INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION ISEA

January 19, 2010

The Hon. Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Re: Petition on NIOSH Administrative/Quality Assurance Proposed Regulation and NIOSH Total Inward Leakage of Respirators Proposed Regulation

Dear Secretary Sebelius:

The International Safety Equipment Association (ISEA) fully supports the need to have high quality and reliable respiratory protective devices available to a wide range of US workers. Recent proposed regulations by NIOSH state this intended purpose. However ISEA believes strongly that the proposed regulations not only fall short of their intended purpose, but may in fact stifle the development and introduction of new and innovative products that would result in increased worker protection.

ISEA, pursuant to subsection 553(e) of the Administrative Procedure Act, 5 U.S.C. §551, *et seq.*, petitions HHS and NIOSH to defer work and re-open the record on the proposed NIOSH Administrative/Quality Assurance (QA) (73 FR 75045) rulemaking until HHS and NIOSH conduct a more complete regulatory flexibility analysis and economic analysis of the proposed QA rule, and to receive and consider additional comments and analyze additional data regarding the need for and effect of that proposed regulation in light of the more recently proposed NIOSH Total Inward Leakage (TIL) rule (74 FR 56141). Specifically, the need for and effect of the proposed QA rule now needs to be analyzed in combination with the proposed TIL rule.

Together, these proposed rules have the potential to very significantly alter the manner in which respirators are made and tested and to negatively affect both the availability of respirators for the community of respirator users as well as the costs incurred by respirator manufacturers and the employers and individuals who purchase respirators. Moreover, the need for these rules has not been established in the record thus far, and is highly suspect.

NIOSH's QA Preamble Questions the Need for the QA Rule

As NIOSH recognized in its proposed QA rule preamble, "most respirator manufacturers maintain effective quality management systems," and the number of times NIOSH has had to take action "cover a small number of the 7,100 respirators approved by NIOSH . . ." By NIOSH's own admission, any problem with respirator quality assurance is small. Nor is there any evidence in the record of either of the proposed rules that performance issues exist with respiratory protection products currently on the market that should require respiratory protection manufacturers to conduct the cumbersome and unreliable procedures outlined under these two proposed rules. In fact, NIOSH's proposed testing regime would likely prevent some respirators from entering the marketplace which are needed to fit facial configurations that differ from the panel norms that NIOSH is attempting to establish. The reduced availability of respirators that could result from the proposed rules would make it more difficult and costly in many cases for employers to comply with the OSHA fit testing requirements for respirators. After all, it is the OSHA fit testing requirement that ensures that the end-user is properly protected.

Discussion of QA and TIL Rules

As pointed out above, and admitted by NIOSH, the justification for these proposals are difficult to evaluate. First, with respect to QA, NIOSH already requires that respiratory protection manufacturers have "quality plans" and comply with other QA-related regulations at 42 C.F.R. §84.40. Nevertheless, the core of the proposed QA rule would require that respirator manufacturers adopt one of four specific

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quality control plans, none of which is presently widely used by the community of respiratory protection manufacturers. The QA rule also imposes a number of requirements for reporting to NIOSH, and would require NIOSH certification holders to conform to ISO9001.

These requirements of the proposed QA rule would unnecessarily change the current quality assurance practices of respiratory protection manufacturers. Currently, sampling of components and finished goods is conducted in accordance with ANSI/ASQ Z1.4-2008, the American National Standard for Sampling Procedures and Tables for Inspection by Attributes, a widely accepted industry consensus standard. The proposed four QA specification standards would greatly increase the number of products that must be tested and the level to which they are tested, and for no apparent reason.

Moreover, the proposed QA rule's overall approach does not comport with current QA practices. The QA rule would require manufacturers to assess quality at the end of a production run, rather than the current practice of assessing the quality of incoming parts and components and training employees to manage quality during a production run. There is no evidence in the record or otherwise that the current practice does not effectively ensure that finished products meet manufacturer specifications for form, fit, function and appearance. In fact, CDC, NIOSH, OSHA and the Institute of Medicine (IOM) have recently underscored and approved the use of fit-tested N95-rated respirators for use to protect wearers from H1N1 exposure. In a recent exhaustive literature survey on respiratory protection, the IOM made no mention of concerns about these devices. As mentioned above, NIOSH has acknowledged that "most respirator manufacturers maintain effective quality management systems."

Rather than unnecessarily changing the current overall approach to QA, an alternate rule could be proposed that includes general updates to quality assurance plans, such as third-party compliance with ISO 9001:2008. This internationally accepted standard assures quality manufacturing processes. In addition, NIOSH should use its current authority under 42 C.F.R. §84.34 and 42 C.F.R. §84.43(c) to audit and penalize respirator manufacturing companies whose respiratory protection products are found to be out of compliance.

