DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

Occupational Exposure to Cotton Dust

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final rule.

SUMMARY: OSHA is amending its occupational health standard for cotton dust issued in 1978 (29 CFR 1910.1043). The revisions for the textile industry will improve the cost-effectiveness and performance-orientation of the standard while maintaining full health protection. The American Textile Manufacturers Institute (ATMI) and the Amalgamated Clothing and Textile Workers Union (ACTWU) submitted many identical recommendations to OSHA. They generally support the final revisions for the textile industry. These revisions include incorporation of an action level; modification of exposure monitoring requirements; extension of compliance deadlines for ring spinning of coarse count yarn with a high cotton content; addition of a protocol for determining equivalency to the vertical elutriator; incorporation of a wage retention provision; exclusion of oil mist from the definition of cotton dust; clarification of scope of coverage; and substantial changes to the washed cotton provisions reflecting current research. The standard's permissible exposure limits (PELs) of 200 micrograms per cubic meter (200 $\mu g/m^3$) for yarn production and 750 $\mu g/m^3$ for slashing and weaving operations and methods of compliance provisions with preference for engineering controls remain unchanged. This reflects the success of the industry in already achieving these levels with more productive modern equipment at less cost than initially predicted and the significantly improved level of health of textile workers resulting from compliance with the standard. Both ATMI and ACTWU agree that no changes are appropriate in these provisions.

The 1978 cotton dust standard in general has not taken effect in the nontextile industries because of judicial and administrative stays and because OSHA has been awaiting the completion of additional research, but it would eventually take effect absent action by OSHA. These segments are currently covered by the 1000 $\mu g/m^3$ limit of 29 CFR 1910.1000. OSHA is deregulating knitting, classing and warehousing operations by exempting them from all provisions of the 1978 cotton dust standard and by exempting them from all provisions of 29 CFR 1910.1000 (the cotton dust standard adopted in 1971). New research does not demonstrate a significant health risk at current exposures for these segments which could be substantially reduced by exposure limits and other provisions nor does it indicate that significant risk would exist if all exposure limits are eliminated. NIOSH will perform a further study of the health of the workers in those operations to check on the corrections of those conclusions. OSHA is also deregulating cotton seed processing operations for similar reasons except that it is retaining medical surveillance because the research indicates medical surveillance is needed to assure the continuing health of employees in this sector.

OSHA is exempting waste processing and garnetting operations from all except the medical provisions of § 1910.1043 and retaining the 1000 $\mu g/m^3$ exposure limit of § 1910.1000 interpreted as a respirable dust limit. Health studies in waste processing indicate that uncontrolled exposure leads to a risk of byssinosis. At current exposure levels, there is evidence of chronic bronchitis and pulmonary function reductions but no evidence of byssinosis. However, there is not sufficient evidence demonstrating a significant risk at current exposures which would be eliminated or substantially decreased by lowering the PEL to justify a lower exposure limit in waste processing operations.

These changes in textiles and nontextiles will result in cost savings of $57.3 million in capital expenditures and $28.9 million per year in annual operating costs. They will maintain health protection for employees.

EFFECTIVE DATE: These amendments take effect February 11, 1986; except for § 1910.1043 which contain information collection requirements that have been submitted to the Office of Management and Budget for approval.

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SUPPLEMENTARY INFORMATION:

I. Introduction

A. The Format of This Document (The Preamble).

The preamble accompanying this final standard is divided into eight parts, numbered I through VIII. The following is a table of contents:

References to the rulemaking record are in the text of the preamble and the following abbreviations have been used: number in Docket H–052.

1. Ex.: Exhibit Docket H–052 is located in Room N3670 at the Department of Labor.

2. Tr.: Transcript page number (All citations are from the 1983 hearings unless otherwise noted).

B. Recordkeeping Requirements

The recordkeeping requirements in this standard are being considered by the Office of Management and Budget under the Paperwork Reduction Act of 1980, Pub. L. 96–511, 44 U.S.C. 3501, *et seq.* They will not take effect until approved.

C. Summary

Pursuant to sections 6(b), 8(c) and 8(g) of the Occupational Safety and Health Act of 1970 (the Act) (84 Stat. 1593, 1599; 29 U.S.C. 655, 657). Secretary of Labor's Order No. 9–83 (48 FR 35736) and 29 CFR Part 1911, OSHA is amending some paragraphs of 29 CFR 1910.1043 (the new cotton dust standard issued in 1978 pursuant to section 6(b) of the OSH Act). It is also issuing an interpretation to and amending the exposure limit for cotton dust contained in 29 CFR 1910.1000, Table Z–1 (the pre-existing standard for cotton dust issued pursuant to 6(a) of the OSH Act).

OSHA proposed amendments to the cotton dust standards (§ 1910.1043 and § 1910.1000) on June 10, 1983 (48 FR 26962). The proposal included an extensive explanatory preamble. Public comments were solicited and public hearings took place in Washington, DC, Dallas, Texas and Columbia, South Carolina. The final amendments are based on an extensive record and are explained in this preamble.

