NIOSH Conformity Assessment Notice

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Subject: Summarized Information about NIOSH Respirator Approval Program (i) Basic Application Procedures (ii) Quality Assurance Requirements and (iii) Supplier or Subcontractor Agreements

Supersedes: April 7, 2005 Letter to All Manufacturers, Clarification of Supplier and Subcontractor Relationships
Supersedes: September 24, 2012 Letter to All Manufacturers, Respirator Sampling Procedures

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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1 SUMMARY

NIOSH requires approval holders to meet performance requirements and the respirators must be manufactured under a quality management system (QMS) that is reviewed and accepted as part of the approval process. To keep NIOSH's applicants informed about the respirator approval program, NIOSH is providing this document to clarify expectations related to (1) the basic application procedures, (2) the quality assurance (QA) requirements in the regulation, 42 Code of Federal Regulation Part 84 (42 CFR 84), Subpart E, and (3) requirements for supplier and subcontractor agreements.

Throughout this document, applicant refers to an individual, partnership, company, corporation, association, or other organization that designs, manufactures, assembles, or controls the assembly of a respirator and who seeks to obtain a certificate of approval for such respirator. **NIOSH considers domestic applicants to be those whose design/development activities, quality assurance activities, and manufacturing sites are located inside the United States. NIOSH considers applicants whose headquarters are located within the United States but whose design/development activities, quality assurance activities, and/or manufacturing sites are not within the United States to be non-domestic applicants.**

This guidance can assist applicants in navigating the NIOSH review process by better outlining the QA requirements in one document, because guidance is currently located in multiple documents. This document does not create any new requirements, although it does provide a new example of acceptable ways to present information to NIOSH for use in the QA review. This guidance is **not** a substitute for reviewing and understanding 42 CFR 84 or the NIOSH Standard Application Procedure (SAP) relevant to the respiratory protective device that an applicant will submit to NIOSH for approval. The example provided is tailored for filtering facepiece respirators (FFRs), but this guidance can be used as a starting point for all applicants. Please consider **all** parts of this document.

Note: If an applicant has already submitted an application and determines, based on this guidance, that the application is not adequate, the applicant should submit a request to withdraw the application. This can be accomplished by emailing the Records Room (RecordsRoom@cdc.gov) or

the Reviewer actively working the application. An approval request can be resubmitted after all guidance is considered and the requirements are met.

Note: It **is not appropriate** to refer to any product as NIOSH approved, pending NIOSH approval, compliant to NIOSH standards, or similar claims prior to achieving the NIOSH approval. NIOSH approval encompasses NIOSH evaluation and acceptance of the respirator and the QMS. This cannot be achieved until the approval process is complete, including engineering review, testing, and the assessment of the QMS by NIOSH.

Note: NIOSH expects the applicant to complete a full or limited production run (if all respirators are produced using the QMS presented to NIOSH) prior to submitting an application. The number of respirators produced prior to achieving NIOSH approval should be carefully considered because respirators not produced under the quality control system evaluated and **accepted** by NIOSH cannot be labeled as NIOSH approved.

2 AUTHORITY

42 C.F.R. Part 84, Respiratory Protective Devices

3 TOPICS EXPLAINED

(i) Basic Application Procedure

a. PRIOR to SUBMITTING an APPLICATION to NIOSH

The applicant shall ensure all required documentation, performance requirements (testing), and quality assurance requirements are met.

A prospective applicant must first request a three-digit manufacturer's code. This code is a tool used by NOSH to track application information and communications with applicants and approval holders. Applicants can request the code by emailing the Records Room (RecordsRoom@cdc.gov). Upon the request for this code, information about the applicant, the first respirator configuration (all applicable parts and accessories) to be submitted for approval, and the applicant's progress towards being able to submit an acceptable application will be collected. Once a code has been issued, NIOSH will provide the standard application form to initiate the application process. This code is for NIOSH tracking purposes, it in no way reflects NIOSH approval.

Every unique respirator submitted to NIOSH for approval requires the submittal of pre-submission test data to demonstrate that the respirator meets the NIOSH minimum performance requirements. These tests can be performed by the applicant or by a third-party laboratory. It is expected that the NIOSH Standard Testing Procedures (STPs) will be followed and appropriate test instrumentation must be used.

If applying for Surgical N95 respirator approval, there are additional pre-submission testing requirements including biocompatibility, flammability, and fluid resistance. A surgical N95 is defined as a single-use, disposable respiratory protective device (RPD) used in a healthcare setting

that is worn by healthcare personnel (HCP) during procedures to protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material at an N95 filtration efficiency level per 42 CFR 84.174. A surgical N95 respirator is a class II device, regulated by FDA under 21 CFR 878.4040 (FDA product code MSH). The guidance for submitting a Surgical N95 application can be found in CA 2018-1010R1.0 and must be followed.