The TIL rule seeks to require respirator manufacturers to test and mark respirators based on a new testing regime meant to simulate the face sizes and shapes of respirator wearers. Under the proposed testing regime, a group of 35 test subjects would represent a certain sector of wearers. But there is great variability even in grouping types of wearers, and 35 subjects do not represent the universe of wearers. The proposed testing regime may prevent some respirators from entering the marketplace which are needed to fit facial configurations that differ from the panel norms that NIOSH is attempting to establish.

While the goal of the proposed regulation is to have in the market respirators that fit a range of users, which ISEA supports, the benchmark testing on which NIOSH based its proposed regulation and the assumptions made based on the data both appear to be flawed. Additionally, the primary manufacturer of the test equipment (TSI, Inc.) does not support the manner in which NIOSH proposes to use their equipment as outlined in their comments to the NIOSH docket. ISEA supports the need for respiratory protective devices to show evidence that they have the capability to fit a range of facial characteristics; however the methodology currently being proposed lacks reproducibility and is overly cumbersome.

Finally, there is no crisis in respiratory protection that demands either of these burdensome proposed rules. Quality respiratory protection products are currently available, and OSHA requires that these respirators fit each wearer properly.

Effect of QA and TIL Rules

The combined regulations will disrupt the market place for respirators when they are needed most – during a flu pandemic – with no real measurable benefit to users. As pointed out the proposed testing regime would unnecessarily prevent some respirators from entering the marketplace which are needed to fit faces with facial configurations that differ from the panel norms that NIOSH is attempting to establish. The proposed QA rule, which unnecessarily adds a layer of requirements over what manufacturers are already doing to ensure respirator quality, would also have the effect of preventing some number of

quality respirators from entering the marketplace. Yet, ISEA is not aware of any workplace performance failures or crisis in products that necessitate either the QA or TIL rules. Nor has the extent of this effect been analyzed by NIOSH.

Regulatory Flexibility Act Concerns

Proposed QA Rule Regulatory Flexibility Act Concerns

In addition to the potentially dangerous disruption of respirator supply at a time when respiratory protection is more necessary than ever, the proposed rules combined would have a significant economic impact on both the respiratory protection industry and the employers and individuals who use respirators. Compliance costs of the QA rule alone are likely to be more than $100 million based on a survey of ISEA members and the number of NIOSH respirator certification holders. Specifically, the five ISEA member companies that were surveyed each estimated the cost to change QA plans in accordance to the proposed rule and to comply with other parts of the measure to be $5 million per company, and possibly more for those companies with multiple product lines. NIOSH recognizes that the majority of respirator manufacturers are small businesses (73 FR 75051). Since there are more than 100 listed respiratory protection approval holders on NIOSH's website, the overall economic impact of this rule could easily exceed $100 million, mainly to small businesses. (*See attached estimates*).

Yet, in the proposed QA rule, NIOSH did not conduct an economic impact analysis. NIOSH instead stated that "it does not have access to information to estimate costs and cost savings associated with changes some manufacturers might make in response to the proposed sampling plan requirements." NIOSH requested information from manufacturers that might be useful in establishing such an estimate, but the agency says it "expects that any company that would be required to make changes would have difficulty estimating *ex ante* the potential economic impact of the changes." (73 FR 75051)

ISEA did submit cost estimates. Based on this limited sampling of manufacturers, it spears that the cost of compliance would be substantial and therefore, ISEA believes that NIOSH can and must develop a comprehensive cost estimate before moving forward with any rulemaking activity.

NIOSH also stated in the QA proposal that there "are substantial difficulties in making such estimates for a company that lacks well-controlled production processes: First, the causes of quality problems must be identified; and second, once such cause or causes are identified, there are likely to be multiple alternatives for solving the problems identified." (73 FR 75052)

ISEA believes, however, that NIOSH could estimate the cost of compliance even for a company that lacks a well-controlled production process. NIOSH could hire a management systems contractor to construct such cost estimates.

NIOSH also says that a company with a high-quality QA plan would be in a position to estimate some of the possible cost savings associated with quality improvements, "such as (1) reduced inspection costs; (2) avoided losses associated with nonconforming materials, components, and final assembled products; and (3) reduced losses." (73 FR 75052)

ISEA members have not identified any cost savings in the proposed QA regulation in any way, and they do not see how the proposed rule offers the three benefits NIOSH suggests. Moreover, current quality control systems work well.

NIOSH ends its regulatory analysis of the QA proposal by stating that "for the reasons provided, a regulatory flexibility analysis, as provided for under the RFA, is not required." (73 FR 75052)

ISEA disagrees. NIOSH did not estimate the baseline compliance costs with the costs to comply with the new proposed rule. In addition, NIOSH did not comply with various sections of the Regulatory Flexibility Act, such as Sec. 603(b)(3) which requires an estimate of the number of entities likely to be impacted; Sec.603(c), which requires a description of alternatives to the proposed rule which accomplish the stated

objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities; Sec. 603(c)(3) which encourages the use of performance rather than design standards; and Sec. 607, which encourages the preparation of quantitative and numerical analyses.

