42 CFR Part 84

Second Notice of Proposed Rulemaking—

Revision of Tests and Requirements

for Certification of Respiratory Protective Devices

PRELIMINARY REGULATORY IMPACT ANALYSIS

September 18, 1989

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health

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A. Introduction and Summary

Under Executive Order 12291 (February 17, 1981), the Department must prepare a "preliminary regulatory impact analysis" for any proposed rule that has an annual effect on the economy of $100 million or more, has certain other effects, or is categorized as a "major rule" by the Office of Management and Budget. Under the Regulatory Flexibility Act (P.L. 96–354, 94 Stat. 1164 [5 U.S.C. 601 et seq.]), the Department must prepare an "initial regulatory flexibility analysis" for any proposed rule that has a significant economic impact on a substantial number of small entities, including small businesses. Because of the substantial concerns of the respirator manufacturing industry and the public, the Department has voluntarily prepared a preliminary regulatory impact analysis (PRIA) and initial regulatory flexibility analysis (IRFA). Together with the main body of the Preamble to the second Notice of Proposed Rulemaking (NPRM), this PRIA constitutes both a PRIA and an IRFA for 42 CFR Part 84.

NIOSH has concluded that the proposed rule, if implemented, would create significant health benefits for up to 6.6 million users of NIOSH-certified respirators. This number could go as high as 10 million in the mid-1990s. Additionally, Part 84 will provide significant economic and other benefits to 32 domestic respirator manufacturers, owners of about 7 million nondisposable respirators, and those employers who annually purchase over 110 million disposable respirators. These benefits will be obtained at reasonable economic cost to respirator owners, purchasers, and manufacturers. The health and economic benefits would be primarily of two types. First, users of respirators will directly benefit because of

both major and mino

ability. Even small improvements in respirator performance would be significant in the aggregate because of the large number of person-years of exposure involved. The total incremental effect for all respirators would depend on how many respirator failures would be prevented and how many ineffective or marginally performing devices are eliminated. However, significant incremental reductions in both chronic and acute exposures to harmful substances would occur over time. Second, the use of performance rather than specification standards would substantially increase the flexibility of manufacturers in designing and marketing new and improved respirator designs. While the specific innovations that might be made cannot be predicted, they could be both performance-enhancing and cost-reducing.

For the potential incremental recurring costs of complying with the new Part 84 requirements, NIOSH's best estimate is about $6 million annually for 32 domestic respirator manufacturers.[1] Additionally, NIOSH's best estimate is that some respirator owners will incur potential costs of $8 million annually for a period confined to the first 5 years after the effective date of Part 84. However, since data were not available to make a multitude of offset adjustments for non-quantifiable benefits to both respirator manufacturers and owners, these best estimates substantially overestimate the actual potential costs.

The potential cost for respirator manufacturers is slightly greater than 1% of estimated industry retail revenues of about $650 million a year and about 2% of

[1] Table XIX, p. 80.

direct revenues to manufacturers. While some manufacturers might face a cost increase of more than 1%, others might have no increase at all. Regardless, NIOSH has concluded that cost increases of this magnitude would not create significant impacts on a substantial number of manufacturers, purchasers, or users.

NIOSH determined that the only provision contributing to potential costs for respirator owners is the Sunset Clause (§ 84.2(b)(1)) for antiquated Part 11 certifications. Based on cost analyses conducted with the spreadsheet model developed for this PRIA and a reanalysis of the benefits created by each regulatory Subpart, NIOSH has substantially revised the Sunset Clause to provide for 5-, 6-, and 8-year expiration periods in lieu of a single 5-year expiration period proposed in the first NPRM.[2] Potential total costs resulting from the original Sunset Clause were reduced by over $56 million with no significant reduction in protection for wearers.[3]

Owners of entry-SCBA respirators used in firefighting applications will incur essentially all potential costs resulting from the revised Sunset Clause.[4] Over the entire population of almost 408,000 firefighter SCBAs in 1990,[5] the potential total nonrecurring costs over the 5-year Sunset Clause period will average about $95 per firefighter-SCBA user ($19/wearer/year) and about $95 for each Part 11

[2] Preamble discussion for § 84.2(b)(1).

[3] Table XVII, p. 77 vs. Table XVIII, p. 78.

[4] Table XVIII, p. 78.

[5] Table XI, p. 67.

SCBA used in firefighting ($19/respirator/year), where the average cost for a new firefighter SCBA is $1,600.

NIOSH concludes that the owners of more than 80% of the atmosphere-supplying respirators in 1990 (i.e., over 1.3 million supplied-air, nonfirefighting entry-SCBAs, and escape-only SCBAs[6]) will incur no potential costs due to the Sunset Clause because the average service lives of these devices are the same as the new 6- or 8-year phase-out periods for Part 11 respirators provided for these devices under the revised Sunset Clause in this NPRM. NIOSH also concludes that the owners of most air-purifying respirators in 1990 (i.e., over 5 million nondisposable, non-powered, air-purifying respirators, and PAPRs[7]) will incur no potential costs due to the Sunset Clause because the average service lives of these devices are the same as their 5-year phase-out period. The only air-purifying respirator owners affected by the Sunset Clause will be those owning 380,000 gas masks in 1990.[8] The 5-year nonrecurring cost impact over this respirator population will average about $5.30 per gas mask (a bit over $1/respirator/year) and about $10.70 per respirator user (a bit over $2/user/year).

As previously discussed in the Preamble to the second Notice of Proposed Rulemaking (NPRM), there are a considerable number of regulatory alternatives at the provision-by-provision level that NIOSH considered, proposed, and revised in many cases. In determining which particular provisions and performance tests

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[6] Ibid.

[7] Ibid.

[8] Ibid.

to propose, NIOSH has sought to minimize unnecessary costs while assuring or improving product performance and safety. The Institute particularly welcomes comments on changes that would make the proposed standards even more cost-effective while providing the same or increased protection to respirator wearers as that given in the second NPRM.

The basis for the preceding findings is presented in the preliminary analysis that follows. Together with the Preamble to the second NPRM, this analysis constitutes both a *Preliminary Regulatory Impact Analysis* (PRIA) and an *Initial Regulatory Flexibility Analysis* (IRFA) for the provisions in the second NPRM. Certain calculations are presented in detail in this analysis in order to facilitate understanding, review, and comment. The Institute welcomes suggestions for improvements.

For this analysis, *potential benefits* and *potential costs* are considered to be the *incremental* benefits and costs created by the proposal above and beyond the benefits and costs of the current regulation. Additionally, the *potential costs* are considered to be the incremental time, effort, or financial resources required to bring currently certified respirators into compliance with the proposed 42 CFR Part 84 requirements. Typical incremental costs would include those specific costs necessary to bring certified devices into compliance (e.g., incremental costs to develop, redesign, modify, construct, or assemble any materials or new test or manufacturing equipment, incremental costs to conduct additional tests, inspections, observations). For this preliminary analysis, note that current costs or activities of respirator manufacturers incurred or performed in the normal course of their manufacturing and sales activities, whether or not required by the current

30 CFR Part 11, are not considered to be potential costs that will be created by the proposed regulation.

B. Regulatory History

1. Background

In 1972 the Departments of the Interior and of Health, Education, and Welfare issued substantial revisions to the Federal regulation in 30 CFR Part 11. This regulation specifies the performance tests and certification criteria for industrial respirators used to protect workers from hazardous atmospheres in American workplaces. Under this regulation the Mine Safety and Health Administration (MSHA) and the National Institute for Occupational Safety and Health (NIOSH) jointly issue certifications to respirator manufacturers. Currently more than 1,600 NIOSH/MSHA certifications are in effect for more than 7,000 industrial respirator models (a certified assembly can be marketed under multiple brand names and model numbers[9]).

NIOSH estimates that up to 6.6 million American workers wear NIOSH-certified respirators,[10] either for full-time use, part-time use, or for emergency use to protect themselves from hazards in their workplaces. This population could grow to almost 10 million by the mid-1990s. Occupational Safety and Health Administration (OSHA) regulations require that NIOSH/MSHA-certified respirators be used by many of these workers. Regulations of the Environmental Protection

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[9] NIOSH: *NIOSH Certified Equipment List as of December 31, 1988*, DHHS (NIOSH) Publication No. 89-105, Cincinnati, OH (January 1989).

[10] Table XV, p. 73.

Agency (EPA) and the Nuclear Regulatory Commission (NRC) also require the use of NIOSH-certified respirators. Many of these workers must wear their NIOSH-certified respirators as an involuntary condition of employment. Hundreds of thousands of American workers wear NIOSH-certified respirators in toxic and lethal environments in which a momentary lapse in respiratory protection can result in serious injury or death.

2. Objectives of Regulatory Revision

During the last 17 years, NIOSH and MSHA have made only minor amendments to the certification test criteria. For more than 10 years there has been a growing consensus among respirator manufacturers and user communities that NIOSH and MSHA should substantially revise the 1972 performance requirements. Many of the current certification tests are obsolete, application-specific, and do not represent typical use conditions for many NIOSH-certified respirators. The current certification categories stifle design flexibility, hamper innovation, and hinder the marketing of more cost-effective respirators. Therefore, respirator users, owners, and manufacturers will substantially benefit from the replacement of design- and application-specific standards with those that are performance-based.

NIOSH requires the procedures and performance tests contained in this proposal to fulfill adequately its legislatively mandated responsibilities for certifying industrial respirators (30 U.S.C. §§ 842(h), 844, and 957). Before NIOSH grants a certification, it must have sufficient evidence of safety and adequate perform-

ance. Health and safety professionals and respirator purchasers appear to rely on these government certifications when they purchase respirators. For example, Howard J. Cohen, corporate manager of industrial hygiene services for Olin Corporation, recently made the following statement to an industry trade publication:

> Most users really can't distinguish between a good and a marginal device. They rely on NIOSH certification, which is like an Underwriters' Laboratories' approval.[11]

Additionally, a major respirator manufacturer has for several years placed in health and safety journals an advertisement that states in large bold letters,

TO MEASURE SAFETY, COMPANIES COMPARE THEIR RESPIRATORS WITH THIS STANDARD

followed by a picture of a NIOSH/MSHA certification label.[12]

However, essentially all these 7,000+ certifications have questionable reliability due to the following obsolete performance testing and quality assurance requirements in the Part 11 regulation:

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[11] Minter, S. G.: Breathing New Life Into OSHA's Respirator Rule, *Occupational Hazards* **51**(5):89–93 (May 1989).

[12] North Safety Equipment advertisement, *Occupation Hazards* **51**(3):4 (March 1989).

- All current certifications were originally issued based on test results from a limited number of samples. For example, many laboratory tests are performed on only three samples. For this sample size, only when 63% or more of a particular model is ineffective will a sample of three have a substantial chance of rejecting the model. For the 7,000+ makes and models holding certifications under Part 11, the certification means only that at least 37% of each make and model met the test requirements of Part 11 at the time of the original testing, if the tested samples represented each production make and model. This problem will be addressed by new statistical methodology and increased sample size given in § 84.229.

- None of the current certifications are based on reliable testing for face-seal efficacy. A respirator face seal is one of the most critical components affecting the safety and efficacy of any respirator. The current testing of this component with qualitative fit tests are fundamentally unreliable for detecting unsafe or ineffective face seals. This applies to both air-purifying and atmosphere-supplying respirators. This area will be addressed with the requirements of Subpart R.

- Over 50% of the current certifications under 30 CFR Part 11 are for air-purifying, charcoal-sorbent devices (e.g., gas masks and chemical cartridge halfmasks). Currently most of these devices are used for protection

against organic vapors (OV). Current certifications effectively permit users to be unknowingly provided with OV sorbents that are likely to have substantially reduced service lives if they have been stored in high humidity conditions. If a sorbent is unsafe or ineffective, the respirator will be unsafe or ineffective. Additionally, any respirators with marginal effectiveness due to short service lives are undetectable to the user when they are taken out of the packing container and put into use. Thus the safety and efficacy of currently-certified sorbent respirators is questionable under high-humidity storage conditions. This issue will be addressed by the "shelf-life disclosure" requirements of §§ 84.304(h) and 84.315(g).

- Over 10% of the current certifications under 30 CFR Part 11 are for widely-used, air-purifying, filter respirators (e.g., (1) dust, fume, and mist; (2) dust and mist; (3) paint lacquer and enamel mist). These certifications were granted based on filter test results that are invalid for many current use conditions in American workplaces. Additionally, there are substantial reliability and validity problems with the current tests. NIOSH researchers have published articles concluding that the current tests are "non-reproducible," are "insensitive" (i.e., cannot discriminate between poor and high efficiency filters), and "have gradually become irrelevant." If a filter is unsafe or ineffective, the respirator will be unsafe or ineffective. Additionally, unsafe or ineffective filters are undetectable to the user. Thus the safety and efficacy of certified filter respirators is of substantial concern.

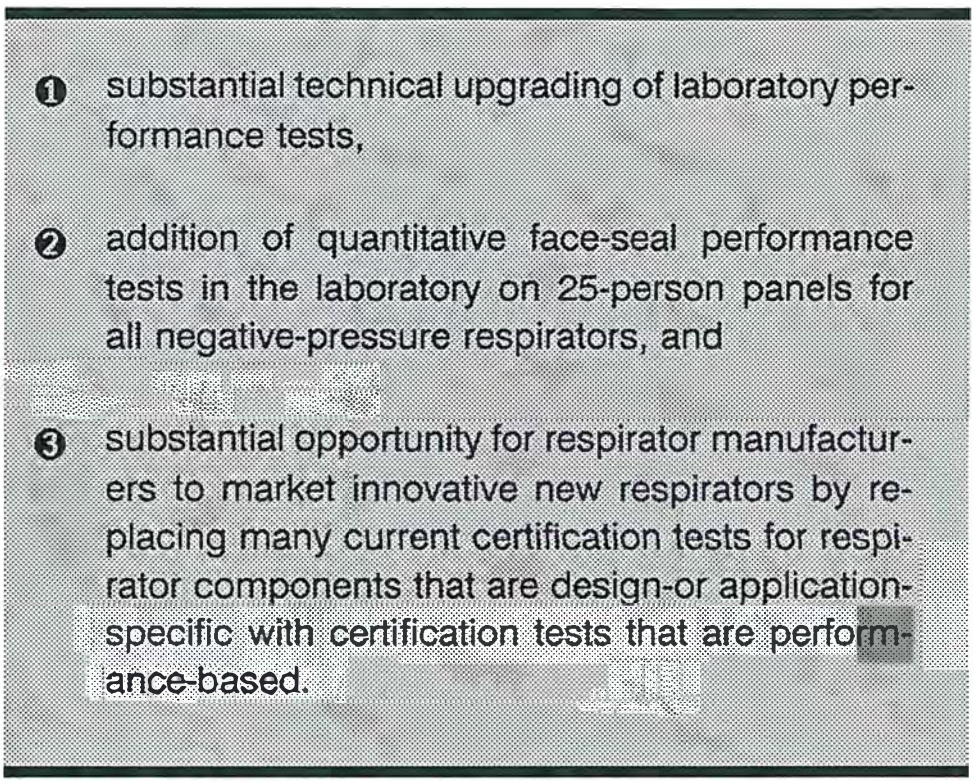
The current filter tests will be substantially revised as provided for in the Subpart V provisions.

- Lastly, for all current certifications under Part 11 (both air-purifying and atmosphere-supplying respirators), the "quality assurance" (QA) regulatory requirements for production-line respirators (those shipped to the public on a daily basis) cannot provide assurance to respirator users that they will receive a respirator meeting 30 CFR Part 11 requirements. Current certifications require manufacturers to use "AQL-type" QA sampling plans that favor respirator manufacturers. For example, 30 CFR 11.41 appears to permit shipment to users only if less than 1.0% of the respirators in a production lot have "major A" defects. A "major A defect" is defined by 30 CFR 11.41(d)(2) as "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 to the wearer." However, the specification standards in the current QA regulations permit manufacturers to ship lots that substantially exceed the 1.0% defects standard. Any lots with 2.0% major-A defects, twice the NIOSH standard, have almost an 80% chance of reaching purchasers and users. Any lots with 4.0% major-A defects, four times the NIOSH standard, have about one chance in three of reaching users. Any grossly defective lots with six times the percentage of defects permitted by the NIOSH standard (6.0% major-A defects) have about a 1 in 10 chance of reaching users.

This area will be addressed with the QA performance requirements given in Subpart C.

Without the procedures and tests in this proposal, NIOSH will be unable to evaluate adequately respirator safety and efficacy. The certification test criteria in the current 30 CFR Part 11 provide insufficient evidence for NIOSH to reliably certify industrial respirators. The present regulatory criteria cannot assure the safety and performance of these devices in all cases. The primary objective of this proposed regulatory revision is to establish rigorous and realistic performance testing for future NIOSH certifications.

On August 27, 1987, NIOSH published in the *Federal Register* (52 FR 32402) a proposed regulatory revision of 30 CFR Part 11 and its recodification as 42 CFR Part 84. In response to the large number of comments submitted to the Record on the first proposal, NIOSH has revised and deleted a large number of provisions in the first NPRM of August 1987. The second NPRM discussed in this Preliminary Regulatory Impact Analysis (PRIA) has three major advantages compared with the present certification requirements in Part 11:



Many changes were made to the first proposal to reduce recertification costs under the new performance requirements. Although NIOSH is well aware that some incremental costs will be created by the new regulation, the Institute's primary responsibility is to adequately protect the health and lives of respirator users.

This regulatory proposal places increased responsibility on the respirator industry to market safe and effective respirators. This proposal provides a substantially expanded role in the certification process for respirator manufacturers. Yet this proposal has ample flexibility for those manufacturers to expand their role even further. This second proposal will permit respirator manufacturers to design

and market respirators that best meet the needs of their customers and respirator users.

Many changes were made to the first proposal to reduce recertification costs under the new performance requirements. Compared with the first proposal, at least seventeen changes incorporated in this proposal will produce significant cost savings for respirator owners, manufacturers, and purchasers. Six of these will produce major savings (i.e., §§ 84.2(b)(1), 84.2(b)(3) with 84.11(a)(9), 84.11(a)(11), 84.290(a), 84.293(e), and 84.304 with 84.314) and eleven will produce significant savings (i.e., §§ 84.11(a)(4), 84.11(a)(6), 84.40(a), 84.50, 84.70, 84.220(e), 84.223, 84.225, former 84.248–3, 84.263, and 84.303(a)).

C. Potential Benefits of Proposed Revision

1. Nature of Benefits

NIOSH has concluded that the proposed revisions to the current respirator certification performance tests will substantially contribute to assuring the safety and adequate performance of NIOSH-certified respirators. The primary objective of the proposed revisions is to reduce substantially the risk to users of potentially unsafe or inadequate performance of NIOSH-certified respirators through substantial improvements in performance-testing, quality-assurance, and user-information requirements (e.g., "package inserts"). However, NIOSH cannot quantitatively establish the specific benefits that it expects the revision will achieve for respirator users, owners, manufacturers, and the Institute. The regulatory revisions proposed by NIOSH are those that the Institute has concluded will substantially increase the Institute's ability to evaluate the safety and adequate performance of respirators submitted for NIOSH certifications.

