

# **Innovative and Experimental Approval Process**

## **Responsibilities**

Several different people and groups are involved in the Innovative and Experimental (I&E) approval process. The different people and groups involved and their responsibilities are outlined below.

### Division of Environmental Health Director

The Division of Environmental Health Director signs all Innovative, Controlled Demonstration, and Experimental Approvals and approval letters, including modifications to approvals and denials. The Director receives recommendations from the On-Site Water Protection Section staff and the I&E Committee with respect to approval or denial of applications.

### On-Site Section Chief

The On-Site Water Protection Section Chief initially receives all applications, logs them in and assigns the On-Site Water Protection Section Project Manager. The Section Chief will provide support as needed to the Project Manager and assure other On-Site Section staff are apprised about pending new/modified approvals and shall receive comments from staff prior to transmitting Section's recommendations to the Director.

### I&E Committee

The I&E Committee advises the Director of the Division of Environmental Health regarding approval or denial of applications or modifications of current approvals.

The Committee is made up of volunteers representing different viewpoints from the industry. The Committee members are as follows: private engineer, environmental health specialist, environmental health supervisor, health director, NC Home Builders Association, trade association, septic system installer, certified subsurface operator, academic community, and soil scientist.

### Chairman, I&E Committee

The I&E Committee Chairman conducts the I&E Committee meetings. The Chairman keeps the discussions on track, calls for decisions/votes/recommendations from the committee, sends out e-mail messages to the Committee reminding them of meeting dates and advising them of agenda items, provides the recommendations of the Committee to the Director (written)

### Note Taker

The note taker is a member of the On-Site Water Protection Section staff. The purpose of this position is to record the meetings notes and type them up so they can be posted on the web page in a timely fashion.

### Liaison

The liaison is a member of the On-Site Water Protection Section (preferably based in Raleigh). This position provides the information to the Chairman, including but not limited to:

- the technologies/products that have applied for approval and have been determined to have a completed application and are ready to present at the next meeting (coordinates with Project Managers),
- the current status of any application that is in the I&E approval process (coordinates with Project Managers),
- reserves the room for the meetings, sets up the room for the meetings,
- transmits notice of application received to the NC Registry and posts Draft approvals/denials on the Section homepage.

### Project Manager

The Project Manager is a member of the On-Site Water Protection Section assigned by the On-Site Water Protection Section Chief to each application. The Project Manager guides the manufacturer through the approval process, including but not limited to, reviewing the application for completeness, organizing and coordinating sub-committee meetings, and coordinating with the Liaison. The Project Manager verifies that the proposed product approval meets the rules. Written notes from sub-committee meetings or correspondence about the proposed product approval will be written by the Project Manager. The Project Manager will keep the Section Chief apprised of the status of the review process, and obtain input/comment on draft approvals from the Chief and other Section staff, as appropriate.

## **Innovative and Experimental System Approval Procedure Summary**

### Application Submitted

Any person seeking a new approval of an experimental, controlled demonstration, or innovative system, component or device must make an application in writing to the State pursuant to 15A NCAC 18A.1969. The application must be sent to the attention of the Section Chief. It must be received at least 45 days prior to the meeting at which the applicant would like to make a presentation. The new application must include the following information and any other information or data required for a complete application:

1. specification of the type of approval requested as either innovative, controlled demonstration, experimental, or a combination;
2. description of the system, including materials used in construction, and its proposed use;
3. summary of pertinent literature, published research, and previous experience and performance with the system;
4. results of any available testing, research or monitoring of pilot systems or full-scale operational systems and shall identify whether the testing, research or monitoring provided was conducted by a third party research or testing organization;
5. specification of system evaluation protocol as either an approved and listed protocol by the State or the applicant shall submit an alternative protocol for the evaluation of the performance of the manufacturer's system. National Sanitation Foundation (NSF) Standard 40 has been approved as an evaluation protocol pursuant to G.S. 130A-343(d);
6. verification that a system being submitted for approval has been tested and certified in accordance with an approved evaluation protocol, if applicable. For systems with no prior approval pursuant to this Rule, the manufacturer shall provide an affidavit certifying that the product submitted for approval is the same as the certified or listed product or identify any modifications made to the submitted product;
7. identity and qualifications of any proposed research or testing organization and the principal investigators, and an 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 E & I system; and a copy of the proposed contract for evaluation between the manufacturer and research/testing entity;
8. objectives, methodology, and duration of any proposed research or testing;
9. specification of the number of systems proposed to be installed, the criteria for site selection, and system monitoring and reporting procedures;
10. operation and maintenance procedures, system classification, proposed management entity and system operator;