Together the final amendments result in substantial deregulation while maintaining health protection for employees. The changes result in cost savings of $57.3 million in capital expenditures and $28.9 million per year in annual operating costs.

Changes are being made to the cotton dust standard in textiles to make it more cost effective and performance oriented. Basic provisions are being retained because they have been achieved and have improved the health of cotton textile workers. Both the American Textile Manufacturers Institutes and Amalgamated Clothing and Textile Workers Union generally approve of the cotton dust standard as amended.

No changes are being made in the permissible exposure limit (PEL) and compliance strategy for the textile industry. The PELs remain 200 $\mu g/m^3$ for yarn production, 750 $\mu g/m^3$ for slashing and weaving and 500 $\mu g/m^3$ for wastehouses in textile mills. The studies by Imbus and ELB indicate that the standard has substantially reduced the incidence of byssinosis and declines in lung function from the levels of the early 1970's, a greater reduction than had been previously predicted. The Beck study confirms and expands on the prior studies by Merchant that the higher exposures of the early seventies and earlier lead not only to significant risk of acute byssinotic symptoms but also to chronic lung disease. OSHA expects that the much lower levels now in effect will substantially reduce and could possibly eliminate this chronic disease for newer employees. Both the American Textile Manufacturers Institute (ATMI) and the Amalgamated Clothing and Textile Workers Union (ACTWU) agree to the retention of the exposure limits. OSHA commends both the industry and the union whose efforts along with OSHA's have led to this substantial improvement in the health of workers currently employed in the cotton textile industry.

Current studies by Centaur and others show that it has been technically and economically feasible to comply with the standard in the textile industry. Virtually the entire industry has come into compliance utilizing modern production equipment in conjunction with increased ventilation (except for certain operations, discussed below). Such new equipment (chute fed cards, projectile looms, open end spinning, etc.) has substantially increased industry productivity while lowering both cotton dust and noise levels. The cost of the standard has proven to be half of the cost predicted by OSHA in 1978 and has proven to be economically feasible for the industry. Therefore, OSHA finds no basis for changing the compliance strategy. Again, both ATMI and ACTWU agree with this conclusion.

A number of amendments are being made to § 1910.1043 for the textile industry reflecting evidence in the record. These changes improve cost-effectiveness and performance-orientation while maintaining full health protection. Some represent new technological developments such as improved monitoring devices and advances in washed cotton. Most of these changes are supported by both ACTWU and ATMI.

The terms "blow off" and "blow down," applicable to the use of compressed air for cleaning, have been clarified. This is being done to indicate when employees must vacate an area and what protective equipment is needed.

Lubricating oils are being excluded from the definition of cotton dust. This decision is based on extensive evidence in the record indicating that lubricating oil mist generated by Sulzer looms was not part of the cotton dust samples measured in the Merchant studies, and thus was not a part of the dose-response calculations. Therefore, this exclusion will not raise risk rates. Some types of modern looms, which were not used in the early seventies, produce a mist composed of lubricating oil. This oil is captured by the vertical elutriator thereby increasing the reported weight of cotton dust present.

The definition of cotton dust continues to include mineral and synthetic dusts present in the atmosphere. They were present in the samples measured in the Merchant and other studies, and were part of the dose-response curve. Excluding these elements from the definition of cotton dust would increase the risk rate of byssinosis at any given exposure limit set. OSHA has no substantial evidentiary base to justify making such a change.

An action level is incorporated into the standard at one-half the PEL. Employers may reduce medical examination frequencies if they develop methods to reduce exposures below the action level. This improves the health of the employees through lower exposures while saving medical costs for the employer, thereby increasing the cost effectiveness of the standard. Medical experts stated that the reduced frequency at lower exposures will be protective for employees.

The amendments set forth a statistically valid method for determining whether alternate exposure monitoring devices are equivalent to the vertical elutriator, the method upon which the standard was based. This will encourage the development and use of alternative devices which are lighter, less labor intensive and easier to use than the vertical elutriator.

Monitoring frequencies are reduced to yearly when worker exposure is less than the PEL because the large data base recently developed means that less frequent monitoring will be as protective at these levels. The time to notify employees of exposures has been

increased from 5 days to 20 days because the shorter notification period created feasibility problems.

The standard is changed to give employers wider discretion in checking ventilation equipment to improve the performance-orientation of the standard and reduce the paperwork burden. Respirator provisions are basically unchanged, but some clarifications are made reflecting current terminology and field practice.

The wage retention provision is incorporated into the standard as recommended both by the ATMI and ACTWU. The existing standard provides that if an employee is working in an area with exposures above the PEL and a medical condition prevents the employee from wearing any type of respirator, the employee is to be transferred to an area where respirator use is not needed if a job is available. The amendment requires that the employer not reduce the employee's pay if such a transfer is made. Of course, if no such job is available, this provision is inoperable.