2. Benefits to Respirator Owners and Users

The basic purpose of any industrial respirator is, simply, to protect a user from inhalation of a hazardous atmosphere. A hazardous or harmful atmosphere is one that is oxygen deficient or contains a toxic or disease-producing particulate, vapor, or gas in a concentration immediately or ultimately dangerous to the user's life or health. Respirators provide their protection either by removing con-

taminants from the air before it is inhaled or by supplying an independent source of respirable breathing gas. Thus if a respirator is unsafe, defective, or ineffective, the risk to an individual user is large because most respirators are worn in hazardous atmospheres.

Mandatory use of industrial respirators by workers is an important method for controlling worker exposure to toxic airborne contaminants in the occupational environment. Respirator use for both routine protection and emergencies is widespread in 4 million American workplaces. They are used in virtually every segment of general industry, as well as in maritime, construction, agriculture, military, and other applications.[13] Typical industries that commonly provide respirators for worker protection include chemicals, petroleum refining, textiles, rubber and plastics, bulk transport, primary metal, machinery, metal fabrication, and transportation equipment.

Reliable current estimates for the number of respirators in use, the number of respirator users, and the general levels these users are protected against are difficult to obtain. The Institute defines a respirator "user" or "wearer" as a worker who meets at least one of the following criteria:

1. uses a NIOSH-certified respirator for either full-time or part-time protection and/or

[13] Centaur Associates, Inc.: *Preliminary Regulatory Impact Analysis of Alternative Respiratory Protection Standards, Volume I*, prepared for the U. S. Department of Labor, Occupational Safety and Health Administration under Contract No. J-9-F-20067, Washington, D.C. (March 30, 1984), pp. 62-92.

❷ has access to a NIOSH-certified respirator that the worker may have to rely on at some time during an emergency.

As discussed later in this PRIA (see material preceding Table XV on page 73 below), NIOSH's best estimate is that up to 6.6 million American workers are users or wearers of NIOSH-certified respirators. However, this number may substantially increase to as high as 10 million over the next five years for the following three reasons.

First, over the next several years (possibly until December 31, 1993) several million American workers may have to wear NIOSH-certified respirators so that their employers can comply with a recent OSHA amendment to its Air Contaminants standard (29 CFR 1910.1000 including Tables Z-1, Z-2, and Z-3).[13] In this amendment OSHA lowered 212 Permissible Exposure Limits (PELs) and set new PELs for 164 substances that had not been previously regulated. OSHA estimated that over four and one-half million workers are currently exposed above the 376 new PELs.[14] This amendment permits the use of any compliance methodology, possibly until December 31, 1993, to comply with the new PELs for millions of workers. Over the years during which feasible engineering

[13] Occupational Safety and Health Administration: Final Rule, Air Contaminants, 29 CFR Part 1910, *Federal Register* 54(12):2332-2983 (January 19, 1989).

[14] Ibid., p. 2725.

controls are being installed in the 131,005 affected plants,[15] it is logical to presume that employers will require their employees to wear NIOSH-certified respirators.

Second, current OSHA policy permits the routine use of respirators only when engineering controls prove infeasible or while they are being installed. OSHA has stated that there may be some situations where respirators may be the most appropriate means to reduce overexposure to a toxic substance, particularly in maintenance operations and for intermittent and short-term exposures and has recently requested public comments on this issue be submitted to the agency by October 3, 1989.[16] If OSHA broadens their guidelines and regulations to permit wider respirator use, the number of respirator users in the U.S. would likely increase.

Third, respirator use in asbestos abatement activities is likely to experience a large increase in the next few years. Recently, Robert J. Hershock, chairman of the board of the Industrial Safety Equipment Association (ISEA), made the following statements to an industry trade publication:

> Asbestos abatement is one of the "driving forces" for the safety equipment industry, noted Hershock. He cited EPA estimates that approximately 750,000 public and commercial buildings in the U.S. have asbestos in a condition which will demand that it either be removed or encapsulated.

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[15] Ibid., p. 2863.

[16] Occupational Safety and Health Administration: Proposed Rule, Health Standards; Methods of Compliance, 29 CFR Part 1910, *Federal Register* **54**(106):23991–23998 (June 5, 1989).

"By 1991, the use of respirators in asbestos abatement will be as large as the total respirator market for all other applications in the U.S.," said Hershock.[17]

Therefore NIOSH has concluded that by the mid-1990s the proposed regulation will benefit up to 10 million American workers who must rely on respirators for routine or emergency protection. In general, these respirators are used routinely or in emergencies only to protect wearers from hazardous exposures. A substantial number of NIOSH-certified respirators are relied upon in situations where a momentary lapse in respirator efficacy can result in death or serious injury (e.g., the over 630,000 full-time, part-time, or emergency users of SCBAs[18]).

It is not possible to quantitatively estimate the potential decrease in morbidity and mortality attributable to use of improved respirators certified under the present proposal. However, it is known that controlling exposures to levels below acceptable exposure limits can result in substantial reductions in occupationally related acute and chronic illnesses and fatalities. For its recent amendment to the air contaminants standard, OSHA estimated that:

Benefits will accrue to approximately 4.5 million workers who are currently exposed in excess of the PEL and are expected to include the reduction of over 55,000 occupational illness cases, includ-

[17] Minter, S. G.: ISEA Focuses on the Future, *Occupational Hazards* **51**(7):9–11 (July 1989).

[18] Table XV, p. 73.

ing almost 24,000 lost workday illness cases and approximately 520,000 lost workdays annually. If not prevented, these illnesses would eventually result in approximately 700 fatalities each year.[19]

Even if the new certification requirements were to reduce the average risk for all respirator wearers by a relatively small amount, the aggregate reduction in risk of injuries and deaths to society as a whole is relatively large because of the millions of users affected. It is difficult to estimate the magnitude of benefits due to reduced morbidity and mortality. For respirator owners and manufacturers, any costs associated with Part 84 certifications would have to be adjusted downward to reflect these effects. Since data were not available to make any offset estimates, the cost effects of the regulation estimated in this PRIA are overstated.

NIOSH welcomes comments and data on present levels of respirator use (e.g., numbers, industries, exposure situations, frequency of use), present levels of morbidity and mortality due to the use of respirators certified under 30 CFR Part 11, and potential reductions in morbidity and mortality due to 42 CFR Part 84 requirements.

The Sunset Clause (§ 84.2(b)(1)) will create potential costs for respirator owners due to the need for "premature replacement" of some fullface air-purifying respirators and firefighting SCBAs.[20] However, for respirators that are replaced before the end of their usable lives, owners will not have to expend late-life

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[19] Occupational Safety and Health Administration: Final Rule, Air Contaminants, 29 CFR Part 1910, *Federal Register* **54**(12):2768–2789 (January 19, 1989).

[20] Section (D)(3), p. 42.

maintenance costs, which can be considerable compared with early-life and mid-life maintenance costs. For these respirator owners, any costs due to the Sunset Clause would have to be adjusted downward to reflect these maintenance cost savings. Since data were not available to make these offset estimates, the cost effects of the Sunset Clause estimated in this PRIA are overstated.

NIOSH expects that many Part 11 SCBAs used for firefighting will meet Part 84 requirements with upgrade kits. NIOSH expects these kits will have an average cost of about $350 each.[21] Currently most major SCBA manufacturers operate voluntary upgrade programs for owners wishing to comply with the 1981–1987 revision of the National Fire Protection Association (NFPA) standard for firefighting SCBAs.[22] For example, Scott Aviation has stated,

> Once upgraded to meet Scott's stringent requirements for NFPA–1981 compliance, each Air-Pak unit will receive a fresh five-year warranty—just as if it had been purchased new.[23]

NIOSH expects that other manufacturers offering relatively expensive upgrade-kit programs will offer similar extended warranties (particularly for those conducted at factory-authorized service centers). Additionally, these upgrades may extend the service life for each device by a few years. For respirator owners, any up-

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[21] Table VII, page 62.

[22] National Fire Protection Association: *NFPA 1981 Open-Circuit Self-Contained Breathing Apparatus for Fire Fighters*, 1987 Edition.

[23] Scott Aviation: Upgrading Your Air-Pak SCBA–Who Do You Turn To?, *Scott News-Pak* 1(1):3 (April 1989).

grade-kit costs due to the Sunset Clause would have to be adjusted downward to reflect future repair cost savings resulting from extended warranties obtained with upgrade kits and resulting from extended service lives. Since data were not available to make these offset estimates, the cost effects of the Sunset Clause estimated in this PRIA are overstated.

Lastly, respirator owners should experience some increased productivity due to the use of more comfortable and improved respirators certified under the new regulatory requirements. Productivity benefits should result from reduced worker illness, absence, and turnover. In addition, more comfortable respirators and knowledge of improved protection and improved workplace health conditions should result in higher workforce morale and productivity. Respirator owners should enjoy reduced new-worker training costs (due to reduced turnover rates), lower health insurance costs, and reduced medical-benefit and worker-compensation claims from workers. It is difficult to estimate the magnitude of the increased-productivity and reduced-claim benefits. For respirator owners any costs due to "premature purchase" of respirators with Part 84 certifications would have to be adjusted downward to reflect these effects. Since data were not available to make any offset estimates, the cost effects of the regulation estimated in this PRIA are overstated.

Many sections in the Preamble to the second NPRM contain detailed discussions of the expected benefits for many individual provisions. Rather than repeat these discussions in this analysis, this section contains a few important examples with expanded discussions for certain provisions.

a. Face-Seal Efficacy Requirements

As noted above, none of the current certifications under Part 11 are based on reliable testing for face-seal efficacy.[24] This problem will be addressed with the requirements in the new Subpart R for both air-purifying and atmosphere-supplying respirators. The new testing required in this Subpart is essential to provide assurance that each negative-pressure, NIOSH-certified respirator has adequate face-seal capability for a wide range of facial sizes and shapes. Currently, most NIOSH-certified respirators have not been validly tested where it really counts—on human faces.

NIOSH does not intend that a certified respirator must accommodate every conceivable user. Instead, each certified respirator must be able to provide effective protection to a majority of prospective facial sizes and shapes. In particular, prospective wearers with small facial sizes (e.g., women, Hispanics, Asians) should have a sound probability of receiving an adequate fit with a NIOSH-certified respirator.

Respirator owners and users should derive substantial benefits from respirators that will provide demonstrated protection for a wide range of facial shapes and sizes. These respirators should substantially reduce respirator program costs since is likely that fewer makes and models will have to be purchased by each employers to fit all workers in a respirator-wearing workforce. Additionally, the training and maintenance costs of a respirator program will be substantially re-

[24] Section (B)(2), p. 10.

duced because training and maintenance programs will involve fewer makes and models of respirators.

For respirator owners any costs associated with Part 84 certifications would have to be adjusted downward to reflect these savings. Since data were not available to make any offset estimates, the cost effects of the regulation estimated in this PRIA are overstated.

b. Shelf-Life Disclosure Requirements for Organic Vapor Devices

As noted above, current certifications under Part 11 for air-purifying respirators effectively permit users to be unknowingly provided with OV sorbents that are likely to have substantially reduced service lives if they have been stored in high humidity conditions.[25] If a sorbent is unsafe or ineffective, the respirator will be unsafe or ineffective. This issue will be addressed by the "shelf-life disclosure" requirements of §§ 84.304(h) and 84.315(g). These new provisions require that a NIOSH-certified respirator provide at least 90% of the required protection capacity at any time during the shelf-life period specified by the manufacturer. Knowledge of shelf life for respirator sorbent elements is crucial for safe and effective respirator use. Substantial reductions in sorbent capacity during storage or use cannot be detected before use by a respirator wearer which creates a hazard. Respirator owners and users should derive substantial benefits from shelf-life labeling. This labeling should reduce any morbidity and mortality

[25] Section (B)(2), p. 10.

occurring from improper storage or use of organic vapor cartridges or canisters in high humidity conditions.

It is difficult to estimate the magnitude of benefits due to any reduced morbidity and mortality. For respirator owners and manufacturers, any costs associated with Part 84 certifications would have to be adjusted downward to reflect these benefits. Since data were not available to make any offset estimates, the cost effects of the regulation estimated in this PRIA are overstated.

c. Labeling Requirements for Organic Vapor Devices

The efficacy of respiratory protection afforded each individual respirator wearer is directly dependent on correct respirator selection and use. NIOSH maintains that respirator manufacturers have important responsibilities to provide respirator owners and users with adequate information on the proper selection and use of their products. One of these responsibilities is the critical obligation to identify those organic gases and vapors against which their respirators will provide safe and effective protection. Correct respirator selection is a critical element of effective respiratory protection. NIOSH has concluded that providing this type of information to prospective purchasers, owners, and users is the most effective way to assure that the correct respirator is provided for each workplace hazard. Therefore NIOSH is proposing labeling requirements for organic vapor cartridge and canister respirators (§ 84.323) and directing that appropriate user information be provided with each NIOSH-certified respirator (§ 84.50).

Manufacturers must be able to provide customers, owners, and users with information on the specific organic chemicals against which their NIOSH-certified respirators are capable of providing adequate protection. This information is particularly vital to purchasers and users because the certification performance tests will use only a single organic vapor—carbon tetrachloride. Numerous articles in the professional literature clearly demonstrate that organic vapor cartridges and canisters can yield widely varying service lives and levels of protection depending on the organic vapor they are used against.[26]

It is difficult to estimate the magnitude of benefits due to reduced incorrect selection of respirators. For respirator users, owners, and manufacturers, any costs associated with Part 84 certifications would have to be adjusted downward to reflect these benefits. Since data were not available to make any offset estimates, the cost effects of the regulation estimated in this PRIA are overstated.

d. Revision of Filter Test Requirements

As noted above, hundreds of respirators with Part 11 certifications are air-purifying filter respirators used for protection against hazardous dusts, fumes, mists, paint lacquers, and enamels.[27] These Part 11 filter-respirator certifications were granted based on results from antiquated filter tests that are invalid for many current use conditions in American workplaces. Additionally, there are

[26] Preamble discussion for § 84.304.

[27] Section (B)(2), p. 11.

substantial reliability and validity problems with the current filter tests. If a filter is unsafe or ineffective, the respirator will be unsafe or ineffective. More importantly, unsafe or ineffective filters are undetectable to the owner or user.

Subpart V requirements will substantially revise the filter tests. New filter certification classes will replace Part 11 classes based on restrictive design specifications such as single-use and reusable respirators. The new certification classifications are based on performance requirements that will permit substantial design flexibility and innovation by respirator manufacturers. Filter respirators will be certified for the following three aerosol classes based on the physical nature of the aerosol they are to be used against:

1. Solid
2. Liquid
3. Both solid and liquid

Each of these three aerosol classes will be further divided into the following three new filter efficacy classes (for a total of nine possible filter certification classes):

1. Type I with a filtration efficiency of at least 90% under the test conditions

❷ Type II with a filtration efficiency of at least 99% under the test conditions

❸ Type III with a filtration efficiency of at least 99.97% under the test conditions

Respirator owners and users should derive substantial benefits from the new filter-test requirements and certification classes. They will be able to select filters that are most appropriate for each hazardous environment. The new test requirements and certification classes should reduce any morbidity and mortality occurring from unknowing use of inadequate or improper filters against hazardous dusts, fumes, or mists.

It is difficult to estimate the magnitude of benefits due to reduced morbidity and mortality. For respirator owners and manufacturers, any costs associated with Part 84 certifications would have to be adjusted downward to reflect these benefits. Since data were not available to make any offset estimates, the cost effects of the regulation estimated in this PRIA are overstated.

e. Defective Respirator Notification Requirements

The proposed provisions requiring the notification of affected parties, such as owners, (§§ 84.21(c) and 84.23) will assure that a manufacturer can rapidly and effectively disseminate reports to users of respirator safety or performance defects or noncompliance with certification requirements. The new provisions also

will assure that a manufacturer informs NIOSH of appropriate corrective measures so that the health and safety of prospective users will not be compromised. These proposed requirements are based on the current notification regulation of the FDA[28] for electronic products subject to the Radiation Control for Health and Safety Act of 1968.

Almost 10 years ago the "Corn Committee Report" recommended that:

> NIOSH should develop a highly efficient system to acquire and distribute information from users and manufacturers on PPE [personal protective equipment] and HMI [hazard measuring instruments] malfunctions.[29]

The Report emphasized that "this is an essential component of an effective testing and certification program." NIOSH has concluded that owners must be promptly notified when a NIOSH-certified device is found to be defective or not meeting certification requirements. Additionally, NIOSH maintains that respirator manufacturers should be responsible for this notification in the same manner that automotive manufacturers are responsible for notifying owners of defective automobiles.

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[28] 21 CFR 1003.10 and 1003.11 in Subchapter J–Radiological Health.

[29] Brief, R., Corn, M., Firenze, R., O Brien, M., and Scott, D.: *Evaluation of the NIOSH Certification Program, Division of Safety Research, Testing and Certification Branch*, DHEW (NIOSH) Publication No. 80–113, National Institute for Occupational Safety and Health, Cincinnati, Ohio, (November 21, 1979), p. 30.

It is difficult to estimate the magnitude of benefits due to nonuse of defective respirators after notification is received by owners and users. For respirator users, owners, and manufacturers, any costs associated with Part 84 certifications would have to be adjusted downward to reflect these benefits. Since data were not available to make any offset estimates, the cost effects of the regulation estimated in this PRIA are overstated.

f. Flammability Tests for Firefighter SCBAs

NIOSH investigations into several fatal firefighter incidents have demonstrated that not all atmosphere-supplying SCBA facepieces retain their structural integrity when exposed to flames or intense heat. In order to prevent these catastrophic types of respirator failures, NIOSH is proposing a flammability performance test for SCBAs in § 84.263. However, this performance test will apply only to those SCBAs designated by their manufacturer as intended for firefighter and mine-rescue use.

NIOSH expects the benefits of increased firefighter protection and reduced risk of firefighter injury from this provision. However, the Institute does not have the means to quantify the injuries that may be prevented by the new test. For respirator users, owners, and manufacturers, any costs associated with Part 84 certifications would have to be adjusted downward to reflect these benefits. Since data were not available to make any offset estimates, the cost effects of the regulation estimated in this PRIA are overstated.

3. Benefits to Respirator Manufacturers

As noted previously, one of the primary benefits of the proposed revision will be to provide respirator manufacturers with an opportunity to market innovative new respirators. NIOSH is doing this by replacing the current certification tests that are design-or application-specific with tests that are performance-based. NIOSH also made many changes to the first proposal to provide manufacturers with additional flexibility in respirator design and permit innovative approaches to safe and effective respirators. This second proposal contains substantially more performance-based certification tests. Respirator manufacturers will have greater opportunity and motivation to develop and market innovative and cost effective respirators for workers. Most importantly, this second proposal will permit respirator manufacturers to design and market respirators that best meet the needs of their customers and respirator users.

NIOSH respirator certifications based on realistic and rigorous performance tests and quality assurance requirements will substantially increase the value of these certifications to respirator manufacturers. In a 1988 meeting with NIOSH, an industry representative stated that an inadequate certification regulation is one that gives the respirator industry "no protection from liability" and that "an adequate rule is clearly in our interest."[30] Recently the chairman of the board of the Industrial Safety Equipment Association (ISEA) stated,

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[30] NIOSH Memorandum to the Record: *Meeting of April 27, 1988 with Representatives of the Jefferson Group and Industrial Safety Equipment Association*, Atlanta, Georgia, May 2, 1988.

The majority of safety equipment manufacturers, he added, are small businesses and product liability, along with attendant soaring insurance costs, presents a "terrible burden on them."[31]

Thus NIOSH expects that respirator manufacturers should be able to obtain reduced liability insurance premiums and experience reduced settlements, reduced litigation costs, and reduced liability awards as the result of substantially improved performance testing and quality assurance requirements proposed by NIOSH in the second NPRM.