The NIOSH STPs list equipment and their specifications. If an applicant uses an alternate test method or equipment that has specifications other than those listed in the NIOSH STP, equivalency data showing correlation to the NIOSH method or specified equipment must be provided through a statistical study.

The following summarizes the **documentation** needed to meet the requirements of the related Standard Application Procedure (SAP). All documentation and respirators should be in their final form prior to submitting the application to NIOSH. Changes to documents submitted to a Reviewer actively working the application, without being requested, will not be accepted. If unrequested changes need to be made, the application should be withdrawn. NIOSH does not offer approval for prototype respirators.

a. Assembly Matrix (a matrix showing all possible hardware configurations to be evaluated in the application – must follow format in the SAP)
b. Draft Approval Label
c. Drawing(s)
d. Inspection Procedures
e. Product Quality Plans/Classification of Defects/Sampling Plans
f. Quality Manual – only required for new applicants and subsequent QA applications
g. Pre-submission Test Data
h. Completed Standard Application Form
i. User Instructions
j. Test Samples

When an applicant submits an application, it is reviewed to ensure that all required sections of the application are included. Documents sent to NIOSH are expected to contain all required information and be compliant with all expectations in the SAP. If the application contains the required documents, application fee and test samples, NIOSH assigns a task number (TN). The TN is the internal tracking number for an application and should be used in all communication regarding the application. Once accepted, the project goes through multiple review stages including initial engineering review, QA review, testing, and final engineering review. For new applicants, prior to final review, NIOSH will conduct a site qualification assessment if all documentation and testing is determined to meet the requirements during initial and QA review.

Note: NIOSH employees cannot review any documents that are not submitted as part of an application. Applicants should not submit any additional documents to NIOSH unless they are specifically requested by a Reviewer actively working the application. If changes that are not identified by a Reviewer are needed, the application should be withdrawn and resubmitted with correct that is correct and meets the requirements in the SAP.

b. APPLYING for APPROVAL/APPLICATION ACCEPTED by NIOSH

Receiving a manufacturer's code **does not** constitute an approval, registration, or acceptance of an application in any way; however, it is **necessary to start the application process**. Test samples provided with any application must be produced under the complete proposed QMS as presented in the application. **NIOSH will verify this during the site qualification assessment**. The minimum number of test samples required can be found by reviewing the information the in SAP relevant to the respiratory protective device that will be submitted for NIOSH approval. For a filtering facepiece, the applicant should provide a minimum of 26 samples. Additionally, it is expected that pre-submission test data also be reflective of products that were manufactured in accordance with the QMS system provided. NIOSH must receive all parts of the application package (i.e., documents, test samples, and $200 application fee) within two weeks of each other, or the application will be rejected. Each unique respirator design requires its own application. Respirators that are identical in all aspects except dimensions can be submitted in one application for one approval number (i.e., regular and small size).

(ii) **NIOSH Quality Requirements**:

NIOSH approval goes beyond assuring the device meets the appropriate minimum performance requirements defined by 42 CFR 84 for the intended protection. The approval extends to the **entire QMS** utilized to produce the respirators, which ensures that products produced continue to meet the NIOSH performance requirements. NIOSH requires respirator approval holders to inspect and/or test samples of respirators and components as part of their quality control plans. This requirement is stated in Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84), specifically in §§ 84.41(b) through 84.41(i). **Because of the stringent quality assurance requirements, this is often the part of the review process that applicants struggle with the most.** The following sections reiterate the necessities of a comprehensive QMS.

a. INSPECTION PROCEDURES and SAMPLING PLANS

The regulation requires applicants to perform inspections before, during, and after production. All *inspection procedures* should be clearly defined in the quality documents and will be examined with scrutiny during the review process. Incoming inspection procedures should serve to verify that the materials received conform to the specifications that were ordered. In-process inspection procedures should verify the specifications and/or performance of all subcomponents of respirators. In-process inspection procedures are not required for single assembly respirators (i.e., FFRs). Final inspection procedures should ensure that the fully assembled respirator conforms to the specifications on the drawing(s) and the required performance specifications. Specifications that are required to be called out on any drawings are expected to be verified as part of the inspections performed.

The overall goal of the quality control plan is to determine that the respirator produced conforms to the documentation submitted to NIOSH and the appropriate NIOSH performance requirements. The *sampling plan* being used for each inspection should be clearly stated and the documentation

should also include the definition of a lot or batch. If an applicant uses a performance testing procedure other than those commonly accepted by NIOSH, the equivalency must be explained.