The Supreme Court had initially invalidated a similar provision in the 1978 standard because OSHA had not clearly explained a health related need for the provision. At the hearing, evidence was introduced that some employees are unwilling to submit to medical examinations because of fear of being transferred to lower-paying jobs. As a result, medical conditions that could be diagnosed and reversed may develop into chronic conditions. This is a special problem for older workers who fear the loss of both current pay and a reduction in their pension and social security benefits which are based on their final few years of pay. In view of the evidence indicating a health need for this provision and the recommendation of the parties with the most direct interest, the ATMI and the ACTWU, OSHA is amending the standard.

The standard is being changed to grant a two-year extension of the requirement to achieve compliance with engineering controls for ring spinning and auxiliary operations of coarse, high cotton content yarns. The record indicates that there are some technical feasibility problems in complying with add-on ventilation at the present time. However, open-end spinning equipment is rapidly being improved to meet the needs of customers and will be able to achieve the exposure limit while substantially increasing productivity. The extension will permit compliance using more efficient new equipment without the major inefficiency of an expensive intermediate stage of limited usefulness.

Based on successful recent research, major changes are being made to the washed cotton provisions. Merchant's studies indicated that cotton washed in a caustic and water solution at high temperatures did not create byssinotic symptoms. However, such cotton could not be processed into usable yarn and cloth. A Washed Cotton Task Force was set up with representatives of ACTWU, ATMI, the National Cotton Council, Cotton Incorporated, NIOSH and the Department of Agriculture and its activities were funded by the Department of Agriculture and Cotton, Inc. Under the direction of the Task Force, various washing methods were tested. The cotton produced was then tested under carefully controlled conditions to determine if it caused any reduction in lung function. Several washing methods were devised which appear to be commercially viable and which result in cotton fibers which can be processed. Most importantly, exposure to dust from cotton washed in certain manners does not result in any acute changes in pulmonary function.

Based on this research, the Task Force made recommendations as to the types of washed cotton that could safely be removed from regulation by some or most provisions of the cotton dust standard. Based on the test results, the recommendations of the Task Force and the evidence in the record, OSHA has broadened the definitions of the type of washed cotton exempt from regulation. These changes, more fully explained elsewhere in this preamble, should increase the cost-effectiveness of the standard, and employees exposed to washed cotton as defined will remain fully protected.

The cotton dust standards (§ 1910.1043 and § 1910.1000) are being substantially changed as to scope of coverage for the nontextile segments of the industry. The nontextile segments are knitting including hosiery manufacturing, classing, warehousing, cotton seed processing and waste processing operations. (Knitting has consistently been included with the nontextile industries in the cotton dust regulatory proceedings and that terminology is maintained in this document.)

The 1978 cotton dust standard, § 1910.1043, was intended to cover the nontextile operations and included a 500 $\mu g/m^3$ exposure limit for those operations. Substantially less health data were available on these segments. The standard is not in effect in any of these segments because of various judicial and administrative stays. However, the standard would take effect eventually if OSHA did not revoke coverage. The nontextile segments are currently covered by the 1000 $\mu g/m^3$ limit of § 1910.1000 Table Z-1 which would remain in effect unless replaced by a 6(b) standard or revoked. The specific legal history of each segment is complex and detailed below. Essentially, each industry segment has been remanded to the Agency by the Court of Appeals for further consideration. This review is pursuant to those remand orders.

Since the issuance of § 1910.1043 in 1978, a number of new studies on these segments have been completed by NIOSH and others. OSHA has reviewed these newer studies in conjunction with the older studies in making its final determinations for the nontextile industries. However, because the exact etiologic agent of byssinosis is not known and because the content of cotton dust may vary from one segment to another, the Agency is not extrapolating the results of the studies conducted in the textile industries to the nontextile industries.

In 1983, Drs. Boehlecke and Battigelli completed an extensive and high quality study of knitting employees. They indicated that there was no difference in pulmonary function between knitters and appropriate controls, and that there was no increased prevalence of byssinotic symptoms. There was some decline in lung function measured over the shift similar to that seen in control groups in woolen mills. Virtually all the employees studied were exposed to less than 500 $\mu g/m^3$. This is the only major study available of the knitting industry. Based on this study and the extensive reviews and comments about it, OSHA concludes that the evidence now available indicates no significant risk of byssinosis existed for the workers studied and that the workers in the industry will remain free of byssinosis without the need for extensive regulation. Therefore, OSHA is excluding the knitting segment from all coverage of § 1910.1043.

OSHA concludes, based on the same data, that it will better effectuate the purposes of the Act also to remove this industry from the PEL specified in § 1910.1000 and the evidence currently available indicates this will not lead to the development of significant risk. NIOSH will perform an additional study to confirm these conclusions.

NIOSH completed studies of classing employees in 1982. The study of classing workers concluded there were no acute or chronic respiratory problems among these workers, but that dust levels had been reduced from earlier levels and were quite low. The NIOSH study of

warehouse workers indicates there was some reduction in pulmonary function compared to controls. However, this was inversely related to cotton dust exposure level and therefore probably related to exposure to vehicle exhaust emissions or other noncotton dust factors.