NIOSH expects that the time spent for NIOSH review, testing, and certification will be more productive. This will enable manufacturers to provide new NIOSH-certified devices to users faster than they can under the current regulation. Under proposed provisions, NIOSH will not be required to perform the complete battery of performance tests (§ 84.31). The benefit to manufacturers will be the expediting of the NIOSH certification process.

The proposed regulation will substantially decrease the amount of documentation required to be submitted to NIOSH for quality assurance requirements. In contrast to the current regulation, under the proposed revision a respirator manufacturer is required to submit for NIOSH certification only major modifications that are proposed for NIOSH-certified respirators (§ 84.60). Major modifications are defined as only those that affect respirator performance. Currently all proposed modifications to a certified device, no matter how trivial (e.g., cosmetic) must be submitted to NIOSH for review and consent.

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[31] Minter, S. G.: ISEA Focuses on the Future, *Occupational Hazards* **51**(7):9–11 (July 1989).

Under the proposed regulation, manufacturers will receive specific appeal rights for NIOSH denial or withdrawal of a certification (§§ 84.71 and 84.80). In accordance with the Administrative Procedure Act, aggrieved parties are entitled to appeal a decision by a Federal agency that affects them. This appeal process is not specifically provided for under the current 30 CFR Part 11.

4. Benefits to NIOSH

As previously noted, the proposed revision will markedly improve NIOSH's ability to meet legislative requirements in the Mine Safety and Health Amendments Act of 1977 (30 U.S.C. §§ 842(h), 844, and 957). The substantial upgrading of laboratory performance tests and the addition of face seal performance tests on 25-person panels will significantly improve NIOSH's ability to evaluate respirator safety and efficacy. The new certification requirements will better assure the safety and performance of these devices for a wider range of typical use conditions.

One of the most significant changes from the current regulation is the revision of the sampling plan for many of the performance tests. The sample size for the performance tests will be increased. Most importantly, for the first time a statistical procedure will be used for analysis of test results. Currently, many of the certification tests in 30 CFR Part 11 specify a maximum test sample of only three components or devices for pass/fail decisionmaking. In some cases only two samples are tested. No statistical procedures are currently used to analyze the test results. Currently, when NIOSH tests three samples, 30 CFR Part 11

specifies that all three must meet the applicable performance criterion. This nonstatistical approach to "data analysis" has minimal ability to detect defective respirators. With zero "failures" from three tests, statistical analysis indicates that the true proportion of test failures could be as high as 63% in the population. Thus the best one can say about currently-certified devices is that there is a 95% or better probability that the true percentage of unacceptable respirators (i.e., components or devices not meeting the certification performance criteria) is 63% or less of the components or devices represented by the NIOSH sample. To remedy the deficiencies in the current data analysis procedures, NIOSH is proposing in § 84.229 a new statistical procedure that limits the *user's risk* to 5% or less (i.e., the probability that NIOSH will certify a device for a particular test when, in fact, the device is unacceptable).

Additionally, in contrast to the current regulation, NIOSH will not have to conduct 100% of the applicable performance tests required for each certification application. Instead, NIOSH will review the necessary laboratory test reports (§ 84.30) and conduct one or more important performance tests to verify the manufacturer's test results (§ 84.31). This change will significantly reduce the resource burden on NIOSH for the conduct of performance tests compared with the testing burden required for Part 11 testing. NIOSH will select the particular test(s) that it will verify in its initial certification testing (see the discussion at § 84.30 in the Preamble to the second NPRM). There also will be some cost savings for NIOSH since there will be less application documentation and fewer modification applications to review.

D. Potential Costs to Respirator Owners Due to Proposed Revision

1. Summary

NIOSH's best point estimate for potential costs that might have to be borne by respirator owners in the U. S. due to the provisions in the second NPRM for 42 CFR Part 84 is $41 million, which is a total nonrecurring potential cost confined to the first five years after the effective date of Part 84. The average annual potential costs for this five-year period are estimated at about $8 million. However, since data were not available to make a multitude of offset adjustments for nonquantifiable benefits to respirator owners, these potential cost estimates are substantial overestimates.

NIOSH concludes that the only provision contributing to these potential nonrecurring costs for some owners is the revised Sunset Clause (§ 84.2(b)) for antiquated Part 11 certifications. The specific assumptions, data, and computational algorithms used to estimate potential costs for affected owners are given below.[32] Each point estimate for potential costs should be understood to represent a range of costs, with varying degrees of uncertainty around the point estimate presented for each true value.

To compute the cost point estimates NIOSH developed a process model describing the "ultimate fate" of all Part 11 nondisposable respirators that will be in the hands of owners (i.e., in service or inventory) as of the effective date of

[32] Section (D)(3), p. 42.

Part 84. Using this p

gy to (1) examine regulatory alternatives, (2) estimate the extent of potential incremental burdens created for respirator owners by different versions of the Sunset Clause, (3) examine the benefits created by different phase-out periods for Part 11 certifications (even though the benefits were nonquantifiable in almost all cases), and (4) revise the phase-out periods when indicated.

The Institute has presented its assumptions and reasoning in substantial detail. This was done so that all potential costs for owners due to the revised Sunset Clause are identified in sufficient detail to allow commenters to provide suggestions for improvements or, if appropriate, changes in the model's assumptions or equations.

2. Significance of Potential Costs to Owners

The significance of the potential nonrecurring costs to respirator owners must be evaluated relative to:

[1] the number of affected respirator users,

[2] the numbers and proportions of Part 11-certified respirators that will have to be upgraded or replaced at the end of the 5-, 6-, and 8-year "grandfather periods" created by the revised Sunset Clause, and

[3] the annual U.S. sales of NIOSH-certified respirators and replacement components (i.e., the amount routinely spent each year by respirator owners and purchasers).

For comparison #1, NIOSH's best estimate is that up to 6.6 million American workers use NIOSH-certified respirators (see material preceding Table XV on page 73 below). However, as discussed earlier in Section (C)(2), up to 10 million American workers could be wearing NIOSH-certified respirators in the mid-1990s due to (1) OSHA's 1989 "PEL regulation,"[33] (2) OSHA's proposed rule for methods of compliance,[34] and (3) substantial increases in American asbestos-abatement activities.[35] As mentioned earlier, the Institute defines a respirator "user" or "wearer" as a worker who meets at least one of the following criteria: [1] uses a NIOSH-certified respirator for either full-time or part-time protection or [2] has access to a NIOSH-certified respirator that the worker may have to rely on at some time during an emergency.

For comparison #2, NIOSH estimates that owners of entry-SCBA respirators used in firefighting will incur the majority of potential costs due to the Sunset Clause. For owners of about 408,000 firefighting SCBAs in 1990,[36] about 11%

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[33] Occupational Safety and Health Administration: Final Rule, Air Contaminants, 29 CFR Part 1910, *Federal Register* 54(12):2768–2789 (January 19, 1989).

[34] Occupational Safety and Health Administration: Proposed Rule, Health Standards; Methods of Compliance, 29 CFR Part 1910, *Federal Register* **54**(106):23991–23998 (June 5, 1989).

[35] Minter, S. G.: ISEA Focuses on the Future, *Occupational Hazards* **51**(7):9–11 (July 1989).

[36] Table XI, p. 67.

(41,000) of these devices should require upgrade kits after 1995 and less than 4% (15,000) should need complete replacement with Part 84 firefighting SCBAs after 1995. For these SCBA upgrades and replacements, the Institute's best estimate is that the potential total nonrecurring costs over the 5-year Sunset Clause period will be about $41 million (an average of about $8 million/year over five years). The 5-year potential cost impact to all firefighting-SCBA owners will average about $95 per firefighting-SCBA user ($19/user/year) and about $95 per Part 11 SCBA used for firefighting ($19/SCBA/year), where the average cost for a new firefighting-SCBA is $1,600. The potential cost impact for firefighting-SCBA owners must be evaluated with recognition that these devices are used by over 400,000 firefighters in highly toxic and lethal environments (professionally referred to as "immediately dangerous to life or health"), where the greatest risk of death to the firefighter is encountered.

NIOSH also estimates that the owners of almost 80% of the atmosphere-supplying respirators (i.e., about 1.1 million supplied-air, 0.07 million nonfirefighting entry-SCBAs, and 0.16 million escape-only SCBAs[37]) will incur no potential costs due to the Sunset Clause because the average service lives of these devices are the same as the 6- or 8-year phase-out periods for Part 11 respirators provided for these devices under the revised Sunset Clause.

For owners of approximately 5.4 million Part 11 nondisposable air-purifying respirators (i.e., non-powered air-purifying respirators, gas masks, and PAPRs) in

[37] Ibid.

1990,[38] the Institute's best estimate is that the potential total nonrecurring costs will be about $2 million (an average of about $0.4 million/year over five years). However, these costs will be confined to the owners of 380,000 gas masks.[39] Thus owners of 93% (over 5 million) of the air-purifying respirators (i.e., nondisposable chemical cartridge and particulate respirators) will incur no potential costs due to the Sunset Clause because the average service lives for these respirator classes are the same as the 5-year phase-out period for these classes provided for under the Sunset Clause.

For the gas mask owners, only 1% (4,700) of these devices should require upgrade kits after 1995 and only 4% (16,000) should need complete replacement with Part 84 respirators after 1995. The 5-year nonrecurring cost impact to all gas mask owners will average about $5.30 per respirator (a bit over $1/respirator/year) and about $10.70 per respirator wearer (a bit over $2/wearer/year).

For comparison #3, NIOSH estimates that respirator owners and purchasers spend about $650 million each year in the U.S. on NIOSH-certified respirators and consumables.[40] Thus, the average potential costs to owners over 1990–1995 of $13 million/year represent only 2% of annual expenditures by U.S. respirator owners and purchasers due to the revised Sunset Clause.

Additionally, for all respirator owners upgrading or replacing Part 11 respirators with Part 84 upgrade kits or new devices, there may be some additional

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[38] Ibid.

[39] Ibid.

[40] Section (E)(2), p. 82.

costs due to cost-passthrough from respirator manufacturers of the $6 million/-year additional costs.[41] Two alternative situations form the range boundaries for possible passthrough costs that would be borne by respirator owners and not by respirator manufacturers.

Situation A is "perfectly-elastic demand" or "zero cost-passthrough" by respirator manufacturers to owners. In this case all regulatory compliance costs are absorbed by respirator manufacturers in the form of reduced profits. This is the "best-case" scenario for owners and "worst-case" for manufacturers, where the maximum reduction in pre-tax profits to respirator manufacturers results. A variation of Situation A might occur that is an "even-better-case" scenario for respirator owners. Certain respirator manufacturers may take an aggressive approach to building or increasing market share by offering rebates, Part 11 respirator-trade-in discounts, etc. for Part 84 respirators, which would significantly reduce replacement or trade-up costs for Part 11 respirator owners.

Situation B is "perfectly-inelastic demand" or "total cost-passthrough" to owners by respirator manufacturers. All regulatory compliance costs are passed to the consumer sector (owners) in the form of higher prices for Part 84 respirators. The resulting price increases would be the maximum theoretically possible to transfer all manufacturing cost increases.

In practice, NIOSH expects that the cost passthrough impact on owners will be substantially less than the potential total cost-passthrough. However, the

[41] Section (E), p. 79.

exact proportion is unpredictable since it depends on marketing decisions yet to be made by individual respirator manufacturers.

3. Derivation of Potential Costs Estimates for Owners

a. Background and Methodology

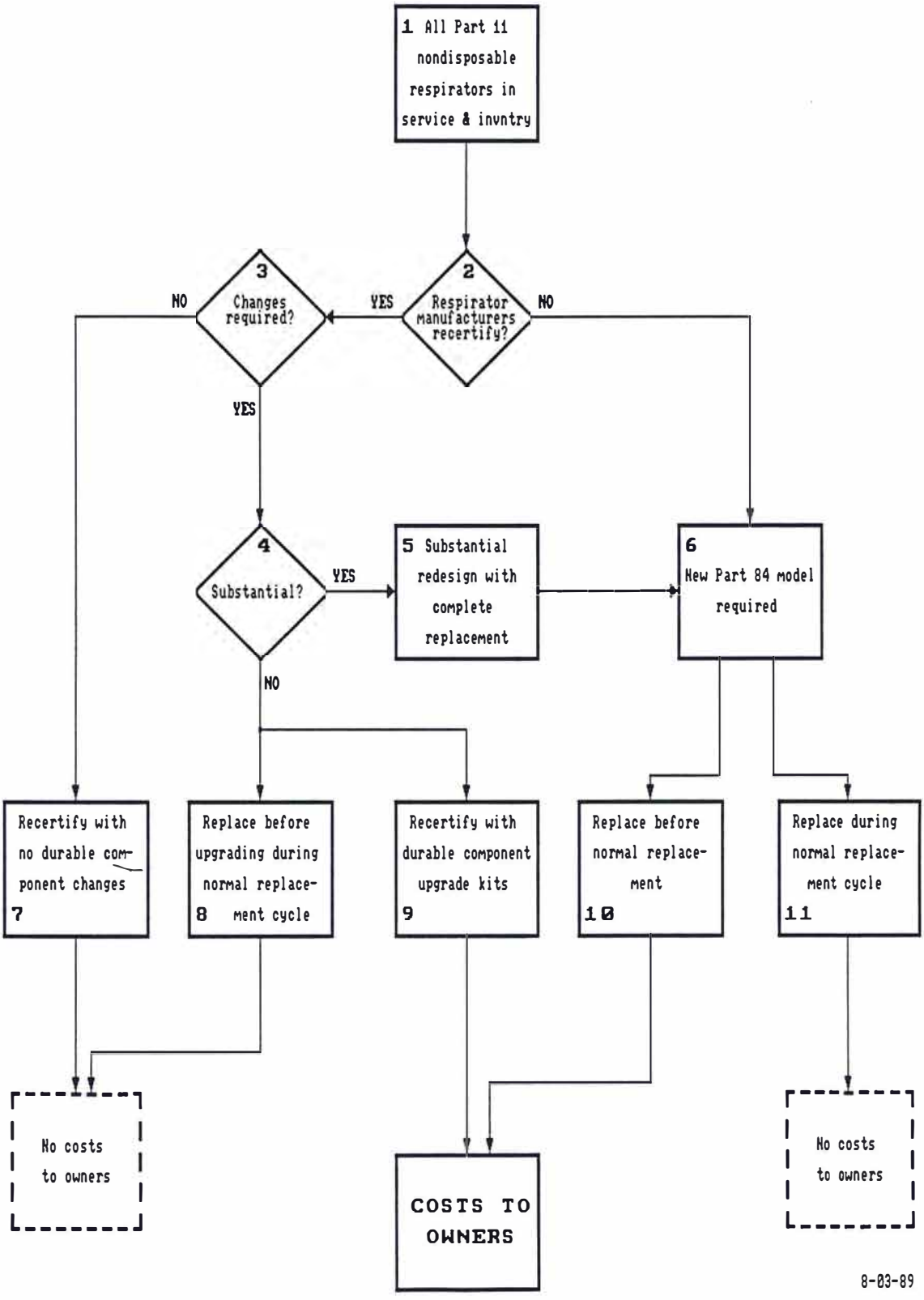
The Sunset Clause (§ 84.2(b)(1)) in Part 84 provides for the expiration of all Part 11 certifications at five, six, or eight years after the effective date of 42 CFR Part 84. After the Part 11 expiration date, respirator manufacturers will not be able to produce, sell, or distribute respirators with 30 CFR Part 11 certifications as NIOSH-certified devices. More important, any devices with expired certificates will no longer meet the requirements of OSHA regulation 29 CFR 1910.134(b)(11). That is, they will no longer meet OSHA requirements for OSHA-mandated respirator programs. For owners to continue to use respirators with expired Part 11 certifications in workplaces covered by OSHA standards, respirator manufacturers will need to apply to NIOSH for recertification under the provisions of Part 84.

For Part 11 respirators that cannot meet the requirements of Part 84 without some modification, § 84.2(b)(3) permits manufacturers to submit certification applications for recertification upgrade kits under Part 84. This provision will minimize the potential costs to owners due to the revised Sunset Clause. A certain percentage of the Part 11 respirators will meet Part 84 requirements with minimal or no modification. The remaining respirators will require varying levels

of upgrade kits or redesign to obtain Part 84 certifications. These kits may range from modified consumables (e.g., modified filters, cartridges, canisters, disposable respirators) to modified "durable-component kits" (e.g., facepieces retrofitted with different straps or exhalation valves, revised regulator components or assemblies, flame-resistant SCBA facepieces, heat-resistant SCBA harnesses). Manufacturers will consider all marketplace forces (not only 42 CFR Part 84) prior to undertaking the incremental costs associated with the various recertification options.

To estimate the potential cost impact on owners of Part 11-certified devices, NIOSH developed a process model describing the "ultimate fate" of those devices that are in service (or in owner inventory) as of the effective date for Part 84. This model is illustrated in the process flowchart on the next page.

Process Flowchart for Part 11 Nondisposable Respirators



Additionally, NIOSH developed a spreadsheet model for the process model to conduct "what-if" cost-benefit analyses for Sunset Clause alternatives.[42] These analyses led to substantial changes in the provision resulting in over $56 million savings to respirator owners with no substantial reduction in protection to users.

Note that disposable respirators (e.g., particulate, chemical cartridge) **are not included** in the process model and potential cost estimates. These respirators are treated as consumable components and NIOSH expects that no Part 11 consumables or disposable respirators will be in use or in inventory on the Part 11 expiration date. Five years will provide ample time for respirator owners to exhaust inventories of Part 11 disposables and rotate Part 84 new disposables into use and inventories.

NIOSH determined that the fate of Part 11 respirators in service on the effective date of Part 11 could be described by one of the following five outcomes:

❶ Flowchart cell 7: Recertification under Part 84 requirements with no component changes is possible for these models and manufacturers elect to recertify them. Owners will incur no potential costs regardless of respirator service life. This outcome also includes all disposable respirators (e.g., particulate, chemical cartridge) and those air-purifying respirators where the upgrade kits will consist of consumable parts that are normally replaced in daily use (e.g., air-purifying

[42] Appendix, p. 119.

filters, cartridges, and canisters). NIOSH assumes that no Part 11 consumable components will be in use or in inventory on the Part 11 expiration date. Five years will provide ample time for respirator owners to exhaust Part 11 consumable inventories and rotate new Part 84 consumables into use and inventories.

❷ Flowchart cell 8: Recertification with upgrade kits is possible for these models and the manufacturers elect to recertify. However these respirators will wear out and be disposed of as part of a normal replacement cycle (i.e., average service life) sometime in the 5-, 6-, or 8-year periods before Part 11 expirations. Thus upgrade-kit installation is not necessary since they will not be in service on the respective expiration date. Thus owners will incur no potential costs for this outcome.

❸ Flowchart cell 9: Recertification under Part 84 requirements is possible for these models with upgrade kits. The manufacturers elect to develop the kits and obtain new certifications. Upgrade kit installations will be required in order to meet Part 84 requirements since these respirators will not have been disposed of during a normal replacement cycle (i.e., they will have useful service life remaining as of the Part 11 expiration dates). Owners will incur potential costs for upgrade kits with nonconsumable components or assemblies in order

to have in-service respirators meet Part 84 requirements. Note that respirators upgraded with consumable components (e.g., filters, chemical cartridges) have no potential costs and are not included in this outcome. The latter devices are included in the cell 7 tally.

