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DRAFT FOR DISCUSSION

QA Module Concepts

Goals

1. Update the Quality Assurance and Quality Control portions of 42 CFR Part 84 to promote improved respirator quality and reliability.

2. Address Administrative Issues and Fees in 42 CFR Part 84 which need to be updated.

3. Provide a new format for air-purifying respirator Labels.

Concept for Update of 42 CFR Part 84 to Address Quality Assurance Provisions, Determination of Fees, Improved Labels and Administrative Issues

1.0 Quality Assurance and Quality Control Proposals

These provisions would be amendments to and incorporated into 42 CFR Part 84 requirements. The provisions apply to companies, corporations, partnerships or individuals seeking NIOSH approval (applicant) or having obtained NIOSH approval (approval holder) of respirator designs.

1.1 General Quality Requirements

Each applicant shall, be responsible for the establishment and execution of a quality system which ensures that requirements are met, and that devices produced are safe, effective, and otherwise fit for their intended uses. The quality system shall contain both quality assurance and quality control activities.

1.2 Quality Assurance Requirements

As a condition of obtaining or retaining approval, an applicant and/or approval holder shall:

(a) Establish a quality system that embraces the management philosophy and fulfills all of the specific requirements of ASQ/ANSI/ISO 9001:2000. A quality system which can meet these requirements, whether formally registered by an accreditation body or not, can be acceptable.

(b) Create and maintain the organizational structure required by and capable of carrying out the provisions established in section (a) above

(c) Submit an acceptable Quality Manual which includes the requirements of the quality system to the Institute, if one is not already on file at NIOSH.

(d) Submit a copy of the Quality Manual to NIOSH whenever the Manual is significantly revised or, no less than once every four (4) years.

(e) Submit a Quality Manual upon request of the Institute.

(f) Establish a retention period for quality records for the expected life of the respirator's major components.

(g) Retain servicing records for a minimum of 7 years.

1.3 Quality Control Requirements

(a) Quality Control Plan. Each applicant must develop a quality control plan which documents all assembly, inspection, test, and service processes applicable to each design of a respiratory device for which approval is sought or maintained. The following documentation is to be submitted for approval as part of the quality control plan.

(1) Quality control plan flowchart. This flowchart is representative of the processes used in the production of the approved device, including production, inspection, test, and servicing activities. All inspection, and test activities shall be included from the point of initial assembly to distribution as a complete functional device which meets all approval requirements.

(2) Design, Production, and/or Engineering Drawings.

(a) Engineering drawings which present pictorial representation(s) of the respiratory device shall be generated and shall include views, dimensions, material(s) requirements, and other information as required to assure correct interpretation of the drawing when used during procurement, manufacturing, inspection, testing activities or as certification records.

(b) Components that are major assemblies must have part numbers located on the component. A part number (as identified on the NIOSH Label) refers to any identification number in which the user can readily identify to verify that the component is approved for a specific configuration. Part numbers shall be clearly and permanently marked on the component.

(3) Assembly, Inspection, and Testing Procedures. Procedures for all assembly, inspection, and testing activities, whether procured or performed by the approval holder, shall be designed, documented, and validated to assure that sufficient process description is available to successfully perform all necessary production activities. Acceptance and rejection workmanship criteria shall be incorporated as necessary to assure that the approved device meets all design, performance, and regulatory requirements. The procedures in this paragraph are required as part of the quality control plan, but do not have to be submitted to the Institute. These procedures must be available for inspection and review by a NIOSH authorized representative upon request.

(4) Classification of Defects. Classification of defects documents shall be generated and maintained for each

production stage of a approved respiratory device. The criteria listed in the classification of defects document shall be incorporated into an inspection procedure at the appropriate level of assembly. The appropriate level of assembly is one at which the defect criteria shall be able to be fully evaluated by the operator and shall not be masked or hidden by other hardware or performance elements. This document shall list all Critical, Major A, Major B, and Minor characteristics for which inspection or testing shall be performed.