Proposed QA Regulatory Flexibility Act Certification Must Be Reversed; No Factual Basis for Claims

HHS certified the proposed QA rule Regulatory Flexibility Act analysis, stating that the proposed QA "would not have a significant economic impact on a substantial number of small entities" (73 FR 75051). ISEA asks how this can be if NIOSH states it "does not have access to information to estimate costs" of the proposed rule (73 FR 75052) and the number of small entities was not mentioned. In fact, NIOSH asks the regulated community for cost information. NIOSH states multiple times throughout its "Regulatory Assessment Requirements" section that there will likely be no costs associated with this proposed rule. ISEA submits there is no factual basis for the claim that there is no significant economic impact. Furthermore, baseline compliance costs and new compliance costs were not discussed.

Proposed TIL Rule Regulatory Flexibility Act Concerns

While the proposed QA rule alone raises significant cost issues for the regulated community, ISEA's concerns are compounded by the recently published proposed TIL rule.

In the proposed TIL rule NIOSH did not comply with Regulatory Flexibility Act Sec. 603(b)(3) which requires an estimate of the number of entities likely to be impacted; Sec.603(c), which requires a description of alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities; Sec. 603(c)(3) which encourages the use of performance rather than design standards; and ISEA questions the validity of the quantitative analysis. The proposed TIL rule's true costs are unknown. Although NIOSH did conduct a TIL cost estimate for the Regulatory Flexibility Act requirements, ISEA members have not yet been able to verify it or conduct their own cost estimates.

Proposed TIL Regulatory Flexibility Act Certification Must Be Reversed

HHS certifies that the proposed TIL rule "would not have a significant impact on a substantial number of small entities" (74 FR 56148), but as noted above, NIOSH did not estimate the number of small businesses that might be impacted. NIOSH even states it "cannot estimate the total costs associated with this rulemaking..." (74 FR 56147). But later in the proposed TIL rule, NIOSH estimates costs to be $3.1 million for the first two years and $825,000 annually after that. ISEA is concerned about the factual basis upon which these estimates were created and the factual basis of the certification that the proposed TIL rule "would not have a significant impact on substantial number of small entities." In the "Relief Requested" section, the Association asks for a one-year extension of the TIL comment period to develop these cost estimates in conjunction with testing the validity and reproducibility of NIOSH's proposed test methods.

Summary

In sum, the proposed TIL rule, with its potential to alter the manner in which respirators are made and tested, combined with the proposed QA rule, would impose significant costs on respiratory protection manufacturers and end-users that far outweigh speculative benefits. More importantly, the combined regulations will disrupt the supply of respirators in the marketplace when they are needed most – during a flu pandemic – with no real benefit to users. And yet ISEA is not aware of any market failures or crisis in products that necessitate the costs and disruption of supply that would be the combined effect of the QA and TIL rules.

Relief Requested

ISEA submits that the requirements of both the Regulatory Flexibility Act and Executive Order 12866 apply to these proposed rules and require NIOSH to complete and support with evidence in the record an assessment of the true costs of the proposed rules, which have a combined effect, as well as an examination of less costly regulatory alternatives. This has not been completed for either proposed rule. ISEA thus respectfully requests that NIOSH keep the record open on both proposed rules until such a cost assessment and examination of alternatives have been completed for the combined effect of the QA and TIL proposals on the community of respirator manufacturers and users.

Specifically, we request that NIOSH defer work on the proposed QA and TIL rules until the following are completed:

NIOSH prepares and publishes a true cost estimate for the proposed QA rule and supports that estimate on a factual basis in the rulemaking record;

NIOSH must assess the combined costs and economic impact of the two proposed rules on the regulated community, including those that are small businesses, and support that assessment in the rulemaking record;

ISEA members have commissioned independent testing of respirators using NIOSH's proposed TIL metrics to obtain data on the validity of NIOSH's TIL assumptions. Following ISEA's independent testing, we ask that NIOSH conduct designed experiments that would enable a statistical evaluation of the impact that subjects, time, and products have upon the output of the proposed TIL rule. For example: What is the variability in subject pass rate in the NIOSH TIL test for a given model of a half facepiece respirator between different panels of subjects? Are three repeat donnings of a single half facepiece respirator in the NIOSH TIL test equivalent to donning three half facepiece respirators? Are the three repeat donnings less variable? The regulated community is open to two-way dialogue with NIOSH about our concerns on the lack of reliability of the TIL method. ISEA asks for a one-year extension of the comment period on the proposed TIL rule so that this data and the cost of the proposed rule can be fully analyzed.

