

RESPIRATOR CERTIFICATION FEES
Questions and Answers
June 15, 2015

1. Why is the National Institute for Occupational Safety and Health (NIOSH) modifying respirator certification fees?

On January 26, 2015, NIOSH published a final rule amending NIOSH regulations in 42 C.F.R. Part 84 pertaining to the respirator certification fee structure (80 Fed. Reg. 3891). Until that time, the fees charged by NIOSH for certification testing and approval had not changed since they were implemented in 1972. That original fee structure charged set fees for the examination, inspection, and testing of eight broad groups of respirators. A single fixed-fee was specified for each type of respirator without regard to the complexity of the respirator or the number of specific tests required. That fee structure favored those companies that demand extensive services and disadvantaged companies that have fairly simple, easily executed requests (these companies tend to be smaller businesses). Further, the original fee structure limited NIOSH's ability to recover the majority of its costs for respirator testing and certification.

Federal law requires that the NIOSH respirator certification program be self-sustaining, and that NIOSH must recover the full cost of the services provided. As discussed, in the [January 26, 2015 final rule](#), NIOSH has modified the certification fees because the agency has able to recover only a small proportion of the annual cost of the respirator certification program.

2. How is the new fee schedule different from the old fee schedule?

The January 26, 2015 final rule 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. Unlike the former fee structure, the new fee structure takes into account the complexity of the class of respirator and the amount of testing required, as well as the work and resources required to perform the testing. Also, the new fee structure charges applicants for the costs of issuing, modifying, and maintaining certificates of approval, production facility inspection (site qualification fee), and for verification of ongoing quality system compliance and commercial product performance.

3. How is the new fee schedule organized?

The revised 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. The fee schedules are included in Appendices A and B to the regulatory text in Part 84, and on the NIOSH National Personal Protective Technology Laboratory (NPPTL) website.

4. When will the new fees be assessed?

The new fee schedules went into effect on May 26, 2015. Beginning on that date, applicants are charged for any new application, approval, approval modification, site qualification, or certification test performed. These application-based fees are detailed in [Fee Schedule B](#).

Annual fees, including records maintenance, quality assurance maintenance, maintenance of testing and approval facilities, and maintenance of test equipment, will be invoiced beginning in 2015 for fiscal year 2016 (FY16) fees. NIOSH will send invoice previews to approval holders for FY16 maintenance fees in July 2015 (previews will only be provided for the first year of implementation) and final invoices in September 2015, with a payment expected no later than October 30, 2015. These annual, or fixed, fees are detailed in [Fee Schedule A](#).

5. How will NIOSH administer the new fee requirements?

Each approval application submitted must be accompanied by the required application fee of \$200.00. Prior to finalizing the Initial Review of each project, NPPTL will create a cost estimate which will be sent to the application representative for acceptance. Once the application representative accepts the estimate, the project will continue in the approval process. At the beginning of the Final Review process, NPPTL will create an invoice and send it to the applicant for payment. Payment must be received within 30 days of the invoice date.

6. When will Pay.gov be available to accept online payments?

Until further notice, the preferred method of payment will be via check; however, [Pay.gov](#) is available to domestic manufacturers making ACH and credit card payments less than \$200,000 per transaction.

7. How will NIOSH use the revenues generated by the increased fees?

NIOSH has historically used retained fees within the certification program to maintain and improve current operations (e.g., to replace equipment and supplies), and intends to continue using the collected fees to augment certification activities. NIOSH is committed to working with approval applicants to maintain efficient turnaround times and expeditiously process the certification applications.

8. How will future revisions be made to the respirator certification fee schedule?

NIOSH will propose future fee schedule revisions in the Federal Register, subject to public comment. Accordingly, the fee schedules will be added to 42 CFR part 84 in a revised Appendix A (annual fees) and a revised Appendix B (application-based fees).

9. How frequently will the respirator certification fee schedule be modified?

NIOSH has established a two-year minimum interval for fee schedule revisions. The fees will be revised as needed based on a biennial review.

The following additional questions and answers were discussed at a Manufacturers Workshop and Webinar that occurred at NIOSH's National Personal Protective Technology Laboratory on March 18, 2015.

Invoice Fees and Billing

10. Will invoices be sent via United States mail or will they be emailed?

NIOSH will send invoices by email to the representative indicated by the approval holder. It is the responsibility of the approval holder to notify NIOSH, in writing, of any change to the official representative.

11. Will the manufacturer be notified if they have a credit?

When a credit has been applied to an approval holder's account, a notification will be provided.

12. If there is a surplus of fees at the end of the year, will refunds be given?

NIOSH does not anticipate a fee surplus. However, if an approval holder is charged for an activity that does not occur, a credit will be issued.

13. Are the fees going to be pro-rated the first year?

The annual fees will go into effect in fiscal year 2016 (FY16). Since they are being collected against an entire year's operation, no apportionment applies.

14. How will fees be assessed for extensions of approval?

An extension of approval application will be assessed a \$200 application fee and \$50 for each approval modification. In addition, the applicant will be charged for each test conducted, as applicable.