(5) Incoming, In-process, and Final Inspection Sampling Plan Requirements.

(a) Where the data is available, the Institute prefers the use of statistical process control to determine product quality. Process capability indices (Cpk) and statistical control processes which meet or exceed the following process characteristics are acceptable:

(i) Critical characteristics shall have Cpk > 2.00;
(ii) Major A characteristics shall have a Cpk > 1.33;
(iii) Major B characteristics shall have a Cpk > 1.33;
(iv) Minor characteristics shall have a Cpk > 1.00.

Upon approval of the assessment plan, the applicant may reduce or eliminate inspection sampling when the plan criteria are met or exceeded. MIL-HDBK-1916 may be consulted for definitions of Cpk and guidance on statistical process control.

The Institute supports the use of zero defect sampling plans where inspection is required. The sampling plans contained within MIL-STD-1916 provide acceptable levels of component acceptability for each product characteristic:

(i) Critical characteristics shall use verification level VII;
(ii) Major A characteristics shall use verification level VI;
(iii) Major B characteristics shall use verification level III
(iv) Minor characteristics shall use verification level II.

Guidance and details on the sampling plans can be found in MIL-HDBK.-1916.

The Institute desires to move away from Acceptable Quality Level (AQL) based detection and inspection plans. Existing Approval Holders may continue to use AQL-based inspection plans for 3 years from the adoption of this revision, at which point one of the above product quality plans must be submitted for approval. The revised level of component acceptability are as follows:

(i) Critical characteristics inspected 100 percent;
(ii) Major A characteristics shall have an acceptable quality level of 0.65 percent;
(iii) Major B characteristics shall have an acceptable quality level of 2.5 percent;
(iv) Minor characteristics shall have an acceptable quality level of 4.0 percent.

Alternative sampling plans, which can be shown to be statistically equivalent to the zero defects or Cpk based plans, may be used with approval by the Institute.

For destructive inspection or test sampling a reduced sampling plan per a standard or manufacturer devised plan can be utilized if found acceptable by NIOSH.

(b) All necessary sampling plan documents shall be available for use at the location of the assembly, inspection, or testing activities.

(c) User Instructions. User instructions which provide clear and concise instructions on the safe use of the approved respiratory device shall be designed, documented, and validated. The current approved revision of the user instructions shall be provided and distributed with each approved device.

(d) Certification Labels. Product certification labeling requirements will vary based upon type and intended use of the respirator. Refer to the current Standard Application Procedures for guidance.

(e) The Institutive reserves the right to request additional documentation as necessary.

(f) Drawings, plans and other documents required in this section shall be approved, maintained, and controlled by a documentation control system.

1.4 Audit Programs

(a) General.
The Institute shall monitor manufacturing facilities utilized in the production of respiratory devices. The Institute shall also monitor respiratory devices for which approval is being sought or has been granted. The interval and level of monitoring activities shall be determined by the Institute, but in the case of manufacturing facilities, shall not be less than 6 months between on-site compliance audits, except for cause.

(b) Pre-approval Audits
The Institute reserves the right to conduct pre-approval quality assurance audits of all new respirator manufacturers and pre-production compliance audits of new manufacturing sites for existing approval holders.

(c) Quality System Compliance Audits
A NIOSH authorized representative shall perform quality system compliance audits at manufacturing or assembly facilities. Two types of on compliance audits will be performed. These may be conducted as part of a single visit or performed during separate site visits.

(1) Quality Management System Audit. The Quality Management System Audit will determine compliance that an appropriate Quality Management System is in place. For those approval holders who are ISO 9001:2000 registered, a recent, less than 12 months old, monitoring report from a registrar accredited by the ANSI-RAB National Accreditation Program (or equivalent national body for non-US approval holders) may be submitted to NIOSH in lieu of an on-site quality system audit. For those approval holders who are not ISO 9001:2000 registered, the audit will be conducted by a NIOSH approved representative. The choice of auditor will be at the discretion of the Institute.

