written request within 30 days after notice of approval. If no such request is made, the respirators will be disposed of by the Institute in such manner as it deems appropriate.

(e) Where a respirator fails to meet the requirements for approval set forth in this part, all respirators and components delivered in accordance with this section may be returned to the applicant at his own expense, upon written request within 30 days after notice of disapproval. If no such request is made, the respirators will be disposed of by the Institute in such manner as it deems appropriate.

[60 FR 30355, June 8, 1995, as amended at 80 FR 3906, Jan. 26, 2015]

Subpart C—Fees

SOURCE: 80 FR 3906, Jan. 26, 2015, unless otherwise noted.

§ 84.20 Establishment of fees.

(a) This section establishes a system under which NIOSH charges a fee for services provided to applicants for conformity assessment activities conducted by NIOSH for respiratory protective devices under 42 CFR part 84. This section specifies the purposes for which fees will be assessed and the cost factors for such assessments.

(b) Fees will be charged for:

(1) *Respirator certification application, approval, approval modification, records maintenance, and testing.* Application processing under this Part by engineers, technicians and other specialists, including administrative review of applications, analysis of drawings, technical evaluation, testing, test set up and tear down, and consultation on applications, clerical services, computer tracking and status reporting, records control and security, and document preparation directly supporting application processing. This fee also contributes to a proportionate share of management, administration and operation of the NIOSH National Personal Protective Technology Laboratory;

(2) *Maintenance of testing and approval facilities and test equipment.* Amortization of facility improvements and depreciation of buildings and equipment used for testing and evaluation or otherwise directly associated with application processing;

(3) *Site qualification.* Initial review and approval, as specified under 42 CFR part 84 subpart E—Quality Control, of manufacturing facilities that may be used to manufacture respirators, principal components, and/or subassemblies;

(4) *Quality assurance maintenance.* Quality site audits to verify conformance to the requirements of §§ 84.33, 84.40, 84.41, 84.42, 84.43; and

(5) *Maintenance of product performance.* Product audits to verify the performance of commercially available respirators which have been granted a NIOSH certificate of approval.

(c) Fees will not be charged for:

(1) Technical assistance not related to application processing;

(2) Technical programs including development of new technology programs;

(3) Participation in research; and

(4) Regulatory review activities, including participation in the development of health and safety standards, regulations, and legislation.

§ 84.21 Fee calculation.

(a) This section explains the process NIOSH uses to calculate estimates of the direct and indirect costs of services provided in the course of application processing.

(b) Upon completion of an initial administrative review of the application, NIOSH will calculate a fee estimate for each application, including the maximum cost of conducting additional tests under § 84.24, and will provide that estimate, with payment details, to the applicant. The fee estimate will be derived using the current schedules of fees published by NIOSH in Part 84. NIOSH will begin the technical evaluation once the applicant accepts the terms of the fee estimate and authorizes payment.

(c) If NIOSH determines that actual costs for application processing and related testing will exceed the fee estimate provided to the applicant, NIOSH will provide a revised fee estimate for completing the application review before exceeding the previously-authorized fees. The applicant will have the