Based on these studies and on its analysis of the record, OSHA concludes that the evidence now available in the classing and warehousing industries does not support a finding of significant risk from cotton dust exposure in these segments and that the employees will remain free of byssinotic symptoms when the industry is exempted from regulations. Accordingly, OSHA is exempting these segments from all provisions of § 1910.1043. OSHA further concludes that it will better effectuate the purposes of the Act to remove these segments from the PEL specified in § 1910.1000 and the evidence currently available indicates this will not lead to the development of significant risk. NISOH will perform an additional study to confirm these conclusions.

There are a series of post-1978 studies on cottonseed processing employees by NIOSH and by a group of investigators at Tulane University. These studies indicate that a portion of cottonseed processing workers experience an acute pulmonary reaction to cotton dust. The dust has some biologic activity but that activity is substantially less than that seen in the textile industry. There is no clear dose-response relationship and a very low prevalence of byssinosis.

Based on the lack of a dose-response relationship, the low prevalence of byssinosis and the views expressed in the record, OSHA concludes that the evidence now available does not establish the need for a permissible exposure limit. Accordingly, OSHA is exempting cottonseed processing from all except the medical surveillance provisions of § 1910.1043. The Agency finds for the same reasons that it will better effectuate the purposes of the Act to remove this segment from coverage of § 1910.1000 and that the evidence currently indicates that this deletion, in conjunction with the retention of medical surveillance, will not lead to the development of significant risk.

OSHA is retaining the requirement for medical examinations for cottonseed processing. There is a reduction in overshift FEV_1 in some current employees. The examinations will identify and provide protection for those employees. All medically qualified experts testifying on this matter recommended retaining medical surveillance for this reason. This will also serve as a backstop to assure that the health of employees not covered by any exposure limit does not decline. It also carries out the Supreme Court's analysis in *IUD* v. *API* that medical examinations may be used as a "back stop" to assure that the health of workers for whom an exposure limit is eliminated does not deteriorate.

NIOSH completed an extensive study of the waste processing industry in 1982. This study indicated an excess prevalence of chronic bronchitis and decreases in pulmonary function but no statistically significant prevalence of byssinosis or clear dose-response relationship. Based on this and other studies and the extensive comments. OSHA concludes that the evidence now available does not support the finding that a reduction of the current exposure limit of 1000 $\mu g/m^3$ total dust would result in a reduction or elimination of a significant risk. Accordingly, OSHA is exempting this sector from all except the medical provisions of § 1910.1043.

Other studies indicate that high, uncontrolled exposures, which may occur if there is no dust control, lead to byssinosis and chronic bronchitis and the NIOSH study indicates that employees currently are not free of cotton dust-related pulmonary dysfunction and chronic bronchitis. Accordingly, the evidence does not justify OSHA concluding that eliminating the § 1910.1000 exposure limit of 1000 $\mu g/m^3$ (the national consensus limit) will better effectuate the purpose of the Act. In addition, in light of the possibility of operations in the waste processing industry leading to high exposures, eliminating all exposure limits would likely lead to the development of a significant risk in this segment.

OSHA is retaining the medical provisions of § 1910.1043 for this segment to assure that cases of bronchitis and reductions in pulmonary function are diagnosed and in conjunction with the exposure limit to protect these employees. Based on the recommendation of medical experts, the 1000 $\mu g/m^3$ limit is being changed from a total dust limit to a respirable dust limit because this is a more appropriate measure of the type of dust that leads to the development of byssinosis and bronchitis. Therefore, this interpretation better relates to improving health. A 1000 $\mu g/m^3$ respirable dust limit also presents substantially fewer feasibility problems.

Miscellaneous segments where there is no evidence of risk such as bedding assembly, furniture assembly and construction are being removed from all cotton dust regulation. Knitting, classing and warehousing are being removed from all cotton dust regulation.

D. State Plans Revisions

The 25 States with their own OSHA-approved occupational safety and health plans must revise their existing standard within six months of this publication date or show OSHA why there is no need for action, e.g., because an existing State standard covering this area is already "at least as effective" as the revised Federal standard. These States are: Alaska, Arizona, California, Connecticut, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, Wyoming. (In Connecticut and New York, the plan covers only State and local government employees.)

E. History of the Regulation

Regulatory steps to address health problems in the cotton textile industry began when Great Britain legislated requirements for medical inspection of workplaces, compulsory reporting of industrial diseases, and compensation for disabled and diseased workers. By 1942, British law recognized byssinosis as an occupational disease.

In the United States, the American Conference of Government Industrial Hygienists (ACGIH) placed cotton dust on its tentative list of Threshold Limit Values (TLVs) in 1964. In 1966, ACGIH adopted 1 $\mu g/m^3$ (1000 $\mu g/m^3$ of total cotton dust as a recommended upper limit for exposure. This TLV was based upon the work of Roach and Schilling in the Lancashire cotton mills (Ex. 6–1).