❹ Flowchart cell 10: Manufacturers elect not to recertify these models or substantial redesign will be needed to meet Part 84 requirements. Thus "premature" purchase of a new model meeting Part 84 requirements will be necessary since these respirators will not have been disposed of during a normal replacement cycle before the Part 11 expiration dates (i.e., they will have useful service life remaining at the time of Part 11 certification expiration). Owners will incur potential costs for replacement respirators in order to have in-service respirators meet Part 84 requirements.

❺ Flowchart cell 11: Manufacturers elect not to recertify these models or substantial redesign would be needed to meet Part 84 requirements and purchase of a new model would be required. However, as with outcome (2), these respirators will wear out and be disposed of during a normal replacement cycle (i.e., a period equal to the average service life for the device) sometime in the 5-, 6-, or 8-year periods before expiration of Part 11 certifications. They will not be in ser-

vice on the expiration dates. Thus owners will incur no potential costs for this outcome.

Based on the analysis given below, NIOSH expects that respirator owners and new purchasers will incur minimal cost increases on new respirator purchases due to direct cost-passthrough effects from the proposed regulation.[43] They might, however, face decisions whether to delay some new purchases pending availability of Part 84 upgrade kits, recertified models, redesigned models, or new models.

b. Major Assumptions

Since the process model must rely on numerous assumptions, it is difficult to estimate precisely the total potential costs for owners of Part 11 respirators due to the proposed Sunset Clause. In many cases the estimates and assumptions in the following analysis are based on professional judgment and 15+ years of NIOSH experience resulting from the issuance of 1,600+ certifications under the current 30 CFR Part 11 regulation. NIOSH invites and welcomes specific comments on the methodology, assumptions, and estimates in this section. The nomenclature used in this section is given in the table on page 49.

A fundamental variable in the potential cost calculations is the number of nondisposable respirators that will be in service on the effective date of Part 84 (estimated as mid-1990 for the computations in this PRIA). NIOSH used sales

[43] Section (E)(2), p. 81.

Table I–Nomenclature for NIOSH-certified nondisposable respirators

APR	Air-purifying respirators
E_i	Estimated 1980 populations of in-service masks in each class
ES	Escape-only SCBA class ("escape SCBAs")
FR_i	Estimated fraction of cell 1 masks going to cells 7, 8, and 9
FS	Entry-into-or-escape firefighting-SCBA class ("entry SCBAs")
FU_i	Estimated fraction = [cells (8 + 9)]\[cells (7 + 8 + 9)]
FW_i	Estimated average ratio of users to respirator in each class
G_i	Estimated real annual growth factor for respirators over 1980–1990
GM	Gas mask respirator class
N_i	Estimated 1990 populations of in-service masks in each class
NP	Non-powered air-purifying respirator class
NS	Entry-into-or-escape nonfirefighting-SCBA class ("entry SCBAs")
PAPR	Powered air-purifying respirator class
P_i	Expiration period for Part 11 certifications after Part 84 promulgation
PR	Powered air-purifying respirator class
R_i	Estimated average cost for a new Part 84 respirator in each class
$\$RP_i$	Estimated total cost in each class for new Part 84 respirators
SA	Supplied-air-masks class (air-line)
SCBA	All SCBA respirators (both entry and escape-only)
T_i	Estimated total 1980 sales for all nondisposable masks
$\$T_i$	Estimated total cost for all classes for new masks plus upgrade kits
U_i	Estimated average cost for an upgrade kit in each class
$\$UG_i$	Estimated total cost in each class for upgrade kits
Y_i	Estimated average service life for each class
W_i	Estimated 1990 user population for each class

estimates for 1980 to forecast in-service-respirator population estimates as of mid-1990. In the process model NIOSH determined the following seven classes of nondisposable respirators with Part 11 certifications should be analyzed:[44]

❶ Non-powered air-purifying respirators

❷ Gas masks

❸ Powered air-purifying respirators

❹ Supplied-air respirators

❺ Entry-into-or-escape [from hazardous atmospheres] SCBAs used for firefighting

❻ Entry-into-or-escape [from hazardous atmospheres] SCBAs used for nonfirefighting environments

❼ Escape-only [from hazardous atmospheres] SCBAs

Combination SCBA and supplied-air devices were not analyzed because NIOSH concluded they constitute a minimal proportion of the atmosphere-supplying device market.

Although NIOSH has provided precise estimates and computations in some cases, we wish to emphasize that this precision is intended to facilitate under-

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[44] NIOSH: *NIOSH Certified Equipment List as of December 31, 1988*, DHHS (NIOSH) Publication No. 89-105, Cincinnati, OH (January 1989).

standing and, if necessary, corrections from reviewers, rather than to imply certainty on our part. To avoid any impression that estimates are quite precise, the Institute has rounded most reported estimates to only two significant figures. **Note that all individual computed values and table totals have been rounded to two significant figures from the original computed values. Therefore the individual values in any given table may not necessarily add to exactly the total given in the table.** Any point estimate should be understood to represent a range of values, with varying degrees of uncertainty around the point estimate presented for each true value.

NIOSH used usage estimates for the year 1980 that were reported in a 1982 report from the Granville Corporation.[45] This report was used as the starting point for the NIOSH usage forecasts for mid-1990 since it contained the most recent and best-documented estimates for most respirator classes. NIOSH reexamined the Granville report and concluded there were both strengths and weaknesses in the usage estimates. These will be discussed below in detail.

One of the strengths in Granville's approach to obtaining 1980 usage estimates was to estimate total market sales and then divide it into market segments. Granville staff first estimated the total dollar size of the NIOSH/MSHA-certified respirator market in 1980.[46] They obtained five informed estimates by "question-

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[45] Granville Corporation: *Preliminary Survey of Existing Data and Economic Overview of the Respirator Industry*, prepared for the U. S. Department of Health and Human Services, National Institute for Occupational Safety and Health under Contract NIOSH-210-81-1102, Washington, D.C. (March 10, 1982), Exhibit 24, p. 41.

[46] Ibid., pp. 28-30.

ing experts who are intimately familiar with the respirator industry, either currently or in the recent past" about the sales volume for each active firm.[47] Granville used 1980 as the year of interest since the discussions took place in January 1982 and most respondents did not have 1981 figures. Granville staff members then derived their best estimate by "taking the most informed estimates for each individual firm from the various respondents and summing them." Granville also noted,

> Where possible, additional information on each firm obtained from respondents was incorporated into this estimate. Several individuals who had done recent private, unpublished market studies shared their figures with us.[48]

Granville then added an estimate for distributors' and private labellers' profits and distribution expenses to arrive at a grand total estimate of $285.2 million in NIOSH-certified respirator sales in the U. S. for 1980.

Granville next divided their total market sales estimate into estimates for six market segments.[49] NIOSH concluded the Granville estimates were reasonable for the non-powered air-purifying respirator, gas mask, PAPR, and disposable classes.[50] Granville's estimates for SCBAs were not used because more recent

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[47] Ibid., Exhibit 13, p. 29.

[48] Ibid., p. 28.

[49] Ibid., pp. 30–42.

[50] Ibid., Exhibit 23, Line 5, p. 39b.

estimates for 1987 were available from the National Fire Protection Association. Additionally, NIOSH concluded that Granville's estimate of 171,000 supplied-air respirators sold in 1980 was about 30% too high. Use of their estimate would have led to an unrealistically high estimate of almost 1.5 million SA respirators in use in 1990. Therefore NIOSH used a revised estimate of 130,000/year for SA sales in 1980.

Table II–1980 annual respirator sales except for SCBAs (Granville, NIOSH)

Non-powered APR	1,700,000/year
Gas masks	44,000/year
PAPRs	24,000/year
SA masks	130,000/year
Disposables	77,000,000/year

Granville personnel had to make several key assumptions in order to derive their estimates. They noted that:

These assumptions were derived from discussions with respondents, and the resulting figures were reviewed by several experts, and some adjustments made, before being finalized. Most reviewers felt the estimates were quite accurate; we should point out, however, that little information was available on fullface respirators.[51]

[51] Ibid., p. 40.

Lastly, Granville estimated the usage figures for 1980 by dividing the "estimated sales in 1980 by the estimated average useful life of one unit."[52] Unfortunately two problems appear to have occurred at this point in the Granville analysis. First, it seems Granville failed to break the 1980 sales estimates into real-growth and replacement-sales components. This overestimated the 1980 units-in-use figures by about 5% in each market segment. Second, the Granville staff made a more serious error by substantially underestimating the average service lives for four of the five respirator classes.[53] The original average service-life estimates reported by Granville and the increased average service-life assumptions used by NIOSH in this analysis are as follows:

Table III–Average respirator service lives (Granville, NIOSH)

Type	Granville	NIOSH
Non-powered APR	1/3 year	2 years
Gas masks	5 years	6 years
PAPRs	2 years	5 years
SA masks	3 years	6 years

[52] Ibid., Exhibit 24, p. 41.

[53] Ibid., Exhibit 24, Line 2, p. 41.

The Granville report included a lengthy discussion of market sales growth for the 3-year period 1977–1980.[54] Using two different approaches Granville computed two estimates for 3-year market sales growth. Their first growth estimate was based on estimates for certified-respirator sales by manufacturers (deflated to 1967 dollars) of $69.4 million in 1977 and $102.6 million in 1980.[55] These two sales values yield an estimated annual compounded real growth rate of about 14% for 1977–1980. Granville noted that this large a growth rate seems "rather high, and can perhaps be viewed as an upper bound."

The second Granville sales growth estimate relied on Bureau of Labor Statistics (BLS) data. Granville estimated two manufacturers' sales figures in deflated dollars of $114.1 million in 1977 and $167.2 million in 1980.[56] These two sales values yield an estimated annual compounded real growth rate of about 13.6% for 1977–1980, which is consistent with the first Granville estimate. As with their first growth estimate, the Granville staff felt that this high a growth rate was difficult to accept and they noted as before that their second estimate "should be viewed as an upper bound, tenuous figure."

For their 1980–1985 sales projections, the Granville staff chose to use two assumed growth rates of 4% (low rate)[57] and 10% (high rate).[58] For this PRIA

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[54] Ibid., pp. 33–38.

[55] Ibid., Exhibit 16, p. 35a.

[56] Ibid., p. 38.

[57] Ibid., Exhibit 22, p. 39a.

[58] Ibid., Exhibit 21, p. 39.

NIOSH chose to use an average annual compounded real growth rate of 4% for all respirator populations over the 10-year period 1980–1990 except for the three SCBA classes. NIOSH projected the 1990 SCBA estimates from 1987 estimates of in-use SCBAs and the Institute concluded that SCBA growth would be relatively flat over this short period. Therefore a zero real growth rate was used for the three SCBA classes. These real growth rate estimates were used to project mid-1990 respirator populations and adjust the 1980 unit sales estimates (see page 53) to replacement-only estimates for unit sales. The average annual real growth factors of zero or 0.04 will be designated below as G_i in the computational equations.

NIOSH had four major reasons for assuming a relatively low real growth rate of 4% annually for 1980–1990. First, NIOSH assumed that the recession in the early 1980s produced either a flat or negative real growth rate for several years (approximately 1981–1983).

Second, from 1980 through 1986 the U. S. labor force changed as follows: 1.03 million miners decreased to 0.79 million workforce in 1986, 4.3 million construction workers grew by 2.2% annually to 5.0 million in 1986, and 20.3 million manufacturing workers decreased by 1% annually to 19.2 million in 1986.[59] These trends reflect the shift over the last decade of American workers from goods-producing industries to service-producing industries, which NIOSH assumes have a much lower usage rate for respirators.

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[59] *Economic Report of the President*, transmitted to the Congress January 1987, U. S. Government Printing Office, Washington, D. C. (1987), Table B–40, pp. 290–291.

Third, use of real growth rates over 4% lead to respirator usage estimates that are unrealistically high. For example, use of a 6% growth rate results in a 1990 estimate of over 8 million nondisposable respirators in use, a 10% growth rate predicts over 11 million nondisposable respirators in 1990, and a 14% growth rate predicts over 15 million nondisposable respirators in use in 1990!

Fourth, Robert J. Hershock, the chairman of the board of the ISEA, was recently interviewed by an industry trade publication and the following statements were subsequently published:

> While past economic forecasts for the [safety equipment] industry had hovered in the 3–4 percent range, he noted that a recent study showed a 9 percent growth rate over the next 3 to 5 years.
>
> "Our traditional areas have been the blue-collar, heavy-industry sectors," he explained, "What we're seeing now is growth in asbestos abatement, biohazards, waste cleanup, and a lot of areas in the service industries."
>
> "By 1991, the use of respirators in asbestos abatement will be as large as the total respirator market for all other applications in the U.S.," said Hershock. He added that the boom will "not only be confined to respirators, but also gloves, hats, clothing, eye and face protection—an enormous amount of product."[60]

Besides the preceding assumptions and information, the following other major assumptions were used by NIOSH in this PRIA to estimate the potential cost estimates for owners over the 5-year period 1990–1995:

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[60] Minter, S. G.: ISEA Focuses on the Future, *Occupational Hazards* **51**(7):9–11 (July 1989).

❶ All in-service NIOSH-certified respirators in 1990 will be in compliance with the current requirements of 30 CFR 11.11(d) and 11.64(b).

❷ NIOSH assumed that most (90%) of all SCBAs in 1990 will be "entry SCBAs" (coded FS and NS) certified for entry into or escape from hazardous atmospheres. NIOSH assumed the remainder (10%) will be "escape-only" SCBAs (coded ES) used in nonmining environments. Additionally, NIOSH assumed that 85% of the entry SCBAs in 1990 will be used in firefighting situations (these are coded FS) and the remaining 15% will be used in nonfirefighting applications (these are coded NS). The latter assumption is based both on NIOSH experience and on an estimate reported by the Granville Corporation.[61]

❸ Except for the supplied-air and SCBA respirator classes, the best available estimates for the number of respirators with Part 11 certifications owned by employers and users in 1980 were based on total unit sales estimates (replacement sales plus real growth) reported to NIOSH by the Granville Corporation in a 1982 contract report (see Table II on page 53). These total annual sales estimates are desig-

[61] Granville Corporation: *Preliminary Survey of Existing Data and Economic Overview of the Respirator Industry*, prepared for the U. S. Department of Health and Human Services, National Institute for Occupational Safety and Health under Contract NIOSH-210-81-1102, Washington, D.C. (March 10, 1982), p. 32.

nated T_i in the computational equations below (where i = NP, GM, PR, and SA for four of the seven respirator classes).

❹ NIOSH assumed the following proportions of all Part 11 respirators (from flowchart cell 1) will be

[A] recertified with no changes (cell 7),

[B] disposed of before upgrading during as part of normal replacement (cell 8), or

[C] recertified with purchased upgrade kits utilizing durable components (cell 9):

Table IV–Estimated proportions FR_i

Non-powered APR	0.75
Gas masks	0.75
PAPRs	0.75
Supplied-air	0.75
Entry SCBAs (FS)	0.90
Entry SCBAs (NS)	0.90
Escape SCBAs	0.65

These proportions estimate the fraction of respirators from cell 1 that will go to cells 7, 8, and 9. These proportions are designated FR_i in the computational equations below (where i = NP, GM, PR, SA, FS,

NS, and ES for the seven respirator classes). Correspondingly, the seven proportions of all Part 11 respirators (from flowchart cell 1) going to cells (10 + 11) are given by $(1 - FR_i)$.

❺ NIOSH assumed the respirators in cells (8 + 9) will be the following proportions of those in cells (7 + 8 + 9):

Table V–Estimated proportions FU_i

Non-powered APR	0.10
Gas masks	0.10
PAPRs	0.40
Supplied-air	0.50
Entry SCBAs (FS)	0.30
Entry SCBAs (NS)	0.30
Escape SCBAs	0.45

Note that NIOSH assumes most upgrade kits for air-purifying respirators will consist of consumables (e.g., modified filters, chemical cartridges) that will not create potential costs. These proportions are designated FU_i in the computational equations below (where i = NP, GM, PR, SA, FS, NS, and ES for the seven respirator classes).

❻ NIOSH assumed the following average service lives for each of the seven respirator classes:

Table VI–Estimated average service lives Y_i

Non-powered APR	2 years
Gas masks	6 years
PAPRs	5 years
Supplied-air	6 years
Entry SCBAs (FS)	8 years
Entry SCBAs (NS)	8 years
Escape SCBAs	8 years

These average service lives are designated Y_i in the computational equations below (where i = NP, GM, PR, SA, FS, NS, and ES for the seven respirator classes).

❼ NIOSH assumed the average cost for an upgrade kit shown in the next table for each of the seven respirator classes. These average costs are designated U_i in the computational equations below (where i = NP, GM, PR, SA, FS, NS, and ES for the seven respirator classes).

Table VII–Estimated average costs U_i for an upgrade kit

Non-powered APR	$5
Gas masks	$10
PAPRs	$10
Supplied-air	$100
Entry SCBAs (FS)	$350
Entry SCBAs (NS)	$350
Escape SCBAs	$200

❽ Because total respirator sales each year are more than 100-fold larger than the $6 million/year potential passthrough costs (see section (E) starting at page 79), NIOSH assumed that new Part 84 respirators will cost about the same as the current Part 11 models. NIOSH assumed the following average cost in 1990 for a new Part 84 respirator in each of the seven respirator classes:

Table VIII–Estimated average costs R_i for a new Part 84 respirator

Non-powered APR	$15
Gas masks	$125
PAPRs	$400
Supplied-air	$500
Entry SCBAs (FS)	$1,600
Entry SCBAs (NS)	$1,600
Escape SCBAs	$800

These average costs are designated R_i in the computational equations below (where i = NP, GM, PR, SA, FS, NS, and ES for the seven respirator classes).

9 NIOSH assumed the following average ratios of users to respirator for each respirator class. They are designated FW_i in the computational equations below (where i = NP, GM, PR, SA, FS, NS, and ES for the seven respirator classes).

Table IX–Estimated average ratios FW_i of users to respirator

Non-powered APR	0.50
Gas masks	0.50
PAPRs	1.00
Supplied-air	1.00
Entry SCBAs (FS)	1.00
Entry SCBAs (NS)	1.00
Escape SCBAs	1.00

The Centaur Corporation reported in 1984 that about 57 percent (about 0.83 million) of all routine and occasional respirator wearers in manufacturing (about

1.44 million) exclusively wore disposable air-purifying respirators in 1983.[62] From this estimate NIOSH estimated that (1.44 - 0.83) million = 0.61 million manufacturing workers in 1983 wore both disposable and nondisposable respirators. The Centaur report also indicated that these manufacturing workers had access to a working stock of about 0.96 million non-emergency, non-powered, air-purifying, reusable respirators in 1983.[63] Based primarily on this data and professional judgment, NIOSH concluded that there will be an average ratio of one user to every two in-service respirators in 1990 for the NP and GM respirator classes. NIOSH concluded that 1.00 was a reasonable user-to-respirator ratio for the other five respirator classes.

c. Computations for Revised Sunset Clause

NIOSH estimated the 1980 respirator populations given in Table X with the following general equation for four of the seven respirator classes *i* (where *i* = NP, GM, PR, and SA):

$$E_i \text{ respirators} = (T_i \text{ respirators/year})(1 - G_i)(Y_i \text{ years})$$

[62] Centaur Associates, Inc.: *Preliminary Regulatory Impact Analysis of Alternative Respiratory Protection Standards, Volume I*, prepared for the U. S. Department of Labor, Occupational Safety and Health Administration under Contract No. J-9-F-20067, Washington, D.C. (March 30, 1984), pp. 86-87.