(2) Quality Control and NIOSH Specific Requirements Audit. This audit will determine compliance with quality control and specific product test requirements of NIOSH. These audits will be performed by a NIOSH authorized representative.

(d) Approved Respiratory Device Compliance Audit Program
NIOSH approved respiratory device compliance audits shall be conducted by the Institute or NIOSH Authorized Representative, through device inspections and testing. The inspections and testing activities shall follow the protocols established by the Institute for evaluation of respiratory devices against the requirements of this section. The NIOSH authorized representative may request from approval holders sufficient samples of approved devices to perform these audit activities. The Institute may request these audit samples(per approval issued) at a rate of no more than once per calendar year, except for cause. Holders of NIOSH approvals shall provide, upon request, at no cost to the Institute, sufficient samples of approved devices to

conduct these activities. These audit samples will be returned free of charge upon the approval holders request. Reports of the audit activities and results shall be provided to the management representative of the approval holder when such reports are completed. The results of these audits which demonstrate noncompliance to the requirements of 42 CFR 84 could be grounds for action outlined in § 84.37.

(e) Certified Product Investigation Process (CPIP)

(f) The current CPIP will continue without significant changes.

1.5 Revocation of Approval for Lack of Maintenance of Quality System

(a) Upon submitting an application, the applicant acknowledges the right of the Institute to have a NIOSH authorized representative inspect/audit the applicant's quality assurance and quality control processes and to interview any employee or agent of the applicant. The applicant is obligated to furnish appropriate information to complete this audit.

(b) The Institute reserves the right to suspend the processing of pending or future approval applications from an applicant who, as a present approval holder, has not demonstrated an ability to comply with the quality assurance and quality control requirements of its existing approvals and, therefore, cannot demonstrate its ability to comply with the quality assurance manual and quality control plan submitted as part of its application. This suspension of processing shall remain in effect until such time as the approval holder demonstrates such compliance.

(c) The Institute reserves the right to revoke, for cause, any certificate of approval where it is found that the applicant's quality assurance and quality control plans do not ensure effective production of the respirator for which the approval was issued.

1.6 Use of External Resources (Auditors and Laboratories) by NIOSH

(a) General

The Institute wishes to use external resources to supplement, not replace, its existing staff and laboratories. Trial and evaluation programs have been implemented in these areas.

(b) External Auditors

(1) For those approval holders who are ISO 9001:2000 registered, an auditor employed by a registrar accredited by the ANSI-RAB National Accreditation Program (or equivalent national body for non-US approval holders) may be used to submit an on-site quality system audit report to NIOSH. For those approval holders who are not ISO 9001:2000 registered, the audit will be conducted by a NIOSH approved representative or by a quality management system auditor selected from an approved NIOSH list.

(2) The choice using a NIOSH or non-NIOSH auditor will be at the discretion of the Institute.

(c) Test requirements

(1) Each respirator and respirator component shall, when tested by the applicant and by the NIOSH authorized representative, meet the applicable requirements.

(2) The NIOSH authorized representative shall hold as confidential any analysis, drawings, specifications, or

materials submitted by the applicant and shall not disclose any principles or patentable features of such equipment, except as required by statute or regulation.

(3) External testing laboratories will be qualified by the Institute for each individual test protocol performed as part of an ongoing laboratory quality program based on the requirements ISO 17025 and internal NIOSH quality requirements.

1.7 Approval Holder Audit, Inspection and Reporting Requirements

(a) General

Documentation of good production practices is required

(b) Changes or modifications of approved respirators

Prior to the implementation of any significant changes, an application shall be submitted as for an original certificate of approval, with a request for a modification of the existing certificate. (This modification application is known as an Extension of Approval.) Changes which require and extension of approval to be filed include changes to any NIOSH required documentation, changes of ownership, liquidations, and changes in processes for the respirator which could effect the form, fit or function of any device which the Institute certifies. Each approval holder shall evaluate all changes made to an engineering/production drawing, specification, procedure or other documentation in accordance with established procedure to determine if the submission of an application to the Institute for an "Extension of Approval" is required. Records of this evaluation and its results shall be maintained. An Extension of Approval shall be approved prior to implementation of change(s).