Examine and discuss with the regulated community any performance-based, less burdensome, and/or less costly alternatives to the proposed rules (as required by the Regulatory Flexibility Act and Executive Order 12866). ISEA understands this may mean the proposed rules are withdrawn and republished as performance-based, less burdensome and less costly proposed rules.

Finally, ISEA respectfully requests that NIOSH carefully evaluate the combined effect of both proposed rules on the availability and cost of respirators for the community of respirator users.

Respectfully Submitted,

Daniel K. Shipp
President

Attachment

Estimated Additional Hours and Cost for Compliance

	Filtering Facepiece Respirators			Facepiece Respirators - Facepiece			Facepiece Respirators - Filter Cartridge		
Initial Compliance	Technician	Engineer	Total	Technician	Engineer	Total	Technician	Engineer	Total
1a	918	5849		1388	4068		9300	16036	
2a	256	102		70	670		68	1370	
3a	200	506		160	255		1760	1869	
Total hours	1374	6457		1618	4993		11128	19275	
Estimated cost	$ 34,350	$ 484,275	$ 518,625	$ 40,450	$ 374,475	$ 414,925	$ 278,200	$ 1,445,625	$ 1,723,825
Ongoing Compliance									
1b	113005.5	1350		7120	500		44010	5908	
2b	1604	2810		3024	3430		21280	28645	
3b	4768	1410		1950	565		15315	4181	
Total hours	119377.5	5570		12094	4495		80605	38734	
Estimated cost	$ 2,984,438	$ 417,750	$ 3,402,188	$ 302,350	$ 337,125	$ 639,475	$ 2,015,125	$ 2,905,050	$ 4,920,175

	Supplied Air Respirators			PAPRs			SCBA		
Initial Compliance	Technician	Engineer	Total	Technician	Engineer	Total	Technician	Engineer	Total
1a	3750	5617		925	2870		7350	12600	
2a	68	170		68	370		0	0	
irators, October 9, 2009	800	834		160	299		125	160	
Total hours	4618	6621		1153	3539		7475	12760	
Estimated cost	$ 115,450	$ 496,575	$ 612,025	$ 28,825	$ 265,425	$ 294,250	$ 186,875	$ 957,000	$ 1,143,875
Ongoing Compliance									
1b	1750	2500		2486	500		86875	5250	
2b	9166	13588		7266	7796		1575	3150	
3b	6856	1814		3212	482		1680	5376	
Total hours	$ 17,772	$ 17,902		$ 12,964	$ 8,778		90130	13776	
Estimated cost	$ 444,300	$ 1,342,650	$ 1,786,950	$ 324,100	$ 658,350	$ 982,450	$ 2,253,250	$ 1,033,200	$ 3,286,450

KEY

1a. Quality Plans: Plan Updates and Documentation Changes, includes updates to drawings, product standards, work instructions, PQPs, etc.
2a. Annual Respirator System Product Quality Audit Testing: Setting up the system
3a. Complaint Handling and Reporting to NIOSH: Setting up the system
1b. Quality Plans: Inspection Testing for Production each year
2b. Annual Respirator System Product Quality Audit Testing: Carrying out the requirements each year
3b. Complaint Handling and Reporting to NIOSH: Carrying out the requirements each year

Estimates $25/hour for a techician and $75/hour for an engineer

Estimated Additional Hours and Costs for Compliance
Summary of All Categories

Additonal one-time compliance cost

	Technician Hours	Engineer Hours	Total
1a. Quality Plans: Plan Updates and Documentation Changes, includes updates to drawings, product standards, work instructions, PQPs, etc.	23,631	47,040	70,671
2a. Annual Respirator System Product Quality Audit Testing: Setting up the system	530	2,682	3,212
3a. Complaint Handling and Reporting to NIOSH: Setting up the system	3,205	3,923	7,128
Total hours	**27,366**	**53,645**	**81,011**
Estimated cost	**$684,150**	**$4,023,375**	**$4,707,525**

Additonal ongoing compliance cost

	Technician Hours	Engineer Hours	Total
1b. Quality Plans: Inspection Testing for Production each year	255,246.5	16,008	271,254.5
2b. Annual Respirator System Product Quality Audit Testing: Carrying out the requirements each year	43,915	59,419	103,334
3b. Complaint Handling and Reporting to NIOSH: Carrying out the requirements each year	33,781	13,828	47,609
Total hours	**332,942.5**	**89,255**	**422,197.5**
Estimated cost	**$16,647,125**	**$4,462,750**	**$21,109,875**

Notes:
1. Salary for technician ($25/hr) and engineer ($75/hr) is based upon National Salary Trend for area and includes overhead.
2. Resource requirements will be adjusted yearly and may increase or decrease depending upon the business opportunities.

This table was submitted as part of ISEA's comments to NIOSH on proposed Quality Assurance Requirements for Respirators, October 9, 2009