The sampling plan procedures that are widely used and accepted as equivalent by NIOSH are listed in Table 1 below. For each sampling plan, there are acceptable minimum inspection levels for normal (defined in 42 CFR 84.41(h)) and destructive inspections. The inspection level decides the number of samples to be drawn for a particular lot size and determines the sampling plan's ability to discriminate between conforming and nonconforming lots. As a special exception, NIOSH is permitted under 42 CFR 84.41(i) to allow a lower inspection level for destructive testing **only**. The minimum level NIOSH will accept under this exception is in the "destructive" column of Table 1 below. Approval of a level lower than the "normal" level is entirely at NIOSH's discretion and will only be granted if the rest of the inspection plan ensures adequate control over product quality. Historical data may be requested.

Stipulations for tightened inspection are required. If an applicant intends to use reduced sampling, those stipulations must be clearly outlined in the quality control plan and the applicant must demonstrate the ability to maintain control of the rules outlined in the sampling plan in use. For more details, see section below on "Use of Switching Rules."

Table 1. Widely used and accepted equivalent sampling plans along with the minimum inspection level accepted for each plan.

Procedure	Minimum Inspection Level	
	Normal	Destructive[1]
MIL-STD-414	IV	I
ANSI/ASQ Z1.9-2003	II	S-3
MIL-STD-105D	II	S-2
MIL-STD-105E	II	S-2
ANSI/ASQ Z1.4-2003	II	S-2
ISO 2859[2]	II	S-2

[1]Destructive inspections are considered those that once performed, render the respirator or respirator component unable to be used.

[2]Reduced sampling is not permitted with this plan.

Note: The Squeglia C=0 [Squeglia 2008] procedure does not use the concept of inspection levels and NIOSH treats it as equivalent to inspection level II of MIL-STD-105D. If applicants or approval holders intend to use alternatives to the procedures described here, they must understand the concepts of acceptance sampling and process control. The use of more modern methods such as calculating process capability values (C_{pk}) or employing statistical process control can be accepted where this is compatible with the approval holder's operations and provides equivalent assurance of respirator performance. Justification to demonstrate the equivalence of these procedures must be provided in the application seeking approval.

Cross-References. See MIL-STD-414 section A7.1; ANSI/ASQ Z1.9-2003 section A7.1; MIL-STD-105D sections 9.2, 9.3; MIL-STD-105E sections 4.9.1, 4.9.2; ANSI/ASQ Z1.4-2003 sections 9.2, 9.3; Squeglia C=0 pages 3, 6

b. CLASSIFICATION of DEFECTS

An important part of the quality control plan is the *classification of defects*. Classifications of defects should be assigned correctly to all inspections according to the regulation (42 CFR 84.41), which are detailed in Table 2. Respirators that consist of only one component (FFRs) are only required to have the classifications of defects assigned to incoming and final inspections. The classifications of defects are very specific to the Respirator Approval Program and the classification of defect definitions in sampling standards should not be used to define defects in NIOSH respirator quality plans. Each classification of defect has a corresponding *acceptable quality limit (AQL)* – as defined by the regulation (42 CFR 84.41) – and all components of the respirator assembly should be appropriately sampled based on the AQL (Table 2).

Table 2. Classification of defect definitions from 42 CFR 84.41 and the corresponding AQLs.

Classification of Defect	**Definition**	**Acceptable Quality Limit (AQL)**[1,2,3]
Critical	A defect that judgment and experience indicate is likely to result in a condition immediately hazardous to life or health for individuals using or depending upon the respirator	100%
Major A	A defect, other than critical, that is likely to result in failure to the degree that the respirator does not provide any respiratory protection, or a defect that reduces protection and is not detectable by the user	1.0
Major B	A defect, other than Major A or critical, that is likely to result in reduced respiratory protection, and is detectable by the user	2.5
Minor	A defect that is not likely to materially reduce the usability of the respirator for its intended purpose, or a defect that is a departure from established standards and has little bearing on the effective use or operation of the respirator	4.0

[1]These are called "index values" in the Squeglia (C=0) procedure.

[2]It is acceptable to use a smaller (more stringent) AQL value.

[3]Use of critical classification of defects should be considered according to the definitions in 42 CFR 84.41(d). This classification is reserved for respirators used in immediately dangerous to life or health (IDLH) conditions.

Characteristics identified as Critical in the classification of defects are not assigned an AQL and are not eligible for any form of sampling. Each item made must be 100% inspected as required by 42 CFR 84.41(f) and the entire lot rejected when a defect is found. NIOSH must approve any plans to perform rework on the lot as part of the product qualityplan.

Note: Care should be taken to ensure that the sampling method, classifications of defects, and AQL are all applied correctly based on the inspection procedure(s) used. An example is provided as supplemental information.