Exposure to cotton dust was first regulated in the United States in 1968, when the Secretary of Labor, acting under the authority of the Walsh-Healey Act (41 U.S.C. 35 *et seq.*), promulgated the 1968 ACGIH list of Threshold Limit Values which included 1000 $\mu g/m^3$ for "Cotton dust (raw)." This Threshold Limit Value was subsequently adopted as an established Federal standard under section 6(a) of the Occupational Safety and Health Act of 1970. On September 26, 1974, pursuant to section 20(a)(3) of the Act, the Director of the National Institute for Occupational Safety and Health (NIOSH) submitted to the Secretary of Labor a criteria document which contained NIOSH's recommendations for a new cotton dust standard.

On December 28, 1976, at 41 FR 56498, OSHA proposed a revised cotton dust standard that would set a permissible exposure limit of 200 $\mu g/m^3$ averaged

over an eight hour period. An extensive record of documentary and testimonial evidence was compiled over a period of more than nine months. Among the witnesses were large corporate and small business employers, manufacturers, representatives from the affected workforce, experts in every relevant field including physicians, scientists, statisticians, economists, industrial hygienists, representatives from agriculture, and other interested parties. Virtually the entire "cotton community" participated in this rulemaking.

On June 23, 1978, at 43 FR 27350, OSHA promulgated 29 CFR 1910.1043 and set permissible exposure limits of 200 $\mu g/m^3$ of lint-free respirable cotton dust, averaged over eight hours, for yarn manufacturing; 750 $\mu g/m^3$ for slashing and weaving operations; and 500 $\mu g/m^3$ for knitting and nontextile industries which used cotton. Petitions for review were promptly filed by interested parties with United States Courts of Appeals.

In *AFL–CIO* v. *Marshall,* 617 F.2d (D.C. 1979), the District of Columbia Circuit upheld the standard for the textile industry (yarn manufacturing, slashing and weaving) and the nontextile processes of warehousing and classing. The Court held that OSHA had demonstrated that the standard would result in a substantial reduction in a significant risk, and that OSHA had demonstrated technical and economic feasibility. The Court vacated the standard for the cottonseed oil industry, finding that OSHA had failed to demonstrate economic flexibility, but it upheld OSHA's determinations of health risk and technological feasibility. The Court then remanded the record on the cottonseed oil industry to the Agency for reconsideration. The Court did not consider the validity of the standard for waste processing and waste utilization, having severed the industry representatives' petitions for review because of an administrative stay issued by OSHA for those segments of the industry (43 FR 39087, September 1, 1978). Although OSHA later lifted the administrative stay, the judicial stay remains in effect (44 FR 5438, January 26, 1979).

Representatives of the textile industry and warehousing and classing industries sought review of the Court of Appeals decision in the Supreme Court. Except for the wage retention provision, the Supreme Court upheld the standard for the textile industry (yarn manufacturing, slashing and weaving). *American Textile Manufacturers Institute, Inc.* v. *Donovan,* 452 U.S. 490 (1981). The Supreme Court upheld OSHA's conclusion that the cotton dust standard in textiles would substantially reduce a significant risk of byssinosis. The Court stated as to this issue: "It is difficult to imagine what else the agency could do to comply with the Courts' decision in *Industrial Union Department* v. *American Petroleum Institute"* (The "Benzene Decision," 448 U.S. 607 (1980) where the Supreme Court set forth the significant risk requirement). The Supreme Court also upheld the Court of Appeals finding that the standard was technically and economically feasible for the textile industry. The Court also rejected the contention that the Agency is to perform cost-benefit analyses in setting permissible exposure limits.

Earlier, on October 6, 1980, the Court at the request of OSHA and the industry had granted a petition for writ of certiorari and vacated the decision of the Court of Appeals with respect to the warehousing and classing segments of the industry. *Cotton Warehouse Association* v. *Marshall,* 449 U.S. 809 (1980). The Supreme Court instructed the Court of Appeals to reconsider the standard for these industries in light of the Supreme Court's decision in *Industrial Union Department AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607 (1980). On joint motion of the parties, the Court of Appeals then remanded the record to OSHA for the warehousing and classing segments of the industry. Order of February 3, 1981, in No. 78–1562. On July 29, 1980, OSHA issued an administrative stay of the standard to re-evaluate its applicability to warehousing and classing industries in view of *IUD* v. *API,* supra.

In its most recent action, the D.C. Circuit, at the request of OSHA, ordered that the records in the cases brought by the waste processing utilization industries, which it had previously stayed, be remanded to the Agency for further consideration. Order of March 30, 1983, in Nos. 78–1784, and consolidated cases Nos. 78–1796, 78–1985, 78–2015, and 78–2017. In addition, the Court noted that its prior remand orders for the cottonseed oil, warehousing, and classing industries remain in effect. Finally, the Agency was ordered to provide the Court with status reports of proceedings on reconsideration at 120 day intervals. These have been filed. It should be noted that the Court retained jurisdiction of the cases and remanded only the record.

