale operational systems (described fully).
- ❷ Proof that materials used in construction are equal or superior in physical properties and chemical durability, compared to materials used for similar proposed systems described in the Rules or previously approved Innovative Systems.

- ③ Any special conditions for use, installation, operation, monitoring and maintenance that should be conditions of any approval document.

The Applicant shall also provide with all Innovative System applications, if applicable:

- | Done | Not
Applicable | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Documentation is provided of: <ul style="list-style-type: none"> <input type="checkbox"/> At least 100 installations operational for at least 12- months, unless: <input type="checkbox"/> Data collected show all other requirements for innovative approval have been met from a lesser number of North Carolina installations in conjunction with a prior- approved Experimental or Controlled Demonstration research or testing program |
| <input type="checkbox"/> | <input type="checkbox"/> | When request is to be “Fast-Track” reviewed: <ul style="list-style-type: none"> <input type="checkbox"/> TS-I or TS-II compliant evaluation data collected under NSF Standard 40 or another prior approved evaluation prior-approved evaluation protocol, have been provided, and <input type="checkbox"/> Statistically valid third-party field verification data demonstrating compliance with TS-I or TS-II standards have been provided which include at least 50 data points from a minimum of 15 sites, with a minimum of two data points per site, collected over at least a 12-month periods, with no data excluded form the field sampling sites proposed research or testing program shall follow, has been identified. |

ACCEPTED SYSTEM

For Accepted System Approval submittals, the applicant shall also provide the following information, as applicable:

- ① Proof that the System has been in general use as an Innovative System in North Carolina for more than five years.
 - Documentation is provided that there have been at least 300 systems installed statewide
- ② Information on number and location of new North Carolina installations and of all known systems required to be repaired
 - Data and findings of prior performance surveys of systems in use in North Carolina for at least the five year period immediately preceding the petition, including any information pertinent to the accuracy and validity of surveys not completed under the control of the manufacturer.
 - Any other information documenting the experiences with system performance in North Carolina.
- ③ Data and findings of all other prior evaluations of the performance of the system (e.g., outside of NC).
- ④ For proprietary nitrification trench system, statistically valid survey, including field evaluation of at least 250 randomly selected systems compared with 250 conventional systems special conditions for use, installation, operation, monitoring and maintenance that should be conditions of any approval document.
- ⑤ For advanced pretreatment system, documentation that system has received certification under NSF Standard 40 or another prior approved evaluation protocol, and performance audit has been run for at least 3 consecutive years or until data have been collected form at least 30 separate operational NC systems.
- ⑥ Other criteria are proposed for determining whether the system has been in general use or other surveys are proposed for approval to verify equal or superior performance under actual field conditions in North Carolina.

APPROVAL MODIFICATION

For Applications for Modification of prior System Approvals, the applicant shall also provide the following information:

- ① Detailed description of proposed approval modifications and edited version of previous approval document.
- ② Justification/demonstration that modified system will perform in a manner equal or superior to the approved system in terms of structural integrity, chemical durability, hydraulic performance and waste treatment.

The Applicant hereby certifies that, to the best of his/her abilities and belief, complete and factual representations of the information requested above have been provided.

Applicant or Applicant's Agent signature (required)

Date

The Research/Testing Organization certifies that, to the best of its knowledge and belief, complete and factual representations of the proposed research/testing program have been provided (*for Experimental and Controlled Demonstration Systems Only*)

Research/Testing Organization Agent signature

Date

Initially submit two (2) copies of all requested material to the Chief, On-Site Water Protection Section, Division of Environmental Health, 1642 Mail Service Center, Raleigh, NC 27699-1642 (Phone: 919-733-2895). Also include **fee payment** in accordance with the fee schedule below. Corporate check, money order, or cashiers check shall be made payable to NC OSWW System Account. Upon receipt of Acknowledgment from Section Chief and assignment of OSWPS staff application manager, enough copies should be submitted to manager for each Innovative/Experimental Advisory Committee Member (12), or the Applicant may directly provide Committee members and OSWPS staff application manager individual copies of all materials.

1. Review of an alternative experimental or controlled demonstration evaluation protocol--\$1,000.00
2. Review of an experimental system--\$3,000.00
3. Review of a controlled demonstration system--\$3,000.00
4. Review of an innovative system--\$3,000.00
5. Review of an accepted system--\$3,000.00
6. Review of a residential wastewater treatment system (NCGS 130A-342)--\$1,500.00
7. Review of a component or device of a system--\$100.00
8. Modification to an approved innovative system--\$1,000.00