Cross-References. See MIL-STD-414 section A4; ANSI/ASQ Z1.9-2003 sections A2.1, A4; MIL-STD-105D section 4; MIL-STD-105E sections 3.1, 4.4; ANSI/ASQ Z1.4-2003 section 4; Squeglia C=0 pages 3, 6.

c. SELECTION of SAMPLING PROCEDURES

Sampling by Variables. The standard sampling procedure specified in 42 CFR 84 is MIL-STD-414 [U.S. Department of Defense 1957]. This is a variable sampling plan, which means that the characteristic must be something that can be measured numerically on a continuous scale. Examples include the diameter of a hole in inches, the mass of a cartridge in grams, or the leakage of an exhalation valve in milliliters per minute. This procedure is only valid when the characteristic being measured has a statistically normal distribution over the population being sampled. The ANSI/ASQ Z1.9 standard [American National Standards Institute 2003b] is derived from MIL-STD-414, and NIOSH considers it to be equivalent.

Sampling by Attributes. The MIL-STD-105D sampling procedure [U.S. Department of Defense 1963] is explicitly accepted as an equivalent procedure in 42 CFR 84. This is an attribute sampling plan, which means that each characteristic is simply checked to see whether it is acceptable. Due to its simplicity, this standard and its derivatives are the most common in use. It has the advantage that it can be applied to characteristics which do not involve a numerical measurement (such as visual checks) as well as to those that are measurable. No calculations are needed to determine acceptance, and the procedure is valid whether the characteristic has a normal distribution or not. Procedures derived from this standard, and which NIOSH considers to be equivalent, include MIL-STD-105E [U.S. Department of Defense 1989] and ANSI/ASQ Z1.4 [American National Standards Institute 2003a].

Zero-Defect Sampling by Attributes. Another attribute sampling plan which NIOSH accepts as equivalent is the Squeglia C=0 procedure [Squeglia 2008]. While not directly derived from MIL-STD-105E, its plans are matched to that procedure and provide an acceptable statistical assurance of lot quality. The chief difference is that in all cases, the lot is only accepted if there are zero defects found in the sample (C=0). This procedure usually requires fewer samples than MIL-STD-105D and related standards and is the simplest to use of those listed in Table 1. However, it is generally only suitable when defects in production are extremely rare.

Equivalent Standards. The ANSI/ASQ standards mentioned above are revised periodically. In general, NIOSH will consider later editions of a given procedure to be equivalent. There may also be other national or international standards based on MIL-STD-414 or MIL-STD-105D that can be

considered equivalent. If such a standard is used, NIOSH may request a copy from the applicant to verify its equivalence.

Use of Switching Rules. Tightened inspection is **not** optional and must be used where specified by the switching rules in the sampling plan being used. Most sampling plans referenced in this letter contain rules allowing reduced inspection under certain conditions. An applicant may use reduced inspection only when all conditions listed in the switching rules in the sampling plan being used are met. This includes the requirement that production is not irregular or delayed. A history of lot acceptance at one manufacturing site cannot be used to move to reduced sampling at another site. Approval holders may choose to stay at normal inspection even when conditions for reduced inspection are met. To use reduced inspection, the approval holder must maintain inspection records showing that the conditions in the applicable procedure are met. Such records must be available for review during NIOSH on-site audits. The Squeglia C=0 procedure does not recommend switching rules, and NIOSH does not permit reduced inspection for that procedure. Tightened inspection is not required for the Squeglia C=0 procedure.

Note: One feature of MIL-STD plans is that, as works of the United States Government, they may be copied free of charge. Those mentioned can be downloaded from the Internet Archive at http://www.archive.org/ and may be available elsewhere. However, all MIL-STD documents in this letter have been cancelled by the Department of Defense and are no longer maintained or revised. The corresponding ANSI/ASQ standards are successors to the MIL-STD documents and have various minor improvements and clarifications added. Copies of these standards may be purchased from the American Society for Quality, the American National Standards Institute, or others who deal in national standards.

Cross-References. See MIL-STD-414 sections A8, B14, C14, D14; ANSI/ASQ Z1.9-2003 section A10; MIL-STD-105D section 8; MIL-STD-105E sections 4.6, 4.7, 4.8; ANSI/ASQ Z1.4-2003 section 8; Squeglia C=0 pages 14, 16.

d. DEFINING LOTS or BATCHES

Definition of Lot. Each procedure listed in this letter requires that product be grouped into inspection lots (the term “batch” means the same as “lot”). Each lot consists of product which has been manufactured under essentially the same conditions, in the same production facility, and at essentially the same time. For example, if an applicant shuts down a production line for a week for maintenance, it is wrong to consider product made before and after the shutdown as part of the same lot. The applicant’s definition of a lot should be included in the application to NIOSH.