(c) First piece inspection

Approval holders shall perform first piece inspections on all production line new start-ups and restarts. A restart is defined as the resumption of production for a respirator type which has not been produced within the last 12 months. A minimum of 2 pieces will be inspected to the specification for full compliance on all production line start-ups and restarts prior to proceeding with production.

(d) Approval holder respirator auditing program

Approval holders shall audit each product line of NIOSH approved devices which have been produced within the calendar year to the requirements of this part on an annual basis. NIOSH will be notified within 3 working days of a non-conformance or failure of a critical or major characteristic(s) during these audits. These audit reports shall be made available upon request to NIOSH for review. These reports shall be held by the approval holder for a period of 3 years.

(e) Approved Respiratory Device Complaint Reporting

Each applicant shall establish and maintain procedures for receiving, reviewing, evaluating, and resolving complaints. Such procedures shall ensure that:

(1) Complaints are to be received, reviewed, evaluated, investigated, responded to, and maintained by a formally designated person or team;
(2) Oral complaints are documented upon receipt;
(3) When no investigation is made, the applicant shall maintain a record that includes the reason that no

investigation was made and the name of the individual or team responsible for the decision not to investigate.

(4) Any substantiated complaint pertaining to death, injury, or hazard involving the health and/or safety of the user or regulatory noncompliance involving a critical or major classification of defect shall be:

(a) Immediately evaluated, and investigated by a designated individual(s).
(b) Communicated in writing to the Institute within 3 working days. This communication will include a summary of the incident, the results of the investigation to date and the plans for any additional investigation activities.

2.0 Administrative Issues and Fee Proposals

2.1 Application procedures

(a) Applications shall be submitted to the NIOSH, and shall be accompanied by a check, bank draft, or money order in the amount specified in subpart C of this part, payable to the order of the National Institute for Occupational Safety and Health.

(b) Except as provided in 42 CFR part 84, the examination, inspection, and testing of all respirators shall be conducted by NIOSH.

(c) Applicants, manufacturers, or their representatives may visit or communicate with NIOSH in order to discuss the requirements for approval of any respirator or the proposed designs thereof. No charge shall be made for such consultation and no written report shall be issued to applicants, manufacturers, or their representatives by the Institute as a result of such consultation.

(d) All primary parties in a purchase or merger involving one or more approval holders shall notify NIOSH in writing of the new organizational structure. The transfer of any approvals shall require the submission of an extension of approval which meets the minimum requirements set forth in subpart B of 42 CFR part 84.

2.2 Application contents

(a) Applications for certifications for respiratory protective devices shall be accepted by the Institute. These applications shall follow the format provided by the Institute. Only applications that follow the approved format shall be accepted by the Institute. An electronic version of the Standard Application Procedures can be viewed at the NIOSH website http://www.cdc.gov/niosh/homepage.html. Copies of the Standard Application Procedures which include this approved format may be obtained by the applicant by sending a request to:

Respirator Branch
ATTN: RB Records Room
NIOSH, NPPTL
PO Box 18070
626 Cochrans Mill Road
Pittsburgh, PA 15236
Phone: (412) 386-4100
Fax: (412) 386-4051

(b) Each application for approval shall contain a complete description of the respirator for which approval is requested with the appropriate documentation as specified in the NIOSH Standard Application Procedures.

(c) Each application for approval shall contain proposed plans for quality control and quality assurance which meets the minimum requirements set forth in subpart E of 42 CFR part 84.

(d) Each application shall contain a statement that the respirator has been pretested by the applicant as prescribed in §84.64, and shall include the results, with data, of such examinations, inspections, and tests.

