

Instructions and Limitations of "Trade Secret Request Declaration"

During the course of an application for a Sealed Source and Device Registration certificate, certain information and details about a product design and its fabrication methods are needed for the evaluation, but are also considered "trade secrets" by the applicant. The evaluation and issuance of an SS&D registration is integrated into a license amendment process. Items that are identified, stamped and justified as trade secrets are not subject to public disclosure.

This form is to be used to justify the trade secret status of each document claimed by the applicant. If, after review, the BRP determines the information qualifies as a trade secret, such information will be treated as confidential by the BRP. The applicant will be notified if a request for a document's status as a trade secret is denied.

Rule 3701:1-40-14(H) of the OAC states:

"Information provided by a licensee or applicant for a license or license renewal that constitutes a "trade secret" as defined in section 1333.61 of the Revised Code is not subject to public disclosure in accordance with sections 1333.61 to 1333.69 of the Revised Code."

Division (D) of section 1333.61 of the ORC states:

"'Trade secret' means information, including the whole or any portion or phase of any scientific or technical information, design, process, procedure, formula, pattern, compilation, program, device, method, technique, or improvement, or any business information or plans, financial information, or listing of names, addresses, or telephone numbers, that satisfies **both** of the following:

- (1) It derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use.
- (2) It is the subject of efforts that are reasonable under the circumstances to maintain its secrecy."

Instructions

1. In the first column, enter the document number or drawing number as it is identified in your QA/QC program.
2. In the second column, enter the descriptive name of the document or drawing.
3. In the third column, state the reason why the document is a "trade secret." The justification must clearly identify that it meets the definition of a trade secret in ORC 1333.61. (A copy of the definition is listed above.) A justification of trade secret status may be made for a series of documents in the application that have the same justification instead of reiterating the same reason several times. However, each document must be listed individually.

The term "**document,**" as used in this form, means a supporting drawing, process or design specification, brochures, manuals or procedures as it relates to a portion of the item for which a source or device registration is sought.