Selection of Samples from Lot. Each sample drawn from a lot must be representative of the entire lot. For example, when drawing a sample of 200 pieces from a lot of 10,000 it would be improper to select the first 200 respirators produced to use as the sample. As another example, if respirators being produced on five machines are being combined into an inspection lot, then one- fifth of the sample drawn must come from each machine. As noted in section 3.ii.e of this letter, each sample taken for double or multiple sampling must be representative of the whole lot.

Inspection Lot vs. Other Lot Designations. The grouping of finished respirators into lots for shipment or other purposes may differ from the grouping used for inspection. The lot number marked on the respirator or its container, as required by 42 CFR 84.33(g), does not necessarily need to be the same number used for inspection purposes. However, the approval holder must maintain traceability between lot numbering systems if more than one is used. For example, a shipping lot number must be traceable to the corresponding production lot number(s).

Cross-References. See MIL-STD-414 sections A5, A7.2; ANSI/ASQ Z1.9-2003 sections A2.4, A5, A7.2; MIL-STD-105D sections 5, 7.2; MIL-STD-105E sections 3.12, 3.13, 4.3, 4.5.1; ANSI/ASQ Z1.4-2003 sections 5, 7.2; Squeglia C=0 page 2.

e. SPECIFIC CONSIDERATIONS for ATTRIBUTE PLANS

Arrows on Sampling Tables. **The Sampling Plan that is selected must be used correctly.** This includes certain sampling plans that have tables containing arrows, which are to be followed to obtain the correct criteria (example below).Where the sampling plan indicated leads to an arrow in the table, follow the arrow to the next available sampling plan. This will correspond to a new code letter row in the table with the acceptance and rejection numbers and a new corresponding sample size to be used.

As an example, consider sampling of a lot of 200 pieces under MIL-STD-105D for a Major A characteristic at inspection level II. Code letter G is selected from Table I, and an AQL of 1.0 is used. An arrow pointing downward is contained in Table II-A for these conditions, indicating that code letter G is not available and code letter H must be used. This means that the appropriate sample size is 50 pieces, not 32, and that the lot is accepted if there are zero or one defective pieces and rejected if there are 2 or more defectives.

Single, Double, or Multiple Sampling. Most attribute procedures include double or multiple sampling plans (the Squeglia C=0 procedure only has single plans). Any of these options included in the procedure may be selected. Note that each sample drawn must be representative of the entire lot. Double and multiple sampling tend to require fewer samples when lot quality is either much better or much worse than the AQL. Single sampling is simpler to administer and apply correctly than double or multiple sampling and should be carefully considered.

As an example, consider a lot of 200 pieces under MIL-STD-105D for a Minor characteristic at inspection level II. Code letter G is selected from Table I, and an AQL of 4.0 is used.

- For single sampling, Table II-A indicates that the sample size is 32. The lot is accepted if there are three or fewer defective pieces, and it is rejected if there are four or more defectives.
- For double sampling, Table III-A is used instead and an initial sample of 20 would be drawn. The lot is accepted if there are zero or one defectives, and it is rejected if there are four or more defectives. If there are two or three defectives, then a second sample of 20 is drawn from the lot and inspected. If after both samples (totaling 40 pieces) are inspected there are a total of four or fewer defectives, then the lot is accepted; if five or more defectives, then the lot is rejected.

- Multiple sampling (Table IV-A) works in a similar fashion, except that there are up to seven rounds of sampling to reach a decision.

Cross-References. See MIL-STD-105D sections 7.4, 9.5, 10.1.1, 10.1.2, 10.1.3; MIL-STD-105E sections 4.5.3, 4.9.4, 4.10.1.1, 4.10.1.2, 4.10.1.3; ANSI/ASQ Z1.4-2003 sections 7.4, 9.5, 10.1.1, 10.1.2, 10.1.3.

f. SPECIFIC CONSIDERATIONS for VARIABLE PLANS

Variability Unknown vs. Variability Known. A variability unknown method should normally be used. The variability known method may only be used when the production process is under strict control and the process parameters influencing final respirator performance are well understood. Data must be provided with the application for approval, available during onsite audits, and continuously updated to support the standard deviation value (σ) used.

Single Specification Limit vs. Double Specification Limit. This is selected based on whether there is only one limit value (such as penetration less than or equal to 5%) or two limit values (such as cartridge mass between 95 and 105 grams) for the characteristic.

Standard Deviation Method vs. Range Method. Either method may be selected. The standard deviation method generally requires fewer samples, but more complex computations.

Cross-References. See MIL-STD-414 Introduction, section A6.2; ANSI/ASQ Z1.9-2003 Introduction, section A6.2.

g. COMMON ERRORS

Selection of Inadequate Inspection Levels. The minimum acceptable inspection level is described in section 3.2 of this letter. If a product quality control plan does not specify inspection levels, NIOSH assumes that the level in the "normal" column of the table will be used. Use of lower levels without specific approval, whatever the reason, is a failure to conform to NIOSH requirements and can result in revocation of approval under 42 CFR 84.43(c).