11. procedure to address system malfunction and replacement or premature termination of any proposed research or testing;
12. notification of any proprietary or trade secret information, system, component, or device;
13. in the case of a request for innovative system approval intended by the applicant to be subsequently reclassified from an innovative to an accepted system, monitoring, reporting and evaluation protocols to be followed by the manufacturer, the results of which shall be submitted in its future petition for accepted status; and
14. fee payment as required by G.S. 130A-343(k), by corporate check, money order or cashier's check made payable to: North Carolina On-Site Wastewater System Account or NC OSWW System Account, and mailed to the On-Site Water Protection Section, 1642 Mail Service Center, Raleigh, NC 27699-1642 or hand delivered to Rm. 1A-245, Parker Lincoln Building, 2728 Capital Blvd., Raleigh, NC.

The application shall also be accompanied by a draft approval document, which is either an original document or an edited version of the previously issued approval for a proposed approval modification. The Section will provide prospective applicants a document template of a draft approval form, upon request. The applicant is also encouraged to review approvals for comparable products on the Section's Homepage when formulating a draft approval. All draft approvals must be clearly labeled as a DRAFT and must reflect a version number and a date.

Any questions, issues, concerns regarding the I&E Committee, application process, etc, shall be directed to the Section Chief until a Project Manager has been assigned to the application.

#### Completeness Review

After the application is received and logged in by the On-Site Water Protection Section Chief, the Section Chief will assign a Project Manager. The Project Manager will make a determination of whether or not the application is complete. The determination of completeness shall be made within 30 days of receiving the application, with the applicant receiving in writing a letter specifying whether the application has been accepted, rejected, or if additional information is needed to complete the application and review. If the application is rejected, the applicant will receive in writing the reasons for rejection and whether additional information would be required for the application to be reconsidered. Any additional information requested from the applicant must be received within 180 days, or the application file will be closed. Acceptance of the application in terms of completeness does not constitute a qualitative review, approval or denial of the application.

Whenever possible, the Project Manager will notify the applicant at least 21 days prior to the I&E Committee meeting at which the applicant will present as to whether or not the application is complete. [The 21 days is within the 30 day determination of completeness.] If the application is complete, the applicant will be provided with a list of names and addresses of I&E Committee Members. The applicant must send a copy of the completed application to all Committee members, so that the Committee members receive the information by the 15<sup>th</sup> of the month prior to the I&E Committee meeting.

Any person seeking to modify an existing approval of an experimental, controlled demonstration, or innovative system, component or device must make an application in writing to the State pursuant to 15A NCAC 18A.1969. The application must be sent to the attention of the Section Chief. It must be received at least 45 days prior to the meeting at which the applicant would like to make a presentation. The application to modify an existing approval must include the same information as specified previously, specifically what changes to the application are being requested and the data or other additional information required to complete the application.

Copies of draft approvals shall be posted on the On-Site Water Protection Section’s Homepage, and notification of the receipt of completed applications for innovative approval shall be sent for posting to the NC Register.

### Completed Application

After a completed application has been received by the On-Site Water Protection Section and the I&E Committee, the applicant will give a presentation to the Committee. The Committee may require additional explanation and/or information and/or data in support of the application.

Review time frames for completed applications are as follows:

|                                   | Normal Review | Fast Track Review* |
|-----------------------------------|---------------|--------------------|
| Experimental Approval             | 90 days       | 45 days            |
| Controlled Demonstration Approval | 120 days      | 60 days            |
| Innovative Approval               | 180 days      | 120 days           |

\*Applies to pretreatment systems only

Applications for Experimental Approval will be “Fast Track” approved or denied within 45 days from the acceptance of a complete application when the proposed research or testing program is a prior approved evaluation protocol.