A separate standard for the cotton ginning industry (43 FR 27418, June 23, 1978; 29 CFR 1910.1046) was vacated by the United States Court of Appeals for the Fifth Circuit in *Texas Independent Ginners Association* v. *Marshall,* 630 F.2d 398 (5th Cir. 1980). The Court found that the record did not demonstrate a significant risk of adverse health effects as required by the benzene decision. In response to the court's decision, OSHA deleted the cotton ginning standard from the CFR and no further action in this area is required.

The knitting industry never challenged the standard in court. Based on available data, however, OSHA temporarily stayed the standard for the knitting industry until the completion of this review of the standard (48 FR 5267, February 4, 1983).

In view of these court and Agency actions, the 1978 cotton dust standard is currently in effect only for the textile industry, yarn production and slashing and weaving operations. All provisions of the standard except the engineering controls provision took effect in 1981 for the textile industry. Compliance with the PEL using engineering controls was required by March 27, 1984. On February 23, 1984 (49 FR 6717), OSHA extended that deadline until September 27, 1984 (subsequently extended to March 27, 1986 at 50 FR 14698 on April 15, 1985), *only* for ring spinning, spooling, winding, twisting, beaming and warping of coarse count, high cotton content yarns as defined. With that limited exception, all provisions of the cotton dust standard are now in full force and effect for the textile industry.

For all segments of the nontextile industry, including knitwear and hosiery manufacturing, the 1978 standard has been stayed and the record is before OSHA for reconsideration in light of the benzene decision, or for other relevant factors. All the nontextile industries' court challenges to the standard have been placed in abeyance pending OSHA's reconsideration. Therefore, it was necessary for OSHA to have this rulemaking to reconsider the application of the standard for the nontextile segments of the cotton industry.

In light of these judicial and administrative actions, OSHA published an Advance Notice of Proposed Rulemaking (ANPR) on February 9, 1982 (47 FR 5906). Extensive comments were received in response to the ANPR and will be referenced throughout this discussion. In addition, OSHA contracted with Centaur Associates to survey the existing published data and to conduct a detailed survey of textile manufacturing establishments, including site visits, the actual cost and technical and economic feasibility of achieving compliance with the standard, productivity effects and the feasibility

and cost-effectiveness of alternative regulatory approaches. References to the Centaur study will be made throughout this discussion.

On June 10, 1983 (48 FR 26962–26984) OSHA proposed a number of amendments to the cotton dust standard for textiles but did not propose changes to the permissible exposure limits or methods of compliance for the textile industry. OSHA proposed deleting the nontextile segments from coverage of 29 CFR 1910.1043. Further, it proposed retaining coverage of waste processing, garnetting and mattress manufacturing under the exposure limit of § 1910.1000, Table Z–1, but deleting the other nontextile segments from that exposure limit. The preamble contained an extensive discussion of the reasoning in support of these proposals. Of course, OSHA made it clear that no final decisions would be made until all public comments and new evidence had been considered and that the evidence might lead OSHA to make new proposals on matters not covered by the notice.

OSHA had received comments on the proposal from 33 individuals and groups when the comment period closed on August 9, 1983. Public hearings held in Washington, DC on September 19–23, in Dallas, Texas on September 28–29, and in Columbia, South Carolina on October 4–6, 1983 generated over 1500 pages of testimony from 70 witnesses. Testimony was received from scientists, physicians, industrial hygienists, directors of state occupational safety and health programs, economists, industry executives, union officials, textile workers and other interested persons testified at the hearings, and all witnesses were available for questioning. In addition, 35 exhibits were entered into the record at the hearings. Following the close of hearing, 58 post hearing comments were filed.

Post hearing evidence was due on October 28, 1983. Post hearing briefs were originally due on November 29, 1983, but the date for submitting them was extended until December 16, 1983 at the request of several parties. The record was certified by the presiding administrative law judge on January 12, 1984.

OSHA has carefully considered all the information submitted into the record including the studies, comments, and testimony. OSHA's final decisions are based on this evidence and all the evidence, comments and data submitted to earlier rulemaking proceedings on cotton dust and in response to prior advance notices on cotton dust, all of which have been incorporated into the record of this proceeding.

II. Occupational Health Implications and Significant Risk Analysis From Exposure to Cotton Dust in the Textile Industry

While lung disease associated with exposure to dust from cotton or flax was described over 200 years ago (Ex. 7), the formal acknowledgment of the relationship has been relatively recent. In 1942, the British recognized this relationship by incorporating into law compensation for pulmonary disabilities due to cotton or flax dust exposure (41 FR 56499). In the United States, it was not until 1964 that ACGIH placed cotton dust on its tentative list of threshold limit values (TLVs). The TLV of 1000 $\mu g/m^3$ was not adopted until 1966 (Ex. 5).

When the Occupational Safety and Health Administration proposed to issue a new standard for occupational exposure to cotton dust in 1976, there was already a substantial amount of evidence linking exposure to cotton dust, particularly in the textile industry, with respiratory disease in exposed workers (41 FR 56500–56502). Byssinosis is the respiratory disease most commonly associated with exposure to cotton dust, but other diseases such as chronic bronchitis, mill fever, weavers' cough, and mattress makers' fever have also been associated with cotton dust exposure. These diseases have been described and their association with cotton dust exposure has been documented extensively in previous **Federal Register** publications. (41 FR 56500–56502; 42 FR 27352–27354; 48 FR 26964–26968.)