Selection of Plan Based on Desired Sample Size. It is entirely improper to choose a desired sample size and work backwards to identify a proposed AQL and inspection level which will yield this result. To do so reflects a fundamental misunderstanding of the basis for sampling plans. The appropriate AQL and inspection level are stated in section 3.ii.b of this letter.

Selection of Defect Classification Based on Desired AQL. As in 9.2, the defect classification drives the selection of AQL, not the other way around. Each defect must be classified based solely on the definitions in 42 CFR 84.41(d).

Modification of AQL or Inspection Level Based on Lot Size or Other Factors. The AQL and inspection level are chosen by the criteria in section 3.ii of this letter. Approval holders are free to use higher inspection levels if greater discrimination is desired, or to use lower (more stringent) AQLs if a smaller percent defective is desired. However, these should not be modified based on lot size or

inspection history, as provisions already exist to account for those factors (i.e. switching rules). Changing AQL values or inspection levels is likely to result in a statistically invalid plan.

Inappropriate Use of Reduced Inspection. As described in section 3.ii.c of this letter, NIOSH permits reduced inspection only when all conditions of the relevant procedure are met. When there are significant delays or changes in production processes, approval holders must revert to normal inspection. It will be considered a nonconformance during NIOSH on-site audits if the records described in section 3.ii.i of this letter are not available.

Incorrectly Following or Not Following Arrows in Sampling Tables. When using attribute sampling, be careful when following applicable arrows in the sampling plan tables. A different sample size must be used to correspond with the new code letter as described in section 3.ii.e of this letter.

Improper Drawing of Samples. Each sample drawn must be representative of the entire lot as described in section 3.ii.d of this letter. The typical method is to select samples at random. However, approval holders may use other methods (such as every tenth piece) so long as the sample is not biased in any way. If a lot contains multiple sublots, the sample must contain a proportional number of pieces from each sublot.

h. QUALITY MANUALS and QUALITY CONTROL PLAN

The requirements of **a Quality Manual and quality control plan** are outlined in the NIOSH Conformity Assessment Notice 2019-1019, derived from 42 CFR Part 84. It is imperative that all elements are completely addressed. These elements must be fully implemented and utilized when samples are manufactured and sent to NIOSH for evaluation. Failure to do so will likely result in a failed site qualification assessment. Applicants must submit quality manuals for all manufacturing sites as well as all subcontractors (defined below).

i. FACILITY and PRODUCT AUDITS

Site Qualification Assessments: For new applicants, a site qualification visit is required for each manufacturing and subcontractor facility prior to gaining NIOSH approval. Depending on the application and manufacturing situation/locations, multiple site qualifications could be conducted before an approval can be issued. If multiple site qualifications are required, the scores of each site qualification are added together to determine the final score. Regardless of whether NIOSH assesses one site or multiple sites, a point system is used to score negative findings and the final additive score is what determines whether the applicant's QA System is Acceptable, Provisionally Acceptable, or Not Acceptable.

For an existing approval holder who wishes to add a new manufacturing site or subcontractor, a Quality Assurance Application is submitted, including the Quality Manual of any proposed new sites or subcontractors. A subcontractor agreement should be submitted for new subcontractors as described in section 3.iii.

The goal of the site qualification is to verify that the complete system that was presented to NIOSH is implemented and functional. NIOSH expects that the complete quality control system is in place before production of samples and submission of any applications. NIOSH performs the site qualification assessments based on the requirements in CA 2019-1019. Elements that are **not** typically assessed during the site qualification include: Contract Review Activities, Corrective Actions, Internal Audits, Training, and Quality Management. However, the auditors completing the assessment can verify these elements if they believe that there is evidence that these elements may cause the quality system to be inadequate. Auditors assigned to conduct these tasks will evaluate the system based on evidence that can be provided during the site qualification visit. If the evidence presented to the auditors does not support the process, it is unlikely that a site qualification assessment will be acceptable.

The auditors will assign any nonconformities or observations a score. The issues identified will be scored as a Major Finding (3 points), Minor Finding (1 point), or an Observation (0 points). At the end of the audit, or end of all audits if there are multiple sites, a final score will be determined.

- Zero points during site qualification assessment will result in an accepted QA System and the subsequent first NIOSH approval.
- One to 11 points will result in a provisionally acceptable site qualification assessment, requiring corrective actions to be defined, implemented and accepted by NIOSH before the QA System is accepted and an approval can be issued.
- Twelve or more points will result in an unacceptable site qualification assessment and the application will be denied; before resubmitting the application, all identified issues must be fully addressed and documented in the re-submitted application.

