



SUMMARY

42 CFR 84

**QUALITY ASSURANCE
IMPROVEMENT CONCEPTS**

84 Manufacturing Sites in 18 Countries



Looking Back

- 1972–1995 No New Respirator Standards
- 1995 Promulgation of 42 CFR 84
 - Modular Process
 - New Technical Standard for Particulate Filters
 - Beginning of Standards Development Activity
- 1996 to Present
 - CBRN SCBA
 - CBRN APR
 - CBRN Escape Respirators -Development
 - Quality Assurance - Development
 - Self-Contained Self Rescuers - Development

Looking Back

- Public Discussion of QA Concepts
 - Stakeholder Meetings (May-Oct. 2000)
 - Private Sector Lab/Auditor Meetings (July 2000)
 - Public Meetings (August 2000)
- ISO 9001 2000 Established
- Establishment of the National Personal Protective Technology Laboratory (2002)
- New Personnel

Public Health & Safety Impact

- Contemporary Manufacturing Processes
- Replace Outdated Quality Requirements
- Significant Nonconformance Rate
- Standards Development
 - Efficient Use of Resources
 - Outside Resources
 - Fees



The Remedy

Objective	Mechanism
<p>Consistency w/International Stds</p> <p>Product Specific QA Requirements</p> <ul style="list-style-type: none"> ▪ Quality Plans ▪ Sampling Procedure ▪ Quality Production Records 	<p>Incorporate ISO 9000 Elements</p> <ul style="list-style-type: none"> ▪ Add In-Process Controls &/or more Stringent Sampling ▪ Incorporate First-Piece Inspections/Tests ▪ Implement Complaint Notification Program ▪ Retention of Quality Records for Life of Major Components
<p>Validate Quality System prior to Approval</p>	<p>Manufacturing Site Approval & Audit</p>

The Remedy

Objective	Mechanism
<p>Audit Frequency Consistent w/QA Practice</p> <ul style="list-style-type: none"> ▪ Semi-Annual Site Audits ▪ Annual Product Audits 	<p>Utilize Private Sector Resources</p> <ul style="list-style-type: none"> ▪ Authorize RAB Accredited Auditors ▪ Authorized Accredited Labs
<p>Recover & Retain Fees</p> <ul style="list-style-type: none"> ▪ Approval Application Processing ▪ Records Maintenance ▪ Quality Activities Fees ▪ Retain fees to Enhance Standards Development Activities & Approval Processing 	<ul style="list-style-type: none"> ▪ Recover costs for Approval Processing Related Activities ▪ Recover costs for Maintenance of Approval Records & Management of Electronic System ▪ Recover costs for Manufacturing Site & Product Audits and Compliance Investigations

The Remedy

Objective	Mechanism
<p>Label Adequacy for Air-Purifying Respirators</p> <ul style="list-style-type: none">▪ Eliminate Complexity & Size▪ Provide User with Necessary Use Information	<p>Proposed New Format</p> <ul style="list-style-type: none">▪ Manufacturer & NIOSH Phone #▪ Emphasis on Caution for Compliance with OSHA & MSHA on Respirator Usage▪ Stipulate Cautions, Limitations, & Restrictions

New and Improved

- The module development process
 - QA Module is relatively mature
 - Hybrid process
 - Periodic posting of concepts
 - Greater opportunity to interact

Update

Objective	Mechanism	New
Consistency w/International Stds	Incorporate ISO 9000 Elements	Incorporate ISO 9001: 2000
Product Specific QA Requirements <ul style="list-style-type: none"> ▪ Quality Plans ▪ Sampling Procedure ▪ Quality Production Records 	<ul style="list-style-type: none"> ▪ Add In-Process Controls ▪ More Stringent Sampling ▪ Incorporate First-Piece Inspections/Tests ▪ Implement Complaint Notification Program ▪ Retention of Quality Records for Life of Major Components 	Through ISO 9001 Options created Limited implementation Retained Retained

Update

Objective	Mechanism	New
Validate Quality System prior to Approval	Manufacturing Site Approval & Audit	Retained
Audit Frequency Consistent w/QA Practice <ul style="list-style-type: none"> ▪ Semi-Annual Site Audits ▪ Annual Product Audits 	Utilize Private Sector Resources <ul style="list-style-type: none"> ▪ Authorize RAB Accredited Auditors ▪ Authorized Accredited Labs 	Retained Utilize RAB auditors (demo by contract) Retained

Update

Objective	Mechanism	New
<p>Recover & Retain Fees</p> <ul style="list-style-type: none"> ▪ Approval Application Processing ▪ Records Maintenance ▪ Quality Activities Fees ▪ Retain fees to Enhance Standards Development Activities & Approval Processing 	<ul style="list-style-type: none"> ▪ Recover costs for Approval Processing Related Activities ▪ Recover costs for Maintenance of Approval Records & Management of Electronic System ▪ Recover costs for Manufacturing Site & Product Audits and Compliance Investigations 	<p>Retained</p> <p>Retained</p> <p>Retained</p>



Update

Objective	Mechanism	New
<p>Label Adequacy for Air-Purifying Respirators</p> <ul style="list-style-type: none"> ▪ Eliminate Complexity & Size ▪ Provide User with Necessary Use Information 	<p>Proposed New Format</p> <ul style="list-style-type: none"> ▪ Manufacturer & NIOSH Phone # ▪ Emphasis on Caution for Compliance with OSHA & MSHA on Respirator Usage ▪ Stipulate Cautions, Limitations, & Restrictions 	<p>Under consideration - Comments?</p>

Opportunities to Improve

- Public Dialogue Facilitates National Acceptance/Familiarity
- Quality Standards Substantially Improved
- NPPTL & Fee Retention Provides Effective Implementation

Implementation Issues

- Establish an Infrastructure to Implement Use of Private Sector Resources
- Completion of an Economic Analysis
- Administrative Funding Mechanism (Completed)

Schedule

- QA Concepts Being Revised
- Public Discussion of Concept Updates (June)
- Posting of Updated Concept (June)
- Concept Docket Closes (July)
- Public Meeting (September/October)
- Notice of Proposed Rule Making (December/January)