15. How will fees be assessed for changes to a product quality plan (PQP)?

All approval modification requests will be assessed a \$200 application fee and \$50 for each approval modified. If testing is required, the applicant will be charged for each test conducted, as applicable.

16. When will unspecified test fees be added to the fee tables?

Unspecified test fees will be added with the next revision of the rule which is anticipated to occur in approximately two years. The [current fees schedule](#) is available on the NIOSH NPPTL website.

17. Will re-estimation of fees cause delays in product testing?

NIOSH expects that the need to re-estimate fees will rarely occur. In the rare instance that a re-estimated fee is necessary, the entire process should not take more than a

week, assuming timely applicant response. However, NIOSH will need to obtain authorization from the applicant of the re-estimated fee before resuming work to ensure the estimate is not exceeded.

Rescinding and Obsoleting

18. What is a rescinded approval and how does it differ from an obsolete approval?

A *rescinded* approval is no longer valid and is therefore removed from the [Certified Equipment List \(CEL\)](#) of NIOSH-approved respirators. All products labeled with the rescinded approval number, including Private Labels, in the distribution chain as well as the field are no longer recognized as being NIOSH-approved products. Rescinded products cannot be sold or distributed as being NIOSH-approved, nor used where NIOSH-approved respirators are required.

An *obsolete* approval is no longer manufactured or supported by the approval holder but can be maintained in an approved configuration as long as Original Equipment Manufacturer replacement parts are available in the distribution chain. Products that are *obsolete* are listed in the CEL as such, and are recognized as approved products, as long as they are maintained in accordance with approval holder recommendations.

19. How can an approval holder request that NIOSH rescind an existing approval?

A request for rescission of an approval should be mailed/emailed to:

Chief, Technology Evaluation Branch
National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
626 Cochrans Mill Road
Pittsburgh, Pennsylvania, 15236
Email: kvh7@cdc.gov

20. How can an approval holder request that NIOSH make an approval obsolete?

Approvals can be made 'obsolete' by submitting an Extension (modification) of Approval request that contains an assembly matrix showing which approvals are to be identified as obsolete. No other approval actions should be requested in a submission made for the purpose of changing the status of approvals from active to obsolete.

21. Is there a fee for rescinding an approval?

No. There is no fee charged for rescinding approvals.

22. How will the end users be notified once an approval holder rescinds an approval?

All rescinded approvals are posted on the [Respirator User Notices](#) page of the NPPTL website and removed (delisted) from the NIOSH Certified Equipment List.

23. If an approval holder is going to request an approval be made obsolete, when should they begin the process?

Because the process to obsolete an existing approval may take several weeks, the approval holder should start the process as early as possible to ensure all desired actions are completed by July 1st. Estimates and invoices will be prepared based on the number of approval and manufacturing sites listed on July 1st of each year.

Audits

24. Are there additional fees assessed, beyond the site audits fees, for audit findings discovered during a site audit?

No additional fees are charged to address findings from site audits unless an approval request is required to modify documentation on file with NIOSH for a specific approval(s).

25. Will an approval holder with more than one manufacturing site be charged per site for each site audit?

Yes. Each manufacturing site is audited every two years. Therefore, approval holders will incur a fee for each manufacturing site that is scheduled for audit in the upcoming year.

26. Will new site fees be charged if a manufacturing facility is relocated on the same property?

No. NIOSH will not consider a manufacturing site that is relocated on the same property as a new site.

27. How will fees be assessed for what is a new manufacturing site for one approval holder but is already a manufacturing site for another approval holder?

The fact that a manufacturing site produces NIOSH-approved equipment for another approval holder will not affect the requirement to assess it as a new manufacturing site for a new approval holder.

28. How will the annual product audit fee be assessed?

The approval holder can choose to either pay for the actual cost of the product to be assessed or provide equipment for evaluation. Additionally, the approval holder will be invoiced for the testing costs for evaluating the product.

29. Can the approval holder provide the respirator for audit?

The approval holder can choose to provide product(s) identified for audit rather than pay purchase price.

CBRN Fees

30. What do the CBRN fees cover?

The [listed CBRN fees](#) are the associated test fees for chemical, biological, radiological, and nuclear (CBRN) respirators and include both live agent testing performed at Edgewood Chemical and Biological Center (ECBC) and NIOSH in-house testing. All other fees such as application fees, new or modification of approval fees, and annual maintenance fees apply to CBRN approvals as well.

31. Since the Edgewood Chemical Biological Center fees for Live Agent Testing (LAT) can be updated on a yearly schedule, where can I find the most recent LAT costs?

The LAT costs are updated in September of each year and published on the NIOSH web site as a Letter to All Manufacturers.

Other

32. Will the “default-to-test” program be discontinued?

Yes. The “default-to-test’ will be discontinued by September 30, 2015.

33. Do the same testing fees in Fee Schedule B apply to correlation testing?

Yes. Correlation testing applicants will be charged the \$200 application fee and the associated testing costs found in Fee Schedule B.

34. Do private labeling requests get a new approval number assigned?

Private labeling requests will be granted only under the approval number assigned to the original approval request.