OSHA concluded that workers in both the textile and the nontextile industries were at a significant risk of byssinosis and other respiratory diseases including chronic bronchitis, as a result of their exposure to cotton dust and in 1978 issued a final standard for cotton dust that covered both the textile and the nontextile industries (43 FR 27350). The 1978 final standard set two permissible exposure limits for the cotton textile industry. For yarn manufacturing operations, the PEL is 200 $\mu g/m^3$ lint-free respirable cotton dust as an 8-hour TWA and for weaving operations, the PEL is 750 $\mu g/m^3$ lint-free respirable cotton dust as an 8-hour TWA.

On review, the U.S. Court of Appeals for the District of Columbia Circuit upheld the standard as it applied to the textile industry and approved the extensive analysis of health data set forth in the preamble to the standard (*AFL–CIO* v. *Marshall, supra*). OSHA's findings of significant risk of adverse health effects due to exposure to cotton dust in the textile industry have been upheld by the Supreme Court. Specifically, the Supreme Court noted that OSHA relied on dose-response curve data from the work of Merchant and his colleagues that showed 25% of employees suffered at least Grade ½ byssinosis at 500 $\mu g/m^3$ and that 12.7% of all employees would suffer byssinosis at 200 $\mu g/m^3$. The Supreme Court commented on the acceptability of OSHA's effort to provide a reliable assessment of health risk in compiance with the Court's decision in *Industrial Union Department* v. *American Petroleum Institute* as follows: "It is difficult to imagine what else the agency could do to comply with this Court's decision . . .". (*ATMI* v. *Donovan, supra* footnote 25.)

Byssinosis, sometimes referred to as "Brown lung" is characterized by coughing, breathlessness or tightness of the chest experienced on the first day of the work week. A grading scheme for byssinosis reflects the differences in duration of the Monday morning symptoms. These may extend into other days of the work week ultimately leading to permanent incapacitation. In addition to the symptoms, byssinosis is often characterized by reductions in pulmonary function and presence of respiratory airway obstruction. These symptoms initially are reversible through removal from exposure but later may become chronic. Substantial reductions in lung function limit physical activity and place stress on other systems such as the cardiovascular system. Pulmonary function can be evaluated through tests such as forced expiratory volume in one second (FEV_1) or forced vital capacity (FVC) which are frequently used to indicate reduction of normal respiratory function.

Other occupational illnesses besides byssinosis have been noted in workers exposed to cotton dust. Some examples of these illnesses are weaver's cough which may be attributed to airborne exposure to fungus from mildewed thread (Ex. 36 and 37) and mill fever which sometimes developed in those unaccustomed to or previously unexposed to cotton dust, followed by a tolerance to the dust after a few days (Ex. 20). The final standard was designed to reduce the incidence of byssinosis and pulmonary dysfunction in affected industries.

British studies published in the 1960's established a dose-response relationship between exposure to cotton dust and prevalence of byssinosis (Exs. 6–1, 6–55, 6–56, 6–66). Studies conducted in the United States documented that byssinosis, bronchitis and lung function abnormalities were also present in

American textile workers (Exs. 6–14, 6–15, 6–18, 6–24).

Beginning in the early 1970's, the North Carolina State Board of Health and researchers from Duke University conducted a study of 3000 textile workers. This study, conducted in cooperation with Burlington Industries, examined the respiratory health, dust, and exposures of workers in cotton, synthetic, wool and blend operations. The results of this study were summarized at the 1983 hearing by Dr. James Merchant, one of the investigators.

The results of this study agreed closely with the findings of Roach and Schilling and with Molyneaux in regard to dose-response relationships. Again a linear dose-response relationship without a clear threshold was observed in preparation in yarn processing areas. It was clear that cotton dust was an important risk factor not only for byssinosis, but also for bronchitis. Similarly cotton dust was found to be associated with decline in pre-shift FEV_1 over a work shift. Smoking was also found to be an important risk factor for byssinosis, for bronchitis, and for a pre-shift FEV_1 and FVC. Evidence of an interaction between smoking and cotton dust was found for byssinosis prevalence and to a lesser extent for bronchitis prevalence when the severity of respiratory symptoms was taken into account. The vertical elutriator was judged, not only from the epidemiological data, but from an industrial hygiene standpoint to be a satisfactory area sampling instrument for this industry. (Ex. 192–9)

The permissible exposure limits for yarn manufacturing and slashing and weaving were based in part on the linear dose-response relationship demonstrated by the Merchant study. It should be noted that OSHA recognized that dust control alone, even to the PEL, would not adequately protect exposed workers. The Merchant study showed the prevalence of byssinosis in yarn areas was 26% at 500 μg^3, 13% at the PEL (200 $\mu g/m^3$) and in weaving areas was 15% at 1000 $\mu g/m^3$ and 5% at 500 $\mu g/m^3$ (Ex. 6–51; 43 FR 27355) when no other provisions were in effect. Therefore, the standard required that dust control be combined with other protective measures such as medical surveillance and job transfer. OSHA predicted that the medical surveillance and other provisions would further reduce byssinosis prevalence (43 FR 27359, col. 3). The Merchant and other earlier health studies are discussed at great length at 43 FR 27352–60 (June 23, 1978). That discussion is not repeated here.

Since the promulgation of the final standard in 1978, additional reports on the effect of exposure to cotton dust in the textile industry have been published or otherwise made available to OSHA and have been made a part of this record (Ex. 177, 170–9, 175–60, 187–17, 271).

At the hearing, Dr. Gerald Beck discussed the results of the study that he coauthored, "Follow-Up of Active and Retired Textile Workers." This 1979 study, sometimes called the "Yale Study", was initiated by the late Dr. Arend Bouhuys. It analyzed the health data on a group of active and retired cotton textile workers in Columbia, SC who had first been examined in 1973. Since all the workers had been employed in the mills for at least 3 years prior to 1955, the study focused on older workers with long work histories in the mills. The study was unique because it included a group of retired cotton textile workers. The data on cotton textile workers were compared to data obtained from community-wide respiratory health surveys of individuals in Lebanon, Connecticut.

Of the 646 cotton textile workers who participated in the initial 1973 survey, 383 participated in the follow-up in 1979. These workers had a higher prevalence (18%) of byssinosis than controls (1%). This difference held true when nonsmokers (12%) as well as smokers (26%) were compared to controls (smokers and non smokers 1%). The cotton textile workers also had a higher prevalence of chronic bronchitis (17%) as opposed to controls (3%). Over the six year interval between the initial study and the follow-up, there was a greater loss of lung function as measured by FEV_1 in the textile workers than in controls.

Work status, active or retired, could also be correlated with respiratory health. Significant differences in prevalence of respiratory symptoms were found among the three work status groups of cotton textile workers: (1) These who were active at both surveys (A–A), (2) those who had retired since the initial survey (A–R), and (3) those who were retired at both surveys (R–R). The prevalence symptoms was lowest in the A–A group, intermediate in the A–R group, and highest in the R–R group. Symptoms for which significant differences were found included chronic bronchitis, phlegm production, dyspnea, cough, and wheeze.

Dr. Merchant commented on the findings of this study and found them "fully consistent with the historical record." He went on to say that the hazard has been clearly established and that the continued use of controls is necessary. He said:

> Therefore, it is reasonable to conclude that cotton dust, if uncontrolled, will result in chronic obstructive lung disease among those with prolonged occupational exposure. This was the conclusion of the World Health Organization in their Recommended Health Based Occupational Exposure Limits for Selected Vegetable Dusts (1983). Although the National Research Council report on byssinosis questioned whether there was enough evidence to conclude that the cotton dust by itself caused chronic obstructive lung disease, they found that this was probable and stated clearly that it was important to regulate cotton dust exposure (Tr. 284–285).

As part of its comments in response to the ANPR, the ATMI submitted a critique of the Yale study prepared by Epidemiology Resources, Inc. This analysis criticized the study on several points including the method of selecting and expanding the cohort; the incomplete follow-up of the original cohort and controls; the use of controls from a separate geographical location; and the lack of dose-response calculations. OSHA concludes that Dr. Beck gave valid responses to many of these criticisms during his testimony and during the question and answer session that followed his testimony (Tr. 1097–1134). He commented on the reasons why all of the individuals eligible for the original cohort were not included; the validity of the controls used; the effect on follow-up when workers die or move from the area; the lack of assistance from the employers; and the difficulties in determining a dose-response when exact exposure levels are unknown.

During the hearings, however, the point was made that the workers studied were exposed to cotton dust in the 1930's, 1940's, 1950's, and 1960's when dust levels were much higher than they are today and when there was little or no medical surveillance. Many witnesses in addition to Dr. Beck were questioned on this point and the consensus was that the conditions in the mills have improved dramatically (Tr. 537–38, Tr. 96, Tr. 517). They agreed that as a result of dust controls, medical surveillance and other protective measures, workers employed in cotton textile mills, particularly new workers, are much better protected and substantially less likely to suffer from the long term as well as short term adverse effects of cotton dust exposure than the workers in the Yale study.

In 1982, the National Academy of Sciences published a report by the National Research Council's Committee on Byssinosis (Ex. 177). The Committee

investigated the scientific literature and reported on the complex nature of cotton dust, the search for an etiological agent, the definition of byssinosis, the identification of risk factors, and the need for additional research. The Committee agreed that the evidence clearly demonstrated an acute response to the dust, but called for additional research to clarify the relationship between cotton dust and chronic lung disease. Although the Committee identified additional research needs relating to the problem of respiratory disease in cotton textile workers, it did not question the appropriateness of or need for the cotton dust standard. Also included was a minority report which expressed disagreement with several of the Committee's findