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## Policy supporting the collections of NIOSH Approval Fees

### 1. PURPOSE

This policy document is intended to provide specific implementation guidance and interpretation to support fee collections in accordance with the requirements of Title 42 Code of Federal Regulations (42 C.F.R.), Part 84, Subpart C--Fees.

### 2. SCOPE

This policy applies to all fees collected by the National Institute for Occupational Safety and Health (NIOSH) in carrying out the provisions for approval of respiratory protective devices in accordance with the provisions of 42 C.F.R. Part 84.

### 3. REFERENCES

3.1 Title 42, Code of Federal Regulations, Part 84.

3.1.1 § 84.20 Establishment of Fees

3.1.2 § 84.34, titled "Revocation of certificates of approval" states, "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."

### 4. BACKGROUND

A final rule was published in the Federal Register on January 26, 2015 that provided a revised fee structure used by NIOSH to charge respirator manufacturers for the examination, inspection, and testing of respirators which are submitted to NIOSH for the purpose of creating or modifying

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a certificate of approval. This fee revision established a new fee structure designed to enable NIOSH to fully recover the costs associated with the examination, inspection, and testing of complete respirator assemblies.

The fee schedule is divided into two parts: (1) Fee Schedule A comprises annual (fixed) fees; and (2) Fee Schedule B comprises application-based fees, including fees for individual test procedures. This final rule and fee schedules became effective May 26, 2015.

## 5. POLICY

5.1. In accordance with the collection of Annual (Fixed) Fees as established at Part 84, Appendix A, the following apply:

5.1.1. NIOSH will issue a single consolidated annual fee invoice for annual maintenance fee assessments in the month of September of each year.

5.1.1.1. With regard to the fee for annual product audit, the annual invoice will assess the approval-holder only for the annual product audit fixed fee. In roughly the same time frame, the approval-holder will be given the option to provide the approved product identified for audit or to reimburse NIOSH for the cost (annual variable fee) to purchase the product. If chosen, the annual variable fee will be assessed at the close of the product audit along with the assessment of testing fees pursuant to Appendix B, Application-Based Fees (see 5.2).

5.1.1.2. Payments not received by October 31 will be considered late. Late notices will be provided at 60 and 90 days.

5.1.1.3. NIOSH will initiate sanctions when payment is past due by 120 days. In addition to the non-payment remedies specified at § 84.22(c)(1), (2), and (3), the following specific actions will be considered as suggested by the specific circumstances related to outstanding, overdue payment(s):

5.1.1.3.1. Suspension of processing for in-house applications.

5.1.1.3.2. Revocation of approvals. (See 3.1.2)

5.2. In accordance with the collection of Application-Based Fees as established at Part 84, Appendix B, the following apply:

5.2.1. NIOSH will not process any application unless it is accompanied by the required application fee.

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- 5.2.2. Upon receipt of a complete application, the initial reviewer will prepare a fee estimate covering the total fee expected to be necessary to complete the request for approval. This estimate will include testing costs and the cost of issuance for approval(s) or extension of approval(s).
- 5.2.2.1. The applicant must respond to this request with either acceptance of the fee estimate and authorization of payment or a request to withdraw the application within two weeks or the application will be denied.
- 5.2.2.2. If during the course of evaluation, NIOSH determines that the original fee estimate is not sufficient to cover the cost of processing the application, a revised fee estimate will be issued. As with the original estimate, the applicant must respond to this request with either acceptance of the re-estimated fee and authorization of payment or a request to withdraw the application.
- 5.2.2.3. NIOSH will send the final fee invoice will be sent with the certificate of approval letter. Payment is due from the approval holder within 30 days.
- 5.2.2.4. Late notices will be provided when payment is past due by 60 and 90 days.
- 5.2.2.5. Should payment pass the due date by more than 120 days, NIOSH will initiate sanctions. In addition to the non-payment remedies specified at § 84.22(c)(1), (2), and (3), the following specific actions will be considered as suggested by the specific circumstances related to outstanding, overdue payment(s):
- 5.2.2.5.1. Suspension of processing for in-house applications.
  - 5.2.2.5.2. Revocation of approvals. (See 3.1.2)