(e) Each application for approval shall contain a statement that the respirator and component parts submitted for approval are either prototypes, or made on and with regular production tooling and manufacturing, with no operation included or excluded which will not duplicate the regular production processing.

(f) The applicant shall deliver, at his own expense, the number of completely assembled respirators and component parts required for testing, to NIOSH.

2.3 Specific Language and Section Changes

Specific obsolete language and references to powered air-purifying respirators will be removed from Subparts K, L, N and KK.

2.4 Voluntary Withdrawal of Approval

For an approval holder to obsolete an existing approval written notification will be provided to NIOSH by the approval holder. The approval holder will also notify all agents and/or distributors of the approval holder of the action to obsolete an existing approval. Upon receipt of notification NIOSH will reflect this status in the certified equipment list. A new application for approval must be submitted and granted for re-approval of an obsolete respirator.

2.5 Fees for Approvals

(a) Method of Fee Calculation for Approvals

(1) Fees for the examination, inspection, testing and approval of respiratory protective devices shall include both direct and indirect costs. Fees would be charged on a flat-rate basis, except for withdrawn or incomplete processing or for unique devices for which a fee does not exist (unlisted fees).

(2) Withdrawn or incomplete processing. If an application does not result in completion of the action, the processing fee will be charged. Incomplete actions could result from withdrawal by the applicant, cancellation by NIOSH for insufficient information or technical problems, or failure to pass a test or examination.

(a) Testing fees will be refunded if the application is withdrawn or canceled prior to commencement of testing.

(b) Testing fees will be charged if testing is initiated prior to withdrawal or cancellation.

(3) An application for approval of unique or new products, for which a published fee does not exist, would be charged at a hourly rate as estimated by NIOSH.

(a) NIOSH reserves the right to conduct any examination, inspection, or test deemed necessary to determine the quality and effectiveness of any unlisted respirator assembly or respirator components or subassembly.

(b) NIOSH reserves the right to assess the cost of such examinations, inspections or tests to the applicant prior to the issuance of an approval.

The following fees are typical of what may be charged (These are based on 2000 costs and will be updated to reflect current costs prior to final CFR submissions):

New Approvals:

N-series Respirator.....	$3,480
Particulate R & P -series Respirator.....	$2,791
Powered Air-Purifying Respirator (PAPR).....	$2,791
Gas Masks-(single).....	$3,436
Gas Masks-Type N.....	$3,436
plus $1583 per additional Gas	
Chemical Cartridge Respirator.....	$3,436
plus $1583 per additional Gas/Vapor	
Supplied-air Respirator.....	$4,492
SCBA Respirator	
> 60 minute	$4,970
< 60 minute.....	$4,970
Escape only.....	$4,970
CBRN Supplied-air Respirator.....	$35,125
Unlisted.....	$33/Hour

Extensions:

Facepiece.....	$2,237
Cannister (filter extra).....	$3,303
Cartridge (filter extra).....	$3,303
Filter (N-series).....	$3,480
Filter R & P-series).....	$2,791
Fit Test.....	$5,000
does not apply to particulate respirators	
Silica Dust.....	$2,206
applies only to PAPRs	

Hoses.....	$2,872
Blower.....	$2,006
Harness.....	$3,350
Cylinder.....	$3,350
Regulator.....	$3,350

Combination.....

All applicable fees

(c) NIOSH reserves the right to to assess a flat hourly rate for quality site audits, reimbursement for travel expenses, and review of third-party audit reports.

(d) NIOSH reserves the right to assess a flat hourly rate for conducting problem investigations where the approval holders is in noncompliance and reimbursement for travel expenses.

(e) NIOSH reserves the right to assess a flat hourly rate for conducting product audits.

(f) The flat hourly rate used will be determined at the time of the audit or investigation as determined by Section 4 below.