Applications for Controlled Demonstration Approval will be “Fast Track” approved or denied within 60 days from the acceptance of a complete application when the application includes TS-I or TS-II compliant certification data collected under NSF Standard 40 or another prior-approved evaluation protocol, and all other available field verification data provided under 15A NCAC 18A.1969(b)(4) are consistent with TS-I or TS-II performance standards.

Applications for Innovative Approval will be “Fast Track” approved or denied within 120 days from the acceptance of a complete application when the application includes: TS-I or TS-II compliant evaluation data collected under NSF Standard 40 or another prior approved evaluation protocol; the system shall have been demonstrated to perform equal or superior to a system, which is described in Rules 15A NCAC 18A.1955, .1956, .1957, or .1958, and to comply with TS-I or TS-II standards based upon statistically valid third-party field verification data 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 period, and with no data excluded from the field sampling sites; and materials used in construction shall be equal or superior in physical properties and chemical durability, compared to materials used for similar proposed systems, specifically described in Rules 15A NCAC 18A.1955, .1956, .1957, or .1958.

### Subcommittee Review

After the full Committee has heard the applicant’s presentation, a subcommittee of the full I&E Committee will be impaneled to review a Draft Approval for the item. The Project Manager will act as a facilitator and staff for the subcommittee. The applicant or applicant’s representative will be a member of the subcommittee. The subcommittee will review and modify a draft approval, agreed to by consensus of the subcommittee, that will be presented to the full I&E Committee as recommended for approval by the subcommittee.

### Director Review

Upon completion of the draft approval and its concurrence by the full I&E committee, a written recommendation from the Committee will be forwarded to the Director of the Division of Environmental Health. The Project Manager will also provide a separate written recommendation to the Director through the On-Site Section Chief. If other Section representatives have concerns with the proposed draft approval that is going before the Director, they may submit their recommendations or concerns to the Director through the Section Chief.

The Director will review all the recommendations and approve or reject the recommended approval. Should the Director reject the recommended approval, the applicant may revise and resubmit the application, withdraw the application, or petition the Office of Administrative Hearings (OAH) for a contested case hearing, thus beginning the appeals process. Should the Director approve the recommended approval, the applicant shall be notified, the approval becomes effective and will be posted as a newly-approved item on the Section's Homepage, and the 30-day appeal period begins.

### 30-Day Appeal Period

Once the Director approves (signs) the recommended approval, a period of thirty (30) days begins, in which appeal(s) of the approval document may be filed with the Office of Administrative Hearings (OAH). The appeals process may require modification of the approval, re-submittal of the application, or a restart of the approval procedure at some point in the process. Upon expiration of the 30-day appeal period, should no one contest the approval it will be distributed to Local Health Departments and posted as a final approved item on the Section's Homepage.

## **Innovative and Experimental Committee Meeting Procedures**

During presentations and discussions concerning a particular product, only the Committee members, the manufacturer and their representatives, and the Project Manager may speak without requesting permission. All other members of the audience are expected to be recognized by the Committee Chair before commenting or asking a question. When other members of the audience do speak they must identify themselves by name and who they represent.

A decision by the Committee requires two thirds (2/3) majority vote.

A quorum is five committee members present at the meeting.

Recommendations for people to replace outgoing Committee members must be sent to the On-Site Water Protection Section Chief. The Section Chief will discuss the recommendations with the Chairman, the Director, and others as he chooses, and make a decision as to whether or not to ask the person to serve on the Committee.

An agenda will be sent to the Committee electronically prior to the meeting.

A Committee member involved in manufacturer-sponsored research, marketing of a particular product, or has a financial interest in the sale of the product, must recuse themselves from any discussion and voting on the product.

Prior to the discussion of any specific product, applicant, or research, Committee members are ethically bound to reveal any connection, personal or professional, that they may have with that product, applicant, or research.

### Language for a Statement of Conduct (to be read at beginning of each meeting)

*The I&E Committee asks that all participants in this meeting, Committee members and audience alike, conduct themselves in a respectful, courteous manner, both with the Committee and fellow audience members. Should any Committee member or audience member fail to act in this manner, the Chairman will ask the offending person to leave the meeting until that individual regains personal control. Should decorum fail to be restored, the Chairman will recess the meeting until such time that all individuals in the meeting can act in the above manner.*