Maintaining NIOSH Approval: After a manufacturing site has passed the initial site qualification and the applicant has received their approval, the applicant and any subcontractors will be added to NIOSH's site audit schedule. NIOSH conducts these audits roughly once every two years to ensure that quality manufacturing practices are continually followed. Quality site audits verify conformance to the requirements of 42 CFR 84.33, 84.40, 84.41, 84.42, and 84.43. All findings during the audit will be issued as corrective action requests that must be addressed for the NIOSH Approval to remain valid. Additionally, annual product audits are performed to verify the performance and labeling of commercially available respirators.

Fees: For all fees associated will all activities, please review the Respirator Certification Fee Schedules.

(iii) Supplier and Subcontractor Relationships

If a company wishes to seek approval but does not manufacture the respirators in house, it is possible to still apply for NIOSH approval, but only if the company who is applying as the approval holder controls the quality and design of the product. In order to correctly present this information to NIOSH, the prospective approval holder should carefully review the definitions of a supplier and

a subcontractor (below). If subcontractors are used, the Quality Manual for the subcontractor should be supplied with the application, along with a subcontractor agreement that covers the elements required by the *Subcontractor Relationship Responsibilities*, outlined below. If multiple manufacturing sites are used for production or quality assurance, the Quality Manual for all applicable sites should be provided with the application.

Approval Holder. The party of record to whom certificates of approval will be or have been issued. The approval holder maintains responsibility for, and control of, product design, performance, configuration management, manufacture, quality, and support.

Supplier. A supplier produces components or subassemblies under their own quality system for delivery to the approval holder. The approval holder confirms the acceptability of incoming goods by accepting a Certificate of Compliance and inspecting incoming goods to ensure compliance with all product design, performance, and quality assurance criteria (drawings and engineering control). The approval holder releases the final product for distribution and sale.

Subcontractor. The approval holder may authorize a subcontractor to release NIOSH-approved respirators directly from the subcontractor's facility for distribution and sale, or to release components and subassemblies directly to an authorized repair center. This role and responsibility should be made clear in the documentation included in the application to NIOSH. The approval holder maintains responsibility for, and control of, product design, performance, configuration management, manufacture, quality, and support by maintaining influence over, and active involvement in, the subcontractor's quality system. As such, the subcontractor's facility is considered to be a manufacturing site for the approval holder.

Subcontractor Relationship Responsibilities. The approval documentation on file at NIOSH must demonstrate that the following criteria have been met for NIOSH recognition of a subcontractor.

- As with all other NIOSH approvals, the approval holder maintains responsibility for all aspects of the approval: control over product design, performance, configuration management, manufacture, quality, and support. This includes product drawings, material specifications, parts lists, and manufacturing processes; control over the requirements for final inspection and testing; and approval of any changes to the above.
- The approval holder must assure that a subcontractor has demonstrated the ability to produce product that consistently meets the established release criteria and has adequate quality systems and procedures in place to assure product quality on an ongoing basis.
- The approval holder must establish and maintain active involvement and influence over subcontractor quality systems. This can be demonstrated in many ways. One example of this involvement and influence can be exhibited by participating in the subcontractor's management reviews (as defined by ISO 9001, 2000, section 5.6) required by the subcontractor's Quality System. A second example is participation in the subcontractor's Material Review Board.

- The approval holder's methods for maintaining active involvement and influence over their subcontractor's quality system needs to be documented in a plan or procedure that suits the individual situation and manufacturing complexity of the secured goods. The approval holder must formally submit this plan or procedure to NIOSH.
- The approval holder will maintain copies of subcontractor quality records that demonstrate compliance with NIOSH performance requirements. It is important to assure that, in the event of a broken relationship, both the approval holder and NIOSH have continued access to those records.
- All submissions related to the approval must be made by an authorized representative of the approval holder. The subcontractor's Quality Manual and related quality system documents must represent how the approval holder establishes and maintains active involvement and influence over the subcontractor's quality system. This information must be specifically indicated and documented as part of a Quality Assurance application if the subcontractor is added after an initial approval application.
- As with all Quality Manuals, a process must be established and followed for ongoing resubmission of the Quality Manual and related quality system documents in the event of significant changes, and on a periodic basis, per NIOSH requirements.
- All subcontractor relationships must be listed as an approval holder's manufacturing site, with a designated point of contact, on the NIOSH Standard Application Form (SAF) for direct shipment from the subcontractor to be acceptable under the NIOSH approval.
- NIOSH will audit all manufacturing sites for NIOSH-approved products, including subcontractor facilities, on a biannual schedule. NIOSH will not contact the subcontractor directly but will always work through the approval holder's designated representative for the specific manufacturing site.