(4) Direct costs for hands-on approval activities would be based on actual costs and average hours to perform approval processing tasks including, but not limited to, application processing, testing, and quality assurance.

(a) Compensation, including benefits, for the engineers, scientists, and technicians who review of applications, perform inspection, conduct tests, evaluate of test results, and prepare decisions as well as consult with product manufacturers and other applicants concerning technical processing of an application.

(b) Fees for this service would be at three flat rates--one rate for application processing and technical evaluation, one for each test type, and one for quality review prior to issuance of the approval.

(5) Indirect Costs would include

(a) Operating costs, including facility operation and maintenance, utilities and other building services

(b) Equipment purchase, rental, and maintenance

(c) Supplies and materials

(d) Depreciation of building and equipment

(6) Where travel by NIOSH personnel is required for respiratory protective device approval-related activity, the applicant would be charged on an actual cost basis for transportation and subsistence in accordance with government travel regulations.

2.6 Maintenance Fees

(a) The maintenance fee would be based on the Institute's costs to maintain the approvals on record.

(1) Compensation, including benefits, for the engineers, scientists, and managers who maintain electronic record keeping, provide technical assistance to industry, publish certification listings, participate on technical committees, and maintain communications on matters of mutual concern and interest with respirator manufacturers and governmental partners. Also, any future program deemed to have direct bearing on the approval program.

(2) Compensation, including benefits, for support staff, including clerical, computer, record keeping and managerial hours expended on this post-approval and approval support programs.

(3) Indirect Costs

(a) Operating costs, including facility operation and maintenance, utilities and other building services

(b) Equipment purchase, rental, and maintenance

(c) Supplies and materials

(d) Depreciation of building and equipment.

(e) Travel for support programs (not payable as actual cost; included in maintenance fee calculation).

(4) The annual maintenance fee would be based on the number of active approvals on file with NIOSH requiring the use of the Electronic Information and Management System (EIMS) and associated activities to maintain accurate and current records on all approval activity.

2.7 Administration of Fees

(1) Fees for Approvals

(a) NIOSH would require a check, bank draft or money order in the amount specified to be submitted to the National Personal Protective Technology Laboratory simultaneous with submittal of the application package to NIOSH in Pittsburgh, Pennsylvania. Receipt of payment by the National Personal Protection Technology Laboratory and receipt of the application package will be communicated between the two organizations. Applicants who do not submit the correct fee will be notified by NIOSH of the balance due or overpayment.

(b) Travel and transportation costs incurred when NIOSH personnel are required to travel to conduct activities associated with the approval process would be billed in all cases when processing of the application is completed.

(c) Payment for travel invoices would be made directly to National Personal Protective Technology Laboratory.

(2) Fees for Annual Maintenance and Other Billable Services

(a) NIOSH would require a check, bank draft or money order in the amount specified to be submitted to National Personal Protection Technology Laboratory on or before the due date. Applicants who do not submit the correct fee will be notified by NIOSH of the balance due or overpayment.

(3) Failure to Make Timely Payment

Failure to make payment of any fee by due date, specified in the final rule, will result in (as appropriate):

(a) Delayed initiation of processing for new approvals or extensions.

(b) Rejection of further applications for approval until payment is received.

(c) Initiation of debt collection procedures that will include interest, penalties and administrative costs.

(d) Curtailment of any further processing of applications in-house at NIOSH.

(e) Notification from NIOSH that the Institute will list the approved product as obsolete on the CEL until the delinquent payment is received.

3.0 Approval Labels

The Institute has received many comments on labels, and while it is believed that most could be addressed within the current regulatory language, remains open to comments on this area of the current regulation.

Comments on the draft module should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone 513–533–8303, Fax 513/533–8285. Comments may also be submitted by e-mail to niocindocket@cdc.gov. E-mail attachments should be formatted as WordPerfect 6/7/8/9 or Microsoft Word. Comments should reference docket number, NIOSH-001, Quality Assurance Module Concept.