

(e) In the event the amount assessed by the Institute for unlisted assemblies, or components or subassemblies is less than the amount of the deposit submitted in accordance with paragraph (a) of this section, the Institute shall refund the overpayment upon the issuance of any approval or notice of disapproval.

### Subpart D—Approval and Disapproval

#### § 84.30 Certificates of approval; scope of approval.

(a) The Institute shall issue certificates of approval pursuant to the provisions of this subpart only for individual, completely assembled respirators which have been examined, inspected, and tested, and which meet the minimum requirements set forth in subparts H through L of this part, as applicable.

(b) The Institute will not issue certificates of approval for any respirator component or for any respirator sub-assembly.

(c) The Institute shall not issue an informal notification of approval. However, if the application for approval, submitted in accordance with § 84.11, states that the submitted respirator and component parts are only prototypes, the Institute will examine, inspect, and test such respirator and component parts in accordance with the provisions of this part. If, upon completion of such examinations, inspections and tests, it is found that the prototype meets the minimum requirements set forth in this part, the Institute may inform the applicant, in writing, of the results of the examinations, inspections, and tests, and may require him to resubmit respirators and component parts made on regular production tooling, with no operations included which will not be incorporated in regular production processing, for further examination, inspection, and testing, prior to issuance of the certificate of approval.

(d) Applicants required to resubmit respirators and component parts made on regular production tooling, with no operation included which will not be incorporated in regular production

processing, shall be charged fees in accordance with subpart C of this part.

#### § 84.31 Certificates of approval; contents.

(a) The certificate of approval shall contain a classification and a description of the respirator or combination of respirators for which it is issued, as provided in this part.

(b) The certificate of approval shall specifically set forth any restrictions or limitations on the respirator's use in hazardous atmospheres.

(c) Each certificate of approval shall be accompanied by the drawings and specifications (and lists thereof) submitted by the applicant in accordance with § 84.11. These drawings and specifications shall be referenced in the certificate of approval, and shall be maintained by the applicant. The drawings and specifications listed in each certificate of approval shall set forth in detail the design and construction requirements which shall be met by the applicant during commercial production of the respirator.

(d) Each certificate of approval shall be accompanied by a reproduction of the approval label design to be employed by the applicant with each approved respirator, as provided in § 84.33.

(e) No test data or specific laboratory findings will accompany any certificate of approval, however, the Institute will release pertinent test data and specific findings upon written request by the applicant, or as required by statute or regulation.

(f) Each certificate of approval shall also contain the approved quality control plan as specified in § 84.42.

#### § 84.32 Notice of disapproval.

(a) If, upon the completion of the examinations, inspections, and tests required to be conducted in accordance with the provisions of this part, it is found that the respirator does not meet the minimum requirements set forth in this part, the Institute shall issue a written notice of disapproval to the applicant.

(b) Each notice of disapproval shall be accompanied by all pertinent data or findings with respect to the defects of the respirator for which approval

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was sought with a view to the possible correction of any such defects.

(c) The Institute shall not disclose, except to the applicant or as required by statute or regulation, any data, findings, or other information with respect to any respirator for which a notice of disapproval is issued.

**§ 84.33 Approval labels and markings; approval of contents; use.**

(a) Full-scale reproductions of approval labels and markings, and a sketch or description of the method of application and position on the harness, container, canister, cartridge, filter, or other component, together with instructions for the use and maintenance of the respirator shall be submitted to the Institute for approval.

(b) Approval labels shall bear the emblem of the National Institute for Occupational Safety and Health and the

seal of the Department of Health and Human Services, the applicant's name and address, an approval number assigned by the Institute and, where appropriate, restrictions or limitations placed upon the use of the respirator by the Institute. The approval number assigned by the Institute shall be designated by the prefix TC and a serial number.

(c) The Institute shall, where necessary, notify the applicant when additional labels, markings, or instructions will be required.

(d) Approval labels and markings shall only be used by the applicant to whom they were issued.

(e) Legible reproductions or abbreviated forms of the label approved by the Institute for use on each respirator shall be attached to or printed at the following locations:

Respirator type	Label type	Location
Self-contained breathing apparatus.	Entire .....	Harness assembly and canister (where applicable).
Gas mask .....	Entire .....	Mask container and canister.
Supplied air respirator .....	.....do .....	Respirator container or instruction card.
Particulate respirator .....	.....do .....	Respirator container and filter container.
Chemical-cartridge respirator ...	Abbreviated .....	Filters.
	Entire .....	Respirator container, cartridge container, and filter containers (where applicable).
	Abbreviated .....	Cartridges and filters and filter containers.

(f) The use of any Institute approval label obligates the applicant to whom it is issued to maintain or cause to be maintained the approved quality control sampling schedule and the acceptable quality level for each characteristic tested, and to assure that it is manufactured according to the drawings and specifications upon which the certificate of approval is based.

(g) Each respirator, respirator component, and respirator container shall, as required by the Institute to assure quality control and proper use of the respirator, be labeled distinctly to show the name of the applicant, and the name and letters or numbers by which the respirator or respirator component is designated for trade purposes, and the lot number, serial number, or approximate date of manufacture.

**§ 84.34 Revocation of certificates of approval.**

The Institute reserves the right to revoke, for cause, any certificate of approval issued pursuant to the provisions of this part. Such causes include, but are not limited to, misuse of approval labels and markings, misleading advertising, and failure to maintain or cause to be maintained the quality control requirements of the certificate of approval.

**§ 84.35 Changes or modifications of approved respirators; issuance of modification of certificate of approval.**

(a) Each applicant may, if he desires to change any feature of an approved respirator, request a modification of the original certificate of approval issued by the Institute for such respirator by filing an application for