[63] Ibid., Exhibit 3-9, p. 90.

Table X–Estimated 1980 populations of nondisposable, non-SCBA respirators

Non-powered APR	3,300,000
Gas masks	250,000
PAPRs	120,000
Supplied-air	750,000

The mid-1990 respirator populations given in Table XI were then estimated with the following general equation for four of the seven respirator classes *i* (where *i* = NP, GM, PR, and SA):

$$N_i \text{ respirators} = (E_i \text{ respirators})(1 + G_i)^{10}$$

NIOSH based its estimates for mid-1990 respirator populations for the FS, NS, and ES classes on recent estimates for 1987 of 1.06 million career and volunteer firefighters (243,000 career and 817,000 volunteer) provided by the NFPA.[64] The Granville Report stated that the International Association of Fire Fighters (IAFF), which represents most full-time firefighters, had roughly estimated that

[64] Private communication with Mr. Ken Taylor, Fire Analysis Division, National Fire Protection Association (July 26, 1989).

about one third of its members had a respirator.[65] The Granville Report also estimated for 1982 that about 45% of the "very roughly 1 million volunteer and other non-municipal firefighters in the U.S." have respirators.[66] NIOSH concluded this percentage was a bit high and assumed that 40% of the latter population use SCBAs for firefighting. NIOSH then computed the 1990 population of firefighter SCBAs as follows:

$$(0.333)(243,000) + (0.40)(817,000) = 407,8000 \text{ FS-class SCBAs}$$

For the 1990 NS- and ES-class populations, NIOSH used previously stated assumptions that most (90%) of all SCBAs in 1990 will be "entry SCBAs" (coded FS and NS) certified for entry into or escape from hazardous atmospheres. NIOSH assumed the remainder (10%) will be "escape-only" SCBAs (coded ES) used in nonmining environments. Additionally, NIOSH assumed that 85% of the entry SCBAs in 1990 will be used in firefighting situations (these are coded FS) and the remaining 15% will be used in nonfirefighting applications (these are coded NS). Use of these assumptions led to estimates of 72,000 for the NS class and 53,333 for the ES class. NIOSH then added another 100,000 to the ES class

[65] Granville Corporation: *Preliminary Survey of Existing Data and Economic Overview of the Respirator Industry*, prepared for the U. S. Department of Health and Human Services, National Institute for Occupational Safety and Health under Contract NIOSH-210-81-1102, Washington, D.C. (March 10, 1982), p. 32.

[66] Ibid.

for the approximately 100,000 escape SCBAs currently carried by approximately 100,000 underground miners. The results are shown in Table XI below.

Table XI–Estimated 1990 populations of nondisposable respirators

Non-powered APR	4,800,000
Gas masks	380,000
PAPRs	170,000
Supplied-air	1,100,000
Entry SCBAs (firefighting)	410,000
Entry SCBAs (nonfirefighting)	72,000
Escape SCBAs	150,000
Total	7,100,000

The potential cost point estimates for necessary upgrade kits (designated $\$UG_i$ for flowchart cell 9) were computed with the following general equation for each respirator class i (where i = NP, GM, PR, SA, FS, NS, and ES):

$$\$UG_i = (FR_i)(FU_i)(1 - P_i/Y_i)(N_i \text{ respirators})(U_i \text{ \$/respirator})$$

The factors $(1 - P_i/Y_i)$ represent the approximate proportions of potentially "upgradable" respirators that will not have been disposed of during a normal replacement cycle (i.e., they will have useful service life remaining as of the Part 11 expiration date for their respirator class). These factors deserve a short explanation.

Note that a *normal replacement cycle* equals the *average* service life of a device. It is the time required for 100% of the devices in service on a given date to routinely wear out and be replaced with new devices. For example, consider nondisposable halfmasks with average service lives of 5 years. One expects that each year 1/5 or 20% of the original population in service on a given date will be routinely replaced. Similarly, at the end of year *n* after the given date, there will be [1 − (*n* years/Y_i years)] of the original respirator population in service. For example, 3 years after a given date for non-powered air-purifying respirators there would be about (1 − 3/5) = 0.4 or 40% of the original population still in service. Thus at the end of the 5-, 6-, or 8-year Sunset Clause periods P_i there will be (1 − P_i/Y_i) of the masks in each respirator class still in service.

NIOSH recognizes that this analysis is relatively simplistic. However, a more precise analysis would be substantially more complex and require knowledge of numerous distributions and their parameters that is not available to NIOSH or others. For example, one would need empirical knowledge of the cumulative hazard functions (i.e., statistical functions for describing failure rate data) for each of the seven respirator classes. These functions require knowledge of the appropriate distributional model (e.g., normal, lognormal, Weibull, extreme value) and associated parameters. NIOSH concluded that the approximations used in this PRIA were adequate for the purposes of Executive Order 12291, which is to assess the approximate potential costs of the regulatory provisions and compare the relative effects of differing regulatory alternatives.

The factors (1 − P_i/Y_i) also represent the cell 9 population values divided by the populations in cells (8 + 9). Additionally, the term

$$(N_i \text{ respirators})(FR_i)(FU_i)(1 - P_i/Y_i)$$

estimates the number of respirators in each class at cell 9.

Based on these equations, the computed point estimates for necessary upgrade kits costs to owners are:

***Table XII**–Estimated costs to owners over 5 years for necessary upgrade kits*

Non-powered APR	$0
Gas masks	$47,000
PAPRs	$0
Supplied-air	$0
Entry SCBAs (firefighting)	$14,000,000
Entry SCBAs (nonfirefighting)	$0
Escape SCBAs	$0
Total	$15,000,000

The potential cost point estimates for required new Part 84 respirators (designated as $\$RP_i$ for flowchart cell 10) were computed with the following general equation for each respirator class *i* (where *i* = NP, GM, PR, SA, FS, NS, and ES):

$$\$RP_i = (1 - FR_i)(1 - P_i/Y_i)(N_i \text{ respirators})(R_i \text{ \$/respirator})$$

As with the upgrade kit estimates discussed above, the factors $(1 - P_i/Y_i)$ represent the proportions of respirators requiring replacement with new Part 84 models that will not have been disposed of during a normal replacement cycle (i.e., they will have useful service life remaining as of the Part 11 expiration date). That is, they are the cell 10 values divided by the cells (6 = 10 + 11). Additionally, the term $[(N_i \text{ respirators})(1 - FR_i)(1 - P_i/Y_i)]$ estimates the number of respirators in each class at cell 10.

Based on these equations, the computed point estimates for necessary purchase costs to owners for purchasing new Part 84 models are:

***Table XIII**–Estimated costs to owners over 5 years for required new Part 84 respirators*

Non-powered APR	$0
Gas masks	$2,000,000
PAPRs	$0
Supplied-air	$0
Entry SCBAs (firefighting)	$24,000,000
Entry SCBAs (nonfirefighting)	$0
Escape SCBAs	$0
Total	$26,000,000

Then the point estimates for potential total costs ($\$T_i$) in the next table were computed with the sums of the two cost group estimates for (1) necessary upgrade kit installations ($\$UG_i$) and for (2) required new respirator models ($\$RP_i$):

***Table XIV**–Estimated total potential costs to nondisposable respirator owners over 5 years due to Sunset Clause*

Non-powered APR	$0
Gas masks	$2,000,000
PAPRs	$0
Supplied-air	$0
Entry SCBAs (firefighting)	$39,000,000
Entry SCBAs (nonfirefighting)	$0
Escape SCBAs	$0
Total	$41,000,000

Lastly, NIOSH computed point estimates given in Table XV for user populations in mid-1990 by starting with the following general equation for each nondisposable respirator class *i* (where *i* = NP, GM, PR, SA, FS, NS, and ES):

$$W_i \text{ users in } 1990 = (FW_i \text{ users/respirator})(N_i \text{ respirators})$$

To estimate the number of users wearing NIOSH-certified disposables in 1990 NIOSH started with the Granville estimate of 76,700,000 disposable respirators sold in 1980.[67] Granville noted that this estimate may have been somewhat high according to one source. Granville then assumed each worker wears disposables about 40 days/year and estimated that 1,918,000 workers were wearing NIOSH-

[67] Ibid., Exhibit 23, Line 5, p. 39b.

certified disposables in 1980.[68] NIOSH then assumed the same growth rate (4%) for disposables that was assumed for the NP-, GM-, PR-, and SA-class respirators and computed the 1990 point estimate for disposable users with the equation (1,918,000 users) times $(1.04)^{10}$ = 2,800,000 disposable users in 1990. Similarly, the point estimate for the number of disposable respirators that will be sold in 1990 is given by (76.7 million) times $(1.04)^{10}$ = 110 million.

Additionally, for the NP-class respirators (nonpowered air-purifying) NIOSH later deducted about 700,000 users who also use supplied-air respirators. This was done because the Centaur report had noted that an estimated 64% of air-line respirator users in manufacturing plants "also wore an air-purifying device part of the time during the year."[69] This correction led to a estimate of 3.8 million total users of nondisposable NIOSH-certified respirators in 1990. Added to the 2.8 million estimated users of disposable respirators resulted in a estimated total of 6.6 million users of all types of NIOSH-certified respirators in 1990. However, NIOSH recognizes that this value overestimates the total number of users because several hundred thousand users probably use both disposable and nondisposable respirators.

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[68] Ibid., Exhibit 24, p. 41.

[69] Centaur Associates, Inc.: *Preliminary Regulatory Impact Analysis of Alternative Respiratory Protection Standards, Volume I*, prepared for the U. S. Department of Labor, Occupational Safety and Health Administration under Contract No. J-9-F-20067, Washington, D.C. (March 30, 1984), pp. 89.

***Table XV**–Estimated respirator user populations in 1990*

Non-powered APR	2,400,000
Gas masks	190,000
PAPRs	170,000
Supplied-air	1,100,000
Entry SCBAs (firefighting)	410,000
Entry SCBAs (nonfirefighting)	72,000
Escape SCBAs	150,000
Disposables	2,800,000
Total	7,400,000*

This is the number of "device users," which overestimates the actual number of users because some workers use more than one class of respirator. **NIOSH estimates a total of up to 6.6 million users of NIOSH-certified respirators in 1990.*

NIOSH then checked its estimated total of up to 6.6 million respirator users for consistency with other available data. The Centaur Report provided an estimated total of 2.63 million respirator-using workers in the manufacturing and non-manufacturing sectors as of 1983.[70] Additionally, after consultation with OSHA personnel, NIOSH developed the respirator-use profile given in Table XVI on the next page.

[70] Ibid., Exhibit 3-6, p. 78.

Table XVI–Estimated user profile of NIOSH-certified respirators in 1990

Manufacturing (M), routine and occasional use	1,400,000
Non-manufacturing (NM), routine and occasional use	1,200,000
Construction (C), routine and occasional use	340,000
M, NM, and C emergency use	600,000
Firefighters	600,000
Military	500,000
Self-employed	500,000
Agriculture	100,000
Mining	100,000
Police	100,000
Prisons	50,000
Longshoring, harbor use	50,000
Total users of NIOSH-certified respirators	5,600,000

There are several likely explanations for the 1-million-user difference between the estimated 6.6 million users in Table XV and the estimated 5.6 million users in Table XVI. First, at noted above, the 6.6-million value probably overestimates the total number of users because several hundred thousand users likely use both disposable and nondisposable respirators. Second, regarding their estimates for the non-manufacturing sector, Centaur noted:

Because non-manufacturing accounts for such a large proportion of plants and workers with respirator use and since no sampling and surveying of plants was performed for non-manufacturing indus-

tries, all results that include non-manufacturing industries are subject to potentially large errors. Consequently, these results should be treated as very rough estimates.[71]

Third, Centaur also noted for their survey results:

. . . emphasis is placed on occasional and routine (i.e., non-emergency, or sometimes referred to as general) respirator use. The frequency of using respirators dedicated to emergency situations is unpredictable, as is the number of persons that may use such respirators during the year.[72]

This caveat emphasizes the difficulty of obtaining precise estimates of respirator emergency use.

Fourth, Centaur used a narrower definition of respirator user than is used by NIOSH. Centaur stated:

Routine use of respirators is defined as a plant with one or more persons wearing a non-emergency respirator as a normal procedure on a regular basis. Occasional use of non-emergency respirators is defined as less than regular use but not just use for escape from a hazardous atmosphere which suddenly occurs (i.e., emergency use). For a plant to have only occasional respirator use, it was required that two or more workers fit this description of use (conversation with Health Standards and Office of Regulatory Analysis, OSHA, June, 1983).[73]

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[71] Ibid., Footnote 1, p. 62.

[72] Ibid., p. 74.

[73] Ibid., Footnote 1, p. 66.

Table XVIII on page 77 summarizes input estimates and output results from the spreadsheet model for the original Sunset Clause as proposed in the first NPRM of August 1987. This table reflects the potential costs for a single 5-year expiration period for all seven respirator classes. Table XIX on page 78 then summarizes the results for the revised Sunset Clause in this NPRM using 5-, 6-, and 8-year expiration periods.

***Table XVII**–Spreadsheet model results for original Sunset Clause in first NPRM of August 1987*

	Air-purifying			Atmosphere-supplying			
Resp class	NP APR NP	Gas masks GM	PAPRs PR	Supld-air SA	Firefg SCBAs FS	Nofr SCBA NS	Escp SCBA ES
'80 Rsps/yr	1,703,000	44,000	24,000	130,000	N/A	N/A	N/A
'80 Resps	3,269,760	253,440	115,200	748,800	N/A	N/A	N/A
'90 Resps	4,840,044	375,153	170,524	1,108,407	408,000	72,000	153,333
'90 Users	2,420,022	187,577	170,524	1,108,407	408,000	72,000	153,333
Growth/year	0.04	0.04	0.04	0.04	0.00	0.00	0.00
FR(i)	0.75	0.75	0.75	0.75	0.90	0.90	0.65
FU(i)	0.10	0.10	0.40	0.50	0.30	0.30	0.45
P(i) yrs	5	5	5	5	5	5	5
Y(i) yrs	2	6	5	6	8	8	8
U(i) in '90	$5	$10	$10	$100	$350	$350	$200
R(i) in '90	$15	$125	$400	$500	$1,600	$1,600	$800
FW(i) usr/rp	0.50	0.50	1.00	1.00	1.00	1.00	1.00
Frac > P(i)	0.000	0.167	0.000	0.167	0.375	0.375	0.375
$UG(i)	$0	$46,894	$0	$6,927,543	$14,458,500	$2,551,500	$3,363,750
$RP(i)	$0	$1,953,922	$0	$23,091,811	$24,480,000	$4,320,000	$16,100,000
$UG + $RP	$0	$2,000,817	$0	$30,019,354	$38,938,500	$6,871,500	$19,463,750

# of nondisposable respirators in-service in 1990	7,127,461
# of disposables used in 1990	113,534,737
# of disposable respirator users in 1990	2,838,368
# of nondisposable respirator users in 1990	3,810,482
Total # users of NIOSH-certified respirators in 1990	6,648,851
Total potential costs to owners for 1990-1995	$97,293,921
Annual potential costs to owners for 1990-1995	$19,458,784

$/respirator	$0.00	$5.33	$0.00	$27.08	$95.44	$95.44	$126.94
$/user	$0.00	$10.67	$0.00	$27.08	$95.44	$95.44	$126.94

Table XVIII–Spreadsheet model results for revised Sunset Clause in second NPRM with 5-, 6-, and 8-year expiration periods

	Air-purifying			Atmosphere-supplying			
Resp class	NP APR NP	Gas masks GM	PAPRs PR	Supld-air SA	Firefg SCBAs FS	Nofr SCBA NS	Escp SCBA ES
'80 Rsps/yr	1,703,000	44,000	24,000	130,000	N/A	N/A	N/A
'80 Resps	3,269,760	253,440	115,200	748,800	N/A	N/A	N/A
'90 Resps	4,840,044	375,153	170,524	1,108,407	408,000	72,000	153,333
'90 Users	2,420,022	187,577	170,524	1,108,407	408,000	72,000	153,333
Growth/year	0.04	0.04	0.04	0.04	0.00	0.00	0.00
FR(i)	0.75	0.75	0.75	0.75	0.90	0.90	0.65
FU(i)	0.10	0.10	0.40	0.50	0.30	0.30	0.45
P(i) yrs	5	5	5	6	5	8	8
Y(i) yrs	2	6	5	6	8	8	8
U(i) in '90	$5	$10	$10	$100	$350	$350	$200
R(i) in '90	$15	$125	$400	$500	$1,600	$1,600	$800
FW(i) usr/rp	0.50	0.50	1.00	1.00	1.00	1.00	1.00
Frac > P(i)	0.000	0.167	0.000	0.000	0.375	0.000	0.000
$UG(i)	$0	$46,894	$0	$0	$14,458,500	$0	$0
$RP(i)	$0	$1,953,922	$0	$0	$24,480,000	$0	$0
$UG + $RP	$0	$2,000,817	$0	$0	$38,938,500	$0	$0

# of nondisposable respirators in-service in 1990	7,127,461
# of disposables used in 1990	113,534,737
# of disposable respirator users in 1990	2,838,368
# of nondisposable respirator users in 1990	3,810,482
Total # users of NIOSH-certified respirators in 1990	6,648,851
Total potential costs to owners for 1990-1995	$40,939,317
Annual potential costs to owners for 1990-1995	$8,187,863

$/respirator	$0.00	$5.33	$0.00	$0.00	$95.44	$0.00	$0.00
$/user	$0.00	$10.67	$0.00	$0.00	$95.44	$0.00	$0.00

E. Potential Costs to Respirator Manufacturers Due to Proposed Revision

1. Summary

The NIOSH point estimates for the annual potential costs that might be borne by the domestic respirator manufacturing industry due to the provisions in the second NPRM for 42 CFR Part 84 are summarized in Table XIX on page 80. This table indicates that the potential incremental costs for the domestic industry will be about $6.3 million in the first year after the effective date of the Final Rule. In the second and subsequent years the annual potential incremental costs will drop to $5.7 million/year. The average annual potential costs over the first five years after the effective date of the regulation are estimated as $5.8 million/year. However, since data were not available to make a multitude of offset adjustments for nonquantifiable benefits to manufacturers, these potential cost estimates are overstated.

Five groups of requirements in the proposal contribute to the majority of the potential cost implications: §§ 84.2, 84.11, 84.21–24, 84.30, and 84.230–235. The specific assumptions, data, and estimation methods used for individual provisions are given in section (E)(3) starting below on page 83. NIOSH has determined that many provisions in Part 84 will have negligible potential costs for the domestic industry. These are listed and discussed in section (E)(4) starting on page 111. For convenience, the analysis and cost estimates apply only to the domestic respirator industry of 32 manufacturers. NIOSH estimates that less than 5% of the respirator sales in the United States are from the 10 foreign

***Table XIX**–Estimated total annual costs to 32 domestic respirator manufacturers due to provisions in 2nd NPRM for Part 84*

Provision	1st year	2+ Years	5–Year Mean
§ 84.2 Sunset Clause	$1,250,000	$1,250,000	$1,250,000
§ 84.11 Applications	2,113,000	2,113,000	2,113,000
§ 84.20 Quality Assurance	9,000	9,000	9,000
§ 84.21 Defect Notification	5,000	5,000	5,000
§ 84.22 Defect Notification	23,000	23,000	23,000
§ 84.23 Defect Notification	1,376,000	1,268,000	1,290,000
§ 84.24 Communications	24,000	24,000	24,000
§ 84.25 NIOSH Determination	13,000	13,000	13,000
§ 84.30 Laboratory Testing	573,000	259,000	322,000
§ 84.32 Certification Denial	7,000	7,000	7,000
§§ 84.230–235 Face Seal Performance	670,000	680,000	678,000
§ 84.293 Filter Performance	229,000	None	46,000
§ 84.331 Applications	2,000	2,000	2,000
§ 84.332 General Requirements	7,000	7,000	7,000
§ 84.334 ESLI Requirements	7,000	7,000	7,000
TOTALS per year:	$6.3 million	$5.7 million	$5.8 million

manufacturers that hold NIOSH Part 11 certifications.

The general approach used by NIOSH for this section was to compare each provision in this second NPRM with current industry and NIOSH practice under Part 11. In each case the Institute attempted to determine the nature and extent of incremental burden, if any, created by this proposal. The Institute has presented its reasoning in substantial detail—more than might be warranted by the magnitude of the costs in some cases. However, this was done so that all incremental costs for manufacturers are identified in sufficient detail to allow commenters to provide suggestions for corrections or, if appropriate, changes in the regulation itself.

2. Significance of Potential Costs to Manufacturers

The significance of potential recurring and nonrecurring costs to respirator manufacturers must be evaluated relative to annual sales in this industry. The Granville report gave an estimate of $285.2 million in NIOSH-certified respirator sales in the U. S. for 1980.[74] Using the previously discussed real growth factor of 4% annually plus an inflation factor of 4% annually for 1980–1990 yields a 1990 sales estimate of ($285.2 million)$(1.08)^{10}$ = $620 million for NIOSH-certified respirators. This estimate agrees rather well with a second NIOSH estimate of

[74] Granville Corporation: *Preliminary Survey of Existing Data and Economic Overview of the Respirator Industry*, prepared for the U. S. Department of Health and Human Services, National Institute for Occupational Safety and Health under Contract NIOSH–210–81–1102, Washington, D.C. (March 10, 1982), p. 30.

about $650 million annual sales derived from figures given in a 1988 cost analysis from the Industrial Safety Equipment Association (ISEA) for the first NPRM.[75]

Additionally, there are four major reasons why purchases of new and replacement respirators will probably substantially accelerate in the next five years: (1) the Sunset Clause in Part 84, (2) OSHA's new "PEL regulation,"[76] (3) OSHA's proposed rule for methods of compliance,[77] and (4) substantial increases in American asbestos-abatement activities.[78] NIOSH anticipates that annual sales of respirators in the U. S. could easily experience a growth of 10% to 30% ($65 million to almost $200 million/year) in the first five years after the effective date of Part 84.

The potential costs to manufacturers of about $6 million annually for the proposed 42 CFR Part 84 can be compared with the annual sales estimate for the respirator industry of $650 million derived from the ISEA analysis. A complete transfer to respirator purchasers of the potential costs of about $6 million annually would amount to about a one percent increase in respirator costs to purchasers. However as discussed on page 41 even this minimal passthrough is unlike-

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[75] Industrial Safety Equipment Association: *Manufacturers' Regulatory Impact Analysis for Implementation of 42 CFR 84*, Arlington, Virginia (September 22, 1988).

[76] Occupational Safety and Health Administration: Final Rule, Air Contaminants, 29 CFR Part 1910, *Federal Register* 54(12):2768–2789 (January 19, 1989).

[77] Occupational Safety and Health Administration: Proposed Rule, Health Standards; Methods of Compliance, 29 CFR Part 1910, *Federal Register* **54**(106):23991–23998 (June 5, 1989).

[78] Minter, S. G.: ISEA Focuses on the Future, *Occupational Hazards* **51**(7):9–11 (July 1989).

ly. Over time purchasers may save money if manufacturers can achieve cost savings through product innovation.

3. Derivation of Potential Cost Estimates for Manufacturers

a. Background, Methodology, and Major Assumptions

The revised Sunset Clause [§ 84.2(b)(1)] provides that all NIOSH certifications issued under the provisions of 30 CFR Part 11 shall expire at five, six, or eight years from the effective date of 42 CFR Part 84. After that date, manufacturers will not be able to produce, sell, or distribute respirators with 30 CFR Part 11 certifications as NIOSH-certified devices. For these respirators a manufacturer will need to apply to NIOSH for recertification under the provisions of 42 CFR Part 84. Note that § 84.2(b)(3) permits manufacturers to submit certification applications for upgrade kits. This provision will minimize the potential costs due to the Sunset Clause for respirator owners, purchasers, and manufacturers.

Based on the analysis in the previous section, NIOSH expects that respirator buyers would incur negligible cost increases on new respirator purchases due to direct effects from the proposal regulation. They might, however, face decisions whether to delay some new purchases pending availability of upgrade kits, recertified models, redesigned models, or new models. It is difficult to estimate precisely the total potential costs for the domestic respirator industry due to the proposed regulatory revision. Some of the cost estimates given in the following sections are based on a study prepared under NIOSH contract to the Decision

Information Systems Corporation (DISC).[79] In many cases the estimates and assumptions in this analysis are based on over 15 years of NIOSH experience resulting from the issuance of over 1,600 certifications under the current 30 CFR Part 11 regulation. NIOSH welcomes specific comments both on the findings in the DISC *Report* and the assumptions discussed below. The five major assumptions used by NIOSH in estimating potential cost estimates for respirator manufacturers in this PRIA are as follows:

❶ All NIOSH-certified respirators are currently in compliance with the requirements of 30 CFR 11.11(d) and 11.64(b).

❷ Currently there are over 1,600 NIOSH/MSHA certifications issued under the requirements of 30 CFR Part 11 that will expire after five, six, or eight years (§ 84.2(b)(1)). For this analysis NIOSH assumed that respirator manufacturers will choose not to recertify 20% (320) of the Part 11 certifications due to reasons such as low market share, substantial redesign and development costs, or because a manufacturer is developing a new line of improved respirators to replace currently certified devices. Thus NIOSH assumed that 80% (1280) of the 1,600 current certifications for all seven respirator classes will be submitted for recertification under 42 CFR Part 84. These assumptions

[79] Decision Information Systems Corporation: *Final Report–Cost Impact Study of 30 CFR 11 Revisions*, Washington, DC (September 5, 1986).

are derived from the assumptions for FR_i[80] and FU_i[81] given in section (D)(3)(b) starting on page 48. Note that a small proportion of the FU_i proportions must be added to the FR_i proportions to account for the respirators that will be recertified with substantial revisions. Also note that the number of certifications (1,600+) is substantially less than the number of certified makes and models (7,000+) because a certified device can be marketed under multiple brand names and model numbers.

❸ NIOSH assumed that about 94% (1,200) of the 1,280 certifications chosen for recertification will require minimal incremental design and development costs to meet performance criteria in 42 CFR Part 84.

❹ NIOSH assumed that about 6% (80) of the 1,280 certifications chosen for recertification will require substantial engineering redesign, redevelopment, and production line changes. These potential costs are difficult to estimate precisely because they are not solely the purview of engineering, but will be evaluated against a manufacturer's return on investment and potential market share. Generally a manufacturer

[80] Table IV, p. 59.

[81] Table V, p. 60.

will choose to incur these costs only if they can be recouped within an acceptable payback period.

❺ In developing these potential cost estimates resulting from the proposed regulation, NIOSH did not include those costs that manufacturers currently incur for their own purposes or that are currently required under the long-standing 30 CFR Part 11. That is, any current voluntary activities that would become mandatory or could be redirected to requirements of the proposal are not considered to create incremental costs due to this proposal. The Institute attributed to the proposal only incremental costs resulting from new requirements (e.g., the defective respirator notification system under § 84.23). This approach required the use of informed judgments and this analysis may have erred in one direction or another in some instances. NIOSH welcomes comments and corrections.

Although NIOSH has provided precise calculations for each cost category, we wish to emphasize that this precision is intended to facilitate understanding and, if necessary, corrections from reviewers, rather than to imply certainty on our part. To avoid any impression that any estimate is quite precise, the Institute has rounded individual estimates to the nearest $1,000 (and would have rounded even more were not some cost estimates so low) and table totals have been rounded to two significant figures from the original computed values. Therefore

the individual values in the summary table may not necessarily add to exactly the total given in the table. Any point estimate for a provision or total should be understood to represent a range of values, with varying degrees of uncertainty around the point estimate presented for each true value.

b. § 84.2 Sunset Clause for 30 CFR Part 11 Certifications

NIOSH assumed that about 80% (1,280) of the 1,600 current certifications will be submitted for recertification under 42 CFR Part 84 (with no changes, upgrade kit changes, or with substantial changes). For these 1,280, part of the potential recertification costs accounted for under this provision are the application fees (§ 84.90) and the costs for shipping the application and respirators to NIOSH. Other recertification costs are accounted for under other applicable provisions. NIOSH estimates that packaging and shipping costs will average $300 for each application. Application fees are dependent upon the type of respirator being evaluated. Using the percentages of respirator types listed in the *NIOSH Certified Equipment List as of October 1, 1987*, NIOSH computed a weighted-average application fee of $2,720 per application. About 5% of the NIOSH certifications are for SCBAs, 9% are for SARs, and 86% are for air-purifying respirators. The computation is as follows:

$$(0.05)(\$6,000) + (0.09)(\$3,000) + (0.86)(\$2,500) = \$2,720/\text{application}.$$

NIOSH expects an increase in new applications for certifications under the requirements of the proposed 42 CFR Part 84 because the proposed Sunset Clause (§ 84.2(b)(1)) provides for the expiration of 30 CFR Part 11 certifications at five, six, or eight years after the effective date of Part 84. This provision permits manufacturers ample time to apply for and obtain new Part 84 certifications. It is not possible to predict accurately whether the annual rate of applications for the 5-year period following the effective date of 42 CFR Part 84 will increase or decrease compared with the annual application rate under 30 CFR Part 11. It is likely that those requiring redesign will not be submitted for new certification until the fourth or fifth year after the implementation of 42 CFR Part 84. However, due to the difficulty in precisely estimating the annual application rate, NIOSH will average estimated costs over the first five years after the effective date of the Final Rule. Thus the annual potential submittal costs for the 1,280 devices over a 5-year period are estimated as:

$$[(1{,}280 \text{ applications})(\$2{,}720 + \$300)/\text{application}]/(5 \text{ yrs}) = \$773{,}120/\text{yr}$$

that will be rounded to $770,000/yr. Since this point estimate is sensitive to the number of devices in each respirator class that will be submitted for recertification, NIOSH welcomes comments on this estimate.

Additionally, based on and consistent with previous assumptions,[82] NIOSH will assume that about 6% (80) of the 1,280 recertifications will require substantial

[82] Section D(3)(b), p. 48.

engineering redesign, redevelopment, and production line changes. These potential costs are difficult to estimate precisely. However, for this analysis NIOSH has computed an upper bound estimate for the potential average cost for redesign and redevelopment costs. Based on available data, NIOSH estimates an average cost of $30,000/certification will be required for the 80 current certifications in order to bring the devices into compliance with the new requirements. Then the annual potential redesign costs for the 80 devices over a 5–year period are estimated as:

$$[(80 \text{ applications})(\$30{,}000)/\text{application}]/(5 \text{ yrs}) = \$480{,}000/\text{yr}.$$

Since this estimate is very sensitive to both the number of Part 11 certified devices that will be substantially redesigned to meet Part 84 requirements and the average redesign cost, NIOSH solicits comments and data bearing on these estimates.

The annual potential costs for recertifying 1,280 current certifications accounted for under this provision are then computed as the sum of the average annual submittal costs and average annual redesign costs. These are:

$$(\$770{,}000/\text{yr}) + (\$480{,}000/\text{yr}) = \$1{,}250{,}000/\text{yr}.$$

Lastly, an argument can be made that manufacturers might incur lost profits for the 320 certifications that NIOSH assumes will not be recertified due to reasons such as low market share, substantial redesign or modification costs, or

because a manufacturer is developing a new line of improved respirators to replace currently certified devices. However, these devices will be permitted to be sold as NIOSH-certified for for up to 8 years after the effective date of the new regulation. The 5-, 6-, and 8-year grandfather periods will permit such "costs" to be subsumed within normal product redesign and replacement cycles. NIOSH has concluded there are no means for validly estimating these potential costs. However, some or all of these potential losses may be offset by profits resulting from increased sales of improved respirators meeting Part 84 requirements. The Institute welcomes comments on this issue. Some of these costs would offset the nonquantifiable benefits to manufacturers that were discussed in section (C)(3) starting on page 32.

c. § 84.11 Certification Applications

The primary cost burden associated with preparing a certification application is the compilation of the proper documentation for a specific respirator. The cost of preparing the source documents themselves (e.g., user instructions, engineering drawings, parts lists) is excluded by NIOSH because these documents are compiled by the manufacturers in the normal course of their activities. These documents are usual and customary in this industry.

The *Report*[83] states that the estimated mean cost for "total aggregate cost of certification" for all 32 domestic manufacturers (the number holding certifications

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[83] Decision Information Systems Corporation: *Final Report–Cost Impact Study of 30 CFR 11 Revisions*, Washington, DC (September 5, 1986), Exhibit 39, p. 90.

at the time of the early-1986 survey) was $81,173/year/mfr under the present regulation (30 CFR Part 11). This estimate is based on data reported by 10 domestic manufacturers (i.e., sample size of n=10). However, the *Report* also states that the estimated mean costs (n=12) for "total personnel and non-personnel costs of certification application, preparation and review" and "total costs associated with application fees and samples" were $53,641/year/mfr and $13,536/year/mfr respectively. The latter two estimated mean costs add to a total aggregate mean cost estimate of $67,177/year/mfr, which is substantially less than the $81,173/year/mfr total aggregate mean cost estimate. To compute the higher possible estimate, NIOSH will use the larger of the two mean cost estimates, $81,173/year/mfr. NIOSH then adjusted this value for 7.5 years of 4% annual inflation over 1985–92. This yielded a 1992 cost estimate of ($81,173) times $(1.04)^{7.5}$ = $108,934. Due to the uncertainties of when the manufacturers will respond to the opportunities created by the proposed 42 CFR Part 84, the preceding average cost estimates from the 1986 *Report* for 30 CFR Part 11 are used as the primary basis for the proposed 42 CFR Part 84 cost estimates.

Compared with the current quality assurance requirements, the proposed regulation will no longer require manufacturers to submit a detailed quality assurance (QA) plan with each application. The *Report*[84] states a mean estimate (n=12) of 37 hrs/yr/mfr for "paperwork savings (in hours) that will derive from the elimination of Q/A plan submission." An informal NIOSH survey of several domestic manufacturers in 1988 indicated that the personnel required for application prep-

[84] Ibid., Exhibit 30, p. 68.

aration included quality control specialists ($60,000/year, $29/hour) and clerical support staff ($20,000/year, $9.70/hour). Based on professional judgment, NIOSH will assume half the personnel savings will be professional staff ($29/hr) and half will be clerical support staff ($9.70/hr). After adjusting for 4.5 years of 4% annual inflation over 1988–1992, the weighted average personnel cost in 1992 is estimated as:

$$[(0.5)(\$29.00/hr) + (0.5)(\$9.70/hr)](1.04)^{4.5} = \$23.09.$$

Then the annual average personnel cost savings for preparing applications under the proposed 42 CFR Part 84 are estimated for 1992 as:

$$(37\ hrs/yr/mfr)(\$23.09/hr) = \$854/yr/mfr.$$

Subtracting this estimated mean saving from the annual mean cost of $108,934/yr/mfr yields a revised mean cost estimate of $108,080/yr/mfr for certification application costs in 1992 (including both new certifications and certification modifications).

Fifteen years of NIOSH experience with the present 30 CFR Part 11 regulation indicates that approximately half of all certification applications are for new certifications and half are for modification of certifications (e.g., certification extensions). Thus for respirator manufacturers NIOSH estimates an annual mean cost in 1992 for § 84.11 of:

$$(0.5)(\$108,080/yr/mfr) = \$54,040/yr/mfr.$$

Then the annual potential costs for preparing certification applications under § 84.11 for the 32 manufacturers in the domestic respirator industry are estimated for 1992 as:

$$(\$54,040/yr/mfr)(32\ mfrs) = \$1,729,273/yr$$

that will be rounded to $1,729,000. Since this estimate is sensitive to the average incremental costs for preparing the new applications, NIOSH solicits comments and data bearing on this cost estimate.

Section 84.11(a)(4) requires that a minimum of six respirators or upgraded respirators be provided to NIOSH as part of each certification application. NIOSH will use these devices for verification testing under § 84.31. Based on the estimated retail prices for new respirators R_i,[85] adjusting for 2 years of inflation at 4% annually over 1990–1992, and assuming manufacturer costs are 50% of retail price, NIOSH estimated the following average manufacturer costs of these devices in 1992:

1. $865 for self-contained breathing apparatus (SCBA) and supplied-air respirators (SAR),

[85] Table VIII, p. 62.

❷ $68 for fullface air-purifying devices and gas masks,

❸ $8.10 for nondisposable air-purifying halfmask respirators, and

❹ $0.54 for disposable air-purifying halfmasks.

For all devices a weighted-average manufacturer cost in 1992 of $128 was estimated based on the relative percentages of all NIOSH certifications allotted to each type of respirator (i.e., about 14% of the NIOSH certifications are for SCBAs and SARs, 4% are for gas masks, 72% are for nondisposable air-purifying devices, and 10% for disposable air-purifying respirators). The computation is as follows:

$$(0.14)(\$865) + (0.04)(\$68) + (0.72)(\$8.10) + (0.10)(\$0.54) = \$128.16.$$

For an upper-bound estimate, NIOSH will assume that an annual average of 500 certifications/year will be submitted by the domestic industry in each of the five years after the effective date of Subpart R. Thus the annual potential costs for respirators submitted to NIOSH under § 84.11(a)(4) with each application from the domestic respirator industry in 1992 are estimated as:

$$(\$128/\text{resp})(500\ \text{applications/year})(6\ \text{resps/application}) = \$384{,}000/\text{year}.$$

Then the annual potential total costs for the domestic industry in 1992 due to § 84.11 are estimated as the sum of the costs for application preparation and test respirators furnished to NIOSH:

($1,729,000/yr) + ($384,000/yr) = $2,113,000/yr.

d. § 84.20 Quality Assurance

For § 84.20(c), quality assurance, the potential cost of preparing and retaining the control drawings and specifications required by § 84.20(c) is excluded by NIOSH. These control drawings and specifications are prepared by respirator manufacturers in the normal course of their activities because the required documents are usual and customary in the respirator manufacturing industry.

For § 84.20(d), report preparation, based on professional judgment NIOSH will assume an annual average of two reports to NIOSH per year per manufacturer will be required under this provision (i.e., 64 per year for the 32 domestic manufacturers). NIOSH assumes each report will require one hour to prepare. Using the previous personnel cost estimate of $23.09/hr in 1992, NIOSH estimates an annual potential mean cost for the domestic industry in 1992 under § 84.20(d) of:

(2 reports/yr/mfr)(32 mfrs)(1 hr/report)($23.09/hr) = $1,489/yr.

For § 84.20(f)(3), certification-performance assurance testing, the cost of triennially conducting the laboratory performance tests required by § 84.20(f)(1) is excluded by NIOSH. The periodic conducting of certification performance tests by manufacturers, as part of an adequate quality assurance program, is a current practice in the industry. Periodically conducting laboratory performance tests to assure continued compliance with certification criteria is considered usual and customary in this industry. This provision is part of the quality assurance program and also refers to § 84.21 (and hence to § 84.23). Thus its potential cost is accounted for under §§ 84.20(d) and 84.23.

For § 84.20(g), records of minor modifications, NIOSH excludes essentially all the time required to prepare and maintain the records of minor modifications as required by § 84.20(g). These records are compiled and retained by the manufacturers in the normal course of their activities. However, in the absence of survey data, based on professional judgment NIOSH will assume an average annual burden of 10 hrs/yr/mfr for the minimal time required to maintain the records in such a manner that a manufacturer can promptly produce necessary records upon request from the Institute. This will permit NIOSH to review promptly a series of minor changes and determine if in the aggregate they compromise the safety and performance of a respirator. At an estimated average personnel cost of $23.09/hr in 1992, NIOSH estimates an annual potential cost for the domestic industry due to § 84.20(g) of:

($23.09)(10 hr/yr/mfr)(32 mfrs) = $7,408/yr.

Then the annual potential total cost in 1992 due to § 84.20 for the domestic respirator industry is the sum of the potential costs for §§ 84.20(d) and 84.20(g):

$$\$1,489/yr + \$7,408/yr = \$8,897/yr$$

that will be rounded to $9,000/yr.

e. § 84.21 Defect Discovery or Noncompliance by Manufacturer; Notice Requirements

Over the last five years NIOSH has received an average of 40 voluntary reports/year concerning compliance deficiencies for 32 domestic manufacturers. In the absence of survey data, based on professional judgment NIOSH will assume that only one in five compliance deficiencies is actually reported. Thus NIOSH estimates the average reporting burden for the domestic industry due to § 84.21(a, b) will be:

(5 required/voluntary)(40 voluntary reports/year) = 200 required reports/year.

NIOSH estimates a average burden of one hour preparation time at $23.09/hr per report in 1992. Thus the annual potential cost for the domestic respirator industry in 1992 under § 84.21(a, b) is:

(200 reports/year)(1 hr/report)($23.09/hr) = $4,620/yr

that will be rounded to $5,000/yr.

f. § 84.22 Manufacturer Notification to NIOSH

NIOSH receives an average of 45 to 50 voluntary reports of defects per year from 43 domestic and foreign respirator manufacturers. This is an average of about one report/yr/mfr. In the absence of survey data, as with § 84.21(a, b), NIOSH will assume that only one in five defects is actually reported under the present voluntary system. Thus NIOSH estimates the average reporting burden for the domestic industry from § 84.22 will be:

(5 required/voluntary)(40 voluntary reports/year) =
200 required defect reports/year.

Based on professional judgment, NIOSH estimates a average burden of five hours to assemble the necessary information and prepare each report. This may be an overestimate of chargeable burden, since many manufacturers routinely record and analyze this information in the normal course of their business activities. Thus the estimated annual mean burden per manufacturer is:

(200 reports/year)(5 hr/report)/(32 mfrs) = 31.25 hrs/yr/mfr.

At an average personnel cost of $23.09/hr in 1992 (i.e., half professional and half clerical wage rates), NIOSH estimates an annual potential cost for the domestic industry in 1992 due to § 84.22 of:

($23.09/hr)(31.25 hr/yr/mfr)(32 mfrs) = $23,102/yr

that will be rounded to $23,000/yr.

g. § 84.23 Manufacturer Notification to Affected Persons

The *Report*[86] states a mean cost estimate (n=13) of $16,700/mfr for one-time "initial costs of establishing a notification procedure." NIOSH then adjusted this value for 5.5 and 7.5 years of 4% annual inflation over 1985–1990 and 1985–92. This yielded a 1990 cost estimate of ($16,700) times $(1.04)^{5.5}$ = $20,720 and a 1992 cost estimate of ($16,700) times $(1.04)^{7.5}$ = $22,411. The *Report* also states a mean estimate (n=11) of $26,953/yr/mfr for "on-going costs for such a procedure." NIOSH then adjusted this value for 5.5 and 7.5 years of 4% annual inflation over 1985–1990 and 1985–1992. This yielded a 1990 cost estimate of ($26,953) times $(1.04)^{5.5}$ = $33,442 and a 1992 cost estimate of ($26,953) times $(1.04)^{7.5}$ = $36,171. For the first year, based on professional judgment NIOSH will assume it will require an average of 1/3 year to establish a notification procedure. Thus in the first year the total potential costs consist of only 2/3 of the

[86] Decision Information Systems Corporation: *Final Report–Cost Impact Study of 30 CFR 11 Revisions*, Washington, DC (September 5, 1986), Exhibit 31, p. 72.

ongoing costs plus all of the initial establishment costs. The annual potential total cost to the domestic industry for the notification system in the first year after the effective date of § 84.23 is estimated as:

$$[(2/3)(\$33,442/\text{mfr}) + (\$20,720/\text{mfr})](32\ \text{mfrs}) = \$1,376,469$$

that will be rounded to $1,376,000. In the second and subsequent years, the total potential costs consist of just the ongoing costs of notification. Thus the annual potential total costs for § 84.23 in the second and subsequent years for the domestic industry are estimated as:

$$(\$36,171/\text{mfr})(32\ \text{mfrs}) = \$1,267,914/\text{yr}$$

that will be rounded to $1,268,000/yr. Since both these estimates are sensitive to the establishment and operating costs for a notification system, NIOSH welcomes comments and data bearing on these cost estimates.

h. § 84.24 Copies of Communications Sent to Purchasers, Dealers or Distributors

Based on professional judgment NIOSH will assume an average of 10 notices will be sent to NIOSH per year per manufacturer (e.g., copies of notices, bulletins, other communications sent to dealers, distributors, or purchasers) as required by part (a) of § 84.24 (i.e., 320 per year for the 32 domestic manufacturers).

NIOSH will assume each notice will require 0.1 hour to send to the Institute. Thus NIOSH estimates an annual mean burden for § 84.24(a) of:

$$(10 \text{ copies/yr/mfr})(0.1 \text{ hr/copy}) = 1 \text{ hr/yr/mfr.}$$

Based on professional judgment NIOSH will assume that the Institute will annually require the 32 domestic manufacturers to send a total of 10 additional notices as provided for in § 84.24(b). NIOSH will assume each mailing will require 100 burden hours. Thus the estimated annual mean burden per manufacturer is:

$$(10 \text{ mailings/year})(100 \text{ hrs/mailing})/(32 \text{ mfrs}) = 31.25 \text{ hrs/yr/mfr.}$$

After rounding to the nearest hour, NIOSH estimates an annual mean burden of 31 hrs/yr/mfr for § 84.24(b). Then for a personnel cost of $23.09/hr in 1992 the annual potential total cost for the domestic respirator industry in 1992 under both parts of § 84.24 is:

$$(32 \text{ mfrs})(\$23.09/\text{hr})(1 + 31) \text{ hrs/yr/mfr} = \$23{,}637/\text{yr}$$

that will be rounded to $24,000/yr.

i. § 84.25 NIOSH Determination of a Defective or Noncomplying Respirator

Based on professional judgment NIOSH will assume that Institute testing will identify an average of one case of noncompliance or respirator defect per year per manufacturer (i.e., 32 cases per year for the 32 domestic manufacturers). NIOSH will assume it will require a manufacturer one hour per case to reply to a NIOSH letter as required by part (b) of § 84.25. Thus NIOSH estimates an annual mean burden for § 84.25(b) of:

(1 reply/yr/mfr)(1 hr/reply) = 1 hr/yr/mfr.

Based on professional judgment NIOSH will assume that the Institute will require a notification of affected parties in only 10 of the 32 cases/year as provided for in part (c) of § 84.25. Since it is likely that this provision will impact a smaller affected population than § 84.24(b), based on professional judgment NIOSH will assume each notification will require 50 burden hours. Thus the estimated annual mean burden per manufacturer for § 84.25(c) is:

(10 notifications/year)(50 hrs/notification)/(32 mfrs) = 15.6 hrs/yr/mfr.

After rounding to the nearest hour, NIOSH estimates an annual mean burden of 16 hrs/yr/mfr for § 84.25(c). Then for a personnel cost of $23.09/hr in 1992, the annual potential cost for the domestic respirator industry in 1992 for both parts of § 84.25 is:

$$(32 \text{ mfrs})(\$23.09/\text{hr})(1 + 16) \text{ hrs/yr/mfr} = \$12{,}563/\text{yr}$$

that will be rounded to $13,000.

j. § 84.30 Laboratory Testing by Applicant

The cost of conducting the laboratory tests required by the proposed Part 84 is excluded by NIOSH. Laboratory tests are currently conducted by manufacturers in the normal course of their activities. This type of testing is considered usual and customary in this industry.

The *Report*[87] states a mean estimate (n=11) of 839 hrs/yr/mfr for the average burden of additional paperwork associated with workplace testing (former §§ 84.32 and 84.33 from the first NPRM of August 1987). Based on professional judgment NIOSH will assume that the preparation of the laboratory test reports required by § 84.30 will produce the same level of burden. At a personnel average cost of ($19.35/hr) times $(1.04)^{2.5}$ = $21.34/hr in 1990–1991, the potential cost for the domestic respirator industry due to § 84.30 is estimated for the first year as:

$$(\$21.34/\text{hr})(839 \text{ hrs/mfr})(32 \text{ mfrs}) = \$572{,}936$$

[87] Ibid., Exhibit 8, p. 26.

that will be rounded to $573,000. This cost estimate is sensitive to the number of preparation hours and labor costs required for these reports. NIOSH welcomes comments and data bearing on this cost estimate.

Note that this cost estimate should hold only for the first year after the implementation of 42 CFR Part 84. NIOSH will assume the average burden hours will substantially decrease to 350 hrs/yr/mfr once each manufacturer establishes laboratory report formats suitable for their needs and the personnel at each manufacturer gain experience with producing them. Once the report formats are established at a manufacturer, only data and results sections of each report will need to be rewritten for each certification application. NIOSH also will assume that manufacturers will use word processors to reduce the paperwork burden hours. NIOSH estimates the potential cost for the domestic industry due to § 84.30 in the second and subsequent years (e.g., 1991–1995) as:

($23.09/hr)(350 hrs/mfr)(32 mfrs) = $258,608/yr

that will be rounded to $259,000/yr.

k. § 84.32 Denial of Certification

Based on professional judgment NIOSH will assume that Institute testing will lead to an average of one certification denial per year per manufacturer (i.e., 32 certification denials per year for the 32 domestic manufacturers). NIOSH will assume it will require a manufacturer ten hours per denial to prepare the

required § 84.32(c) report if the manufacturer elects to resubmit the certification application. Thus NIOSH estimates an annual mean burden for § 84.32(c) of:

$$(1 \text{ denial/yr/mfr})(10 \text{ hrs/reply}) = 10 \text{ hrs/yr/mfr.}$$

Then for a personnel cost of $23.09/hr in 1992, the annual potential cost for the domestic respirator industry under § 84.32(c) is:

$$(32 \text{ mfrs})(\$23.09/\text{hr})(10) \text{ hrs/yr/mfr} = \$7{,}408/\text{yr}$$

that will be rounded to $7,000/yr.

l. §§ 84.230–235 Face Seal Performance Test

NIOSH has estimated the potential costs due to the new face seal performance test requirements as the sum of three component costs: (1) capital costs of the quantitative fit test equipment, (2) operating costs for identifying and maintaining each 25–person panel, and (3) operating costs to conduct the tests. For the capital costs of the test equipment, NIOSH will assume that most, if not all, respirator manufacturers currently have this equipment. The use of the proposed 25–person panel for respirator design and evaluation is not new to the respirator industry. Mr. Dick Flynn of North Safety Equipment recently stated that "many respirator manufacturers now use a 25–person panel to develop and test respira-

tor fit characteristics."[88] Thus, no potential costs will be estimated for the purchase of capital equipment.

For the operating costs necessary for identifying and maintaining a 25-person test panel (makeup of which will be dependent upon facial size), NIOSH estimates that it will take 40 hours to initially identify each 25-person test panel and 8 hours/year to maintain the appropriate facial sizes on the panel. For operating costs, NIOSH will assume professional level personnel are required at a cost in 1992 of ($60,000/year) times $(1.04)^{4.5}$ = $34.60/hour. Thus the initial cost to identify and maintain each 25-person test panel in the first year is estimated as:

$$(40 \text{ hours/panel} + 8 \text{ hours/panel})(\$34.60/\text{hr}) = \$1,661/\text{panel}.$$

Then NIOSH will assume a worst case situation whereby all 32 domestic manufacturers will need to maintain their own panel. Then the initial cost for the domestic industry to identify and maintain 32 25-person test panels in the first year (1990-1991) is estimated as:

$$(32 \text{ panels})(\$1,661/\text{yr/panel}) = \$53,154.$$

The annual operating costs for panel maintenance in the second and subsequent years (e.g., 1991-1995) for 32 panels are estimated as:

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[88] PPE: Balancing Supply and Demand, *Occupational Hazards* (August 1988), p. 41.

(8 hrs/yr/panel)($34.60/hr)(32 panels) = $8,859/yr

each facepiece model, NIOSH estimates that 10 panel members can be fit tested daily. NIOSH also estimates that the 1988 cost for technical personnel and quantitative fit testing equipment was about $900/day. The estimated cost in 1992 is ($900/day) times $(1.04)^{4.5}$ = $1,074/day. Then the operating costs for conducting the quantitative fit tests on 25 persons for each respirator in 1992 are estimated as:

[(25 persons/facepiece)/(10 persons/day)]($1,074/day) = $2,685/facepiece.

NIOSH will assume that 250 negative pressure facepieces will need to be tested by the domestic industry in each of the five years after the effective date of Subpart R. Thus the annual potential operating costs for facepiece performance testing by the domestic industry in 1992 are estimated as

($2,685/facepiece)(250 facepieces/yr) = $671,250/yr.

Finally, the annual potential total cos
der Subpart R are estimated as the sum of the panel identification/maintenance costs plus the operating costs. In the first year of Subpart R:

$($53,154/yr)(1.04^{2.5}/1.04^{4.5})$ + $($671,250/yr)(1.04^{2.5}/1.04^{4.5})$ = $669,784

that will be rounded to $670,000. In the second and subsequent years:

($8,859/yr) + ($671,250/yr) = $680,109/yr

that will be rounded to $680,000/yr. The incremental cost estimate in this section are sensitive to multiple variables given in the cost algorithms. NIOSH welcomes specific comments and data bearing on these estimates.

m. § 84.293 Particulate Air-Purifying Respirators: Filter Tests

NIOSH is proposing to modify the current filter performance requirements by deleting the time-integrated performance tests and replacing them with instantaneous penetration tests conducted under representative environmental conditions. The new performance tests will utilize severe test conditions that are representative of conditions typically encountered in actual filter respirator use. The new test requirements proposed by NIOSH will change the certification classifications of air-purifying respirators, but the overwhelming majority of currently certified respirators will need no or minimal design changes.

The potential costs created by this section are due to the potential need to purchase the necessary aerosol test equipment. Two alternative scenarios form the range boundaries for potential costs of this equipment. The first scenario is a worst case and assumes that all 16 manufacturers of filter respirators will need to purchase the equipment. The second scenario is the best case for respirator

manufacturers and assumes that a third party will purchase the necessary test facilities and perform filter testing for small manufacturers on a fee-for-service basis. This approach would save respirator manufacturers about $100,000 to $200,000 in the first year after the effective date of Part 84 since each filter-respirator manufacturer would not have to purchase the necessary test equipment. For this analysis NIOSH assumed the first and worst-case scenario.

The minimum cost for the test equipment in 1988 was $12,000. These costs will occur only in the first year after the effective date of 42 CFR Part 84. Thus the first year potential costs in 1990 – 1991 due to § 84.293 are estimated as

$$(\$12{,}000/\text{mfr})(1.04)^{4.5}(16 \text{ mfrs}) = \$229{,}110.$$

that will be rounded to $229,000.

n. § 84.331 Certification Applications

NIOSH experience under 30 CFR Part 11 indicates that manufacturers rarely submit certification applications for respirators intended for protection against specific unlisted gases or vapors. In the absence of survey data, based on professional judgment NIOSH estimates an average annual burden for § 84.331 of 3 hrs/yr/mfr (i.e., 96 hrs/yr for the 32 domestic manufacturers) for the required information on safety and health effects. At an average personnel cost of $23.09/hr in 1992, NIOSH estimates an annual potential cost for the domestic industry due to § 84.331 of:

($23.09/hr)(3 hr/yr/mfr)(32 mfrs) = $2,215/yr

that will be rounded to $2,000/yr.

o. § 84.332 General Test Requirements

NIOSH experience under 30 CFR Part 11 indicates that manufacturers rarely submit certification applications for specific unlisted gases or vapors. In the absence of survey data, based on professional judgment NIOSH estimates an average annual burden for § 84.332 of 10 hrs/yr/mfr (i.e., 320 hrs/yr for the 32 domestic manufacturers) for the required data on toxicity and chemical behavior. At an average personnel cost of $23.09/hr in 1992, NIOSH estimates an annual potential cost for the domestic industry due to § 84.332 of:

($23.09/hr)(10 hr/yr/mfr)(32 mfrs) = $7,408/yr

that will be rounded to $7,000/yr.

p. § 84.334 Requirements for End-of-Service-Life Indicators

NIOSH experience under 30 CFR Part 11 indicates that manufacturers rarely submit certification applications for end-of-service-life indicators (ESLI). NIOSH has certified only two ESLIs under similar existing provisions. In the absence of

survey data, based on professional judgment NIOSH estimates an average annual burden for § 84.334(b) of 10 hrs/yr/mfr (i.e., 320 hrs/yr for the 32 domestic manufacturers) for the required ESLI performance data. At an average personnel cost of $23.09/hr in 1992, NIOSH estimates an annual potential cost for the domestic industry due to § 84.334(b) of:

$$(\$23.09/hr)(10\ hr/yr/mfr)(32\ mfrs) = \$7,408/yr$$

that will be rounded to $7,000/yr.

4. Provisions with Negligible Potential Costs

a. § 84.50 User Instructions

The potential costs to prepare the user instructions required in § 84.50 are excluded by NIOSH because these instructions are presently prepared by the manufacturers in the normal course of their marketing activities. The required documents are considered usual and customary in the respirator manufacturing industry.

b. § 84.51 Maintenance Manual

The potential costs to prepare the maintenance manuals required in § 84.51 are excluded by NIOSH because these manuals are currently prepared by the manufacturers in the normal course of their activities. Their preparation is usual and customary in the respirator manufacturing industry.

c. § 84.258 SCBA Vibration Tests

NIOSH proposes to incorporate requirements for SCBA vibration resistance under conditions representing the transport of these respirators on mobile fire apparatus, heavy construction equipment, and mining equipment. The majority of SCBA manufacturers claim that one or more of their respirators have been successfully tested for vibration resistance in accordance with the NFPA vibration and shock standard[89] that NIOSH has proposed as an SCBA certification test. Thus, NIOSH concludes that negligible potential costs will result from this provision.

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[89] National Fire Protection Association: *NFPA 1981 Open-Circuit Self-Contained Breathing Apparatus for Fire Fighters*, 1987 Edition.

d. § 84.263 SCBA Flammability Test

For SCBAs intended for firefighting and mine rescue applications, NIOSH proposes to incorporate heat- and flame-resistance requirements for SCBA harnesses and full facepieces. The performance test will represent emergency exposure to flame and radiant heating incurred by firefighters and other users in similar environments. At least five manufacturers of NIOSH-certified SCBAs claim to meet all of the NFPA criteria of 1981–1987.[90] Usually these criteria are met through the use of specially designed fire-service modifications to standard-service SCBAs. One manufacturer claims that all new harnesses on standard backmounted SCBAs are flame-resistant. NIOSH estimates these manufacturers produce at least 90% of all NIOSH-certified SCBAs sold in the United States. Thus, NIOSH has concluded that negligible potential costs will result from this provision.

However, some current SCBA facepieces cannot pass the proposed NIOSH test without modifications to the facepiece, valves, and fittings. NIOSH assumes that the several European facepieces available on NIOSH-certified SCBA will be able to comply, without modification, with the proposed provision, since the proposal is similar to European approval requirements. Thus incremental costs for several American SCBA manufacturers could be incurred for the development or procurement of nonflammable plastic parts. NIOSH concludes that negligible potential costs will result from this provision for SCBA facepieces because it

[90] Ibid.

could be handled as part of routine product redesign for upgrading purposes or routine changes in component subcontracting.

e. § 84.304 Gas and Vapor Cartridge Service Life Test

NIOSH proposes to modify the current performance test requirements for gas and vapor air-purifying elements by using test conditions that are more representative of typical storage and use conditions in high humidity environments. The new performance tests will also classify these respirators by performance instead of the current design criteria which may lead to selection errors. NIOSH concludes that negligible potential costs for different sorbents will result from this provision.

f. § 84.304(h) and .315(g) Gas and Vapor Cartridge Shelf-Life Labeling

The potential costs to prepare the shelf-life information for the purchaser and user required in §§ 84.304(h) and 84.315(g) are excluded by NIOSH. Shelf-life information is prepared by respirator manufacturers in the normal course of their activities.

g. § 84.323 Gas and Vapor Cartridge Labeling Requirements

The potential costs to prepare the user information required in § 84.323 are excluded by NIOSH because this information is prepared by the manufacturers in

the normal course of their current activities. The required information is usual and customary in the respirator manufacturing industry.

Additionally, NIOSH has concluded that the following proposed performance tests will also create negligible potential costs when compared to the current regulation. This determination assumes that all NIOSH-certified respirators are in compliance with the current requirements of 30 CFR 11.11(d) and 11.64(b). These performance test requirements are based on modifications to current tests in 30 CFR Part 11.

h. Subpart S—Self-Contained Breathing Apparatus

§ 84.243	Pressure Indicators
§ 84.244	Timers; remaining-service-life indicators
§ 84.251	Breathing-resistance test
§ 84.252	Gas-flow test
§ 84.253	By-pass flow test
§ 84.254	Service-time test: open-circuit
§ 84.255	Service-time test: closed-circuit
§ 84.256	Test for carbon dioxide
§ 84.257	Test during low-temperature operations
§ 84.260	Use tests 1 through 5
§ 84.261	Use-transfer test
§ 84.264	Regulator overpressurization

i. Subpart T—Air-line Respirators

§ 84.274	Air-supply line tests
§ 84.277	Airflow-resistance tests: Continuous -low
§ 84.278	Airflow-resistance tests: Negative-pressure
§ 84.279	Airflow-resistance tests: Positive-pressure

j. Subpart V—Particulate Air-Purifying Respirators

§ 84.292	Airflow-resistance tests

k. Subpart W—Gas and Vapor Cartridge Respirators

§ 84.303	Breathing-resistance test

l. Subpart X—Gas and Vapor Canister Respirators

§ 84.313	Breathing-resistance test

m. Subpart Y—Organic Gas and Vapor Cartridge/Canister Respirators

§ 84.326	Breathing-resistance test
§ 84.327	Particulate tests; canisters and cartridges containing filters
§ 84.328	Service-life test

F. Alternative Strategies for the Same Regulatory Goal

1. Option 1

This is a status quo option whereby NIOSH would continue to certify respirators in accordance with current provisions of 30 CFR Part 11. However, the certification test criteria in the current 30 CFR Part 11 provide insufficient evidence for NIOSH to reliably certify industrial respirators. The present regulatory criteria cannot assure the safety and performance of these devices in all cases. Many of the current certification tests are obsolete and do not represent typical use conditions for many NIOSH-certified respirators. The current certification categories stifle design flexibility, hamper innovation, and hinder the marketing of more cost-effective respirators. Manufacturers, users, and NIOSH are in general agreement that 30 CFR Part 11 must be revised. For these reasons this option is not acceptable.

2. Option 2

NIOSH would certify respirators in accordance with 42 CFR Part 84 requirements as proposed in the *Federal Register* on August 27, 1987. This option does not incorporate the numerous valid comments from manufacturers and users and would require workplace or simulated workplace testing. Such testing has many valuable aspects associated with it, is ultimately the only way to demonstrate the level of protection provided to the user, and will provide maximum protection to the public health. However, the concerns regarding the technical feasibility of workplace or simulated workplace testing submitted to the docket cannot be dismissed. For these reasons this option is not feasible.

3. Option 3

Because of the deficiencies of the preceding two options, NIOSH chose instead to extensively revise the first NPRM for 42 CFR Part 84. The Institute not only removed the proposal for workplace or simulated workplace testing, but also made hundreds of major and minor revisions, deletions, and additions to improve the first proposal and reduce potential incremental costs. The Institute estimates that the direct incremental costs of this second proposal are substantially lower than they would have been had not the cost-reducing changes been made. At the same time, NIOSH has concluded that the second NPRM will retain and may even accelerate both the cost-reducing and health risk-reducing benefits of the first proposal.

Appendix—Cell Formulae for Spreadsheet Model

B1: [W13] '|========= Air-purifying ==========|
E1: [W13] '|========== Atmosphere-supplying ==========|

B2: [W13] ' NP APR
C2: [W13] ' Gas masks
D2: [W12] "PAPRs
E2: [W13] ^Supld-air
F2: [W13] "Firefg SCBAs
G2: [W12] "Nofr SCBA
H2: [W12] ^Escp SCBA
I2: [W13] ^Disposables
J2: [W18] "ALL RESPS

A3: [W12] 'Resp class
B3: [W13] ^ NP
C3: [W13] ^ GM
D3: [W12] ^ PR
E3: [W13] ^ SA
F3: [W13] ^ FS
G3: [W12] ^ NS
H3: [W12] ^ ES
J3: [W18] "(Row totals)

A5: [W12] ''80 Rsps/yr
B5: (,0) U [W13] 1703000
C5: (,0) U [W13] 44000
D5: (,0) U [W12] 24000
E5: (,0) U [W13] 130000
F5: (,0) [W13] "N/A
G5: (,0) [W12] "N/A
H5: (,0) [W12] "N/A
I5: (,0) [W13] 76700000
J5: (,0) [W18] "N/A

A6: [W12] ''80 Resps
B6: (,0) [W13] +B5*(1-B10)*B14
C6: (,0) [W13] +C5*(1-C10)*C14
D6: (,0) [W12] +D5*(1-D10)*D14

E6: (,0) [W13] +E5*(1-E10)*E14
F6: (,0) [W13] "N/A
G6: (,0) [W12] "N/A
H6: (,0) [W12] "N/A
I6: (,0) [W13] 76700000
J6: (,0) [W18] "N/A

A7: [W12] ''90 Resps
B7: (,0) [W13] +B6*(1+B10)^10
C7: (,0) [W13] +C6*(1+C10)^10
D7: (,0) [W12] +D6*(1+D10)^10
E7: (,0) [W13] +E6*(1+E10)^10
F7: (,0) U [W13] 408000
G7: (,0) U [W12] 72000
H7: (,0) [W12] (F8+G8)/0.9*0.1+100000
I7: (,0) [W13] 76700000*(1+I10)^10
J7: (,0) [W18] @SUM(B7..H7)

A8: [W12] ''90 Users
B8: (,0) [W13] +B36*B17
C8: (,0) [W13] +C36*C17
D8: (,0) [W12] +D36*D17
E8: (,0) [W13] +E36*E17
F8: (,0) [W13] +F36*F17
G8: (,0) [W12] +G36*G17
H8: (,0) [W12] +H36*H17
I8: (,0) [W13] +I7*I17
J8: (,0) [W18] @SUM(B8..I8)

A10: [W12] 'Growth/year
B10: U [W13] 0.04
C10: [W13] +B10
D10: [W12] +C10
E10: [W13] +D10
F10: [W13] 0
G10: [W12] +F10
H10: [W12] +F10
I10: U [W13] 0.04
J10: [W18] "N/A

A11: [W12] 'FR(i)
B11: U [W13] 0.75
C11: U [W13] 0.75
D11: U [W12] 0.75
E11: U [W13] 0.75
F11: U [W13] 0.9
G11: U [W12] 0.9
H11: U [W12] 0.65
I11: [W13] "N/A
J11: [W18] "N/A

A12: [W12] 'FU(i)
B12: U [W13] 0.1
C12: U [W13] 0.1
D12: U [W12] 0.4
E12: U [W13] 0.5
F12: U [W13] 0.3
G12: U [W12] 0.3
H12: U [W12] 0.45
I12: [W13] "N/A
J12: [W18] "N/A

A13: [W12] 'P(i) yrs
B13: (F0) U [W13] 5
C13: (F0) U [W13] 5
D13: (F0) U [W12] 5
E13: (F0) U [W13] 6
F13: (F0) U [W13] 5
G13: (F0) U [W12] 8
H13: (F0) U [W12] 8
I13: [W13] "N/A
J13: [W18] "N/A

A14: [W12] 'Y(i) yrs
B14: (F0) U [W13] 2
C14: (F0) U [W13] 6
D14: (F0) U [W12] 5
E14: (F0) U [W13] 6
F14: (F0) U [W13] 8
G14: (F0) U [W12] 8

H14: (F0) U [W12] 8
I14: [W13] "N/A
J14: [W18] "N/A

A15: [W12] 'U(i) in '90
B15: (C0) U [W13] 5
C15: (C0) U [W13] 10
D15: (C0) U [W12] 10
E15: (C0) U [W13] 100
F15: (C0) U [W13] 350
G15: (C0) U [W12] 350
H15: (C0) U [W12] 200
I15: [W13] "N/A
J15: [W18] "N/A

A16: [W12] 'R(i) in '90
B16: (C0) U [W13] 15
C16: (C0) U [W13] 125
D16: (C0) U [W12] 400
E16: (C0) U [W13] 500
F16: (C0) U [W13] 1600
G16: (C0) U [W12] 1600
H16: (C0) U [W12] 800
I16: (C0) [W13] 1
J16: [W18] "N/A

A17: [W12] 'FW(i) usr/rp
B17: U [W13] 0.5
C17: U [W13] 0.5
D17: U [W12] 1
E17: U [W13] 1
F17: U [W13] 1
G17: U [W12] 1
H17: U [W12] 1
I17: [W13] 1/40
J17: [W18] "N/A

A18: [W12] 'Frac > P(i)
B18: (F3) [W13] @IF(B14<B13,0,1-(B13/B14))
C18: (F3) [W13] @IF(C14<C13,0,1-(C13/C14))

```
D18: (F3) [W12] @IF(D14<D13,0,1-(D13/D14))
E18: (F3) [W13] @IF(E14<E13,0,1-(E13/E14))
F18: (F3) [W13] @IF(F14<F13,0,1-(F13/F14))
G18: (F3) [W12] @IF(G14<G13,0,1-(G13/G14))
H18: (F3) [W12] @IF(H14<H13,0,1-(H13/H14))
I18: [W13] 0
J18: [W18] "N/A

A20: [W12] '$UG(i)
B20: (C0) [W13] @IF(B14<B13,0,+B11*B12*B18*B7*B15)
C20: (C0) [W13] @IF(C14<C13,0,+C11*C12*C18*C7*C15)
D20: (C0) [W12] @IF(D14<D13,0,+D11*D12*D18*D7*D15)
E20: (C0) [W13] @IF(E14<E13,0,+E11*E12*E18*E7*E15)
F20: (C0) [W13] @IF(F14<F13,0,+F11*F12*F18*F7*F15)
G20: (C0) [W12] @IF(G14<G13,0,+G11*G12*G18*G7*G15)
H20: (C0) [W12] @IF(H14<H13,0,+H11*H12*H18*H7*H15)
I20: (C0) [W13] 0
J20: (C0) [W18] @SUM(B20..H20)

A21: [W12] '$RP(i)
B21: (C0) [W13] @IF(B14<B13,0,(1-B11)*B18*B7*B16)
C21: (C0) [W13] @IF(C14<C13,0,(1-C11)*C18*C7*C16)
D21: (C0) [W12] @IF(D14<D13,0,(1-D11)*D18*D7*D16)
E21: (C0) [W13] @IF(E14<E13,0,(1-E11)*E18*E7*E16)
F21: (C0) [W13] @IF(F14<F13,0,(1-F11)*F18*F7*F16)
G21: (C0) [W12] @IF(G14<G13,0,(1-G11)*G18*G7*G16)
H21: (C0) [W12] @IF(H14<H13,0,(1-H11)*H18*H7*H16)
I21: (C0) [W13] 0
J21: (C0) [W18] @SUM(B21..H21)

A22: [W12] '$UG + $RP
B22: (C0) [W13] +B20+B21
C22: (C0) [W13] +C20+C21
D22: (C0) [W12] +D20+D21
E22: (C0) [W13] +E20+E21
F22: (C0) [W13] +F20+F21
G22: (C0) [W12] +G20+G21
H22: (C0) [W12] +H20+H21
I22: (C0) [W13] 0
J22: (C0) [W18] @SUM(B22..H22)
```

B24: [W13] '# of nondisposable respirators in-service in 1990.....
G24: (,0) [W12] @SUM(B7..H7)

B25: [W13] '# of disposables used in 1990.....
G25: (,0) [W12] +I7

B26: [W13] '# of disposable respirator users in 1990.....
G26: (,0) [W12] +I8

B27: [W13] '# of nondisposable respirator users in 1990
G27: (,0) [W12] @SUM(B8..H8)-(0.64*E8)

B29: [W13] 'Total # users of NIOSH-certified respirators in 1990.....
G29: (,0) [W12] +G26+G27

B30: [W13] 'Total potential costs to owners for 1990-1995.....
G30: (C0) [W12] @SUM(B22..H22)

B31: [W13] "Annual potential costs to owners for 1990-1995.....
G31: (C0) [W12] +G30/5

A33: [W12] '$/respirator
B33: (C2) [W13] +B22/B36
C33: (C2) [W13] +C22/C36
D33: (C2) [W12] +D22/D36
E33: (C2) [W13] +E22/E36
F33: (C2) [W13] +F22/F36
G33: (C2) [W12] +G22/G36
H33: (C2) [W12] +H22/H36
I33: (C0) [W13] 0
J33: [W18] "N/A

A34: [W12] '$/user
B34: (C2) [W13] +B22/B8
C34: (C2) [W13] +C22/C8
D34: (C2) [W12] +D22/D8
E34: (C2) [W13] +E22/E8
F34: (C2) [W13] +F22/F8
G34: (C2) [W12] +G22/G8
H34: (C2) [W12] +H22/H8

I34: (C0) [W13] 0
J34: [W18] "N/A

A36: [W12] 'Cell 1 rsps
B36: (,0) [W13] +B7
C36: (,0) [W13] +C7
D36: (,0) [W12] +D7
E36: (,0) [W13] +E7
F36: (,0) [W13] +F7
G36: (,0) [W12] +G7
H36: (,0) [W12] +H7
I36: [W13] "N/A
J36: (,0) [W18] @SUM(B36..H36)

A37: [W12] 'Cell 6 rsps
B37: (,0) [W13] +B7*(1-B11)
C37: (,0) [W13] +C7*(1-C11)
D37: (,0) [W12] +D7*(1-D11)
E37: (,0) [W13] +E7*(1-E11)
F37: (,0) [W13] +F7*(1-F11)
G37: (,0) [W12] +G7*(1-G11)
H37: (,0) [W12] +H7*(1-H11)
I37: [W13] "N/A
J37: (,0) [W18] @SUM(B37..H37)

A38: [W12] 'Cell 7 rsps
B38: (,0) [W13] +B7*B11*(1-B12)
C38: (,0) [W13] +C7*C11*(1-C12)
D38: (,0) [W12] +D7*D11*(1-D12)
E38: (,0) [W13] +E7*E11*(1-E12)
F38: (,0) [W13] +F7*F11*(1-F12)
G38: (,0) [W12] +G7*G11*(1-G12)
H38: (,0) [W12] +H7*H11*(1-H12)
I38: [W13] "N/A
J38: (,0) [W18] @SUM(B38..H38)

A39: [W12] 'Cell 8 rsps
B39: (,0) [W13] +B7*B11*B12*(1-B18)
C39: (,0) [W13] +C7*C11*C12*(1-C18)
D39: (,0) [W12] +D7*D11*D12*(1-D18)

E39: (,0) [W13] +E7*E11*E12*(1-E18)
F39: (,0) [W13] +F7*F11*F12*(1-F18)
G39: (,0) [W12] +G7*G11*G12*(1-G18)
H39: (,0) [W12] +H7*H11*H12*(1-H18)
I39: [W13] "N/A
J39: (,0) [W18] @SUM(B39..H39)

A40: [W12] 'Cell 9 rsps
B40: (,0) [W13] +B7*B11*B12*B18
C40: (,0) [W13] +C7*C11*C12*C18
D40: (,0) [W12] +D7*D11*D12*D18
E40: (,0) [W13] +E7*E11*E12*E18
F40: (,0) [W13] +F7*F11*F12*F18
G40: (,0) [W12] +G7*G11*G12*G18
H40: (,0) [W12] +H7*H11*H12*H18
I40: [W13] "N/A
J40: (,0) [W18] @SUM(B40..H40)

A41: [W12] 'Cell 10 rsps
B41: (,0) [W13] +B37*B18
C41: (,0) [W13] +C37*C18
D41: (,0) [W12] +D37*D18
E41: (,0) [W13] +E37*E18
F41: (,0) [W13] +F37*F18
G41: (,0) [W12] +G37*G18
H41: (,0) [W12] +H37*H18
I41: [W13] "N/A
J41: (,0) [W18] @SUM(B41..H41)

A42: [W12] 'Cell 11 rsps
B42: (,0) [W13] +B37-B41
C42: (,0) [W13] +C37-C41
D42: (,0) [W12] +D37-D41
E42: (,0) [W13] +E37-E41
F42: (,0) [W13] +F37-F41
G42: (,0) [W12] +G37-G41
H42: (,0) [W12] +H37-H41
I42: [W13] "N/A
J42: (,0) [W18] @SUM(B42..H42)

A44: [W12] ''88 Sales
B44: (C0) [W13] +B5*(1+B10)^8*B16
C44: (C0) [W13] +C5*(1+C10)^8*C16
D44: (C0) [W12] +D5*(1+D10)^8*D16
E44: (C0) [W13] +E5*(1+E10)^8*E16
F44: (C0) [W13] +F7/F14*F16
G44: (C0) [W12] +G7/G14*G16
H44: (C0) [W12] +H5*(1+H10)^8*H16
I44: (C0) [W13] +I5*(1+I10)^8*I16
J44: (C0) [W18] @SUM(B44..I44)

A45: [W12] | |\012