4 SUPPLEMENTAL INFORMATION – EXAMPLE ONLY

The following table is provided merely as an example. The numbers and plans in Table 3 are not a representation of a quality plan used for a currently approved respirator but were included to show that a combination of various sampling plans can be utilized. Information and values, presented as "#" below, are for illustrative purposes only.

Table 3. Example of how the sampling method, classifications of defects, and acceptable quality limits could be presented to NIOSH (provided for illustrative purposes only).

Inspection	*Procedure*	*Classification of Defect*	*AQL*	*Sampling Standard*	*Sampling Level*	*Inspection Description*	*Inspection Method/ Equipment*	*Inspection Criteria*
Incoming	IN1	Major A	1.0	C=0		Filter Media basis weight	Balance	## gsm* +/-## gsm
	IN2	Major A	1.0	MIL-STD-105D	S-2	Filter Media filtration efficiency	TSI 8130	Particle filtration ≥ 95%
	IN3	Major A	1.0	MIL-STD-105D	S-2	Strap elasticity	Tensile tester	###%, # N
	IN4	Minor	4.0	MIL-STD-105D	General Level II	Media Appearance	Visual	No stains, defects visible
	IN5	Major A	1.0	C=0		Outer layer basis weight	Balance	## gsm +/-## gsm
	IN6	Major A	1.0	C=0		Inner layer basis weight	Balance	## gsm +/-## gsm
In-Process	IP1	Major B	2.5	MIL-STD-105D	General Level II	Head strap length verification	Steel ruler	### ± # mm
	IP2	Major B	2.5	MIL-STD-105D	General Level II	Dimension verification	Caliper	Length ### ± ## mm Width ### ± ## mm
	IP3	Major A	1.0	MIL-STD-105D	General Level II	Strap attachment strength	Weight	Breakage point
Final	FI1	Major A	1.0	MIL-STD-105D	S-2	Filtration efficiency	TSI 8130	Particle filtration ≥ 95%
	FI2	Major A	1.0	MIL-STD-105D	S-2	Inhalation resistance	Manometer	≤ 35 mmH20
	FI3	Major A	1.0	MIL-STD-105D	S-2	Exhalation resistance	Manometer	≤ 25 mmH20
	FI4	Major A	1.0	MIL-STD-105D	S-2	Exhalation valve leakage	Gilibrator	≥ 30 mL/min
	FI5	Minor	4.0	MIL-STD-105D	General Level II	Appearance	Visual	No stains, printing legible, no frayed edges

*gsm is defined as grams per square meter

5 CONTACTING THE RESPIRATOR APPROVAL PROGRAM

If you have any questions regarding the information provided in this document or elsewhere, please feel free to reach out to the Respirator Approval Program. You will be put in contact with the appropriate party to answer your question(s). Respirator Approval Program employees cannot act as consultants, but they will be able to answer specific questions about the approval process and requirements.

All emails to the Respirator Approval Program should include your company name in the subject line. If you have a 3-letter manufacturer's code, this should also be included.

6 REFERENCES

Approval of Respiratory Protective Devices, 42 C.F.R. Part 84

Standard Application Procedure for the Approval of Air-Purifying Filtering Facepiece Respirators Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Closed-Circuit Escape Respirators Under 42 CFR Part 84, revised October 16, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Supplied-Air Respirators, Industrial Self-Contained Breathing Apparatus, and Combination Supplied-Air Respirators/Industrial Self-Contained Breathing Apparatus Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Powered Air-purifying Respirators and Chemical, Biological, Radiological and Nuclear Powered Air-Purifying Respirators Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Air-purifying Respirators and Chemical, Biological, Radiological and Nuclear Air-Purifying Respirators Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Self-Contained Breathing Apparatus, and Chemical, Biological, Radiological and Nuclear Self-Contained Breathing Apparatus Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

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American National Standards Institute [2003a]. Sampling procedures and tables for inspection by attributes. Milwaukee, WI: American Society for Quality, American National Standard ANSI/ASQ Z1.4-2003.

American National Standards Institute [2003b]. Sampling procedures and tables for inspection by variables for percent nonconforming. Milwaukee, WI: American Society for Quality, American National Standard ANSI/ASQ Z1.9-2003.

Squeglia NL [2008]. Zero acceptance number sampling plans. 5th ed. Milwaukee, WI: American Society for Quality.

U.S. Department of Defense [1957]. Sampling procedures and tables for inspection by variables for percent defective. Washington, DC: Office of the Assistant Secretary of Defense (Supply and Logistics), Military Standard MIL-STD-414 (including Notice 1, 8 May 1968).

U.S. Department of Defense [1963]. Sampling procedures and tables for inspection by attributes. Washington, DC: U.S. Government Printing Office, Military Standard MIL-STD-105D (including Change Notice 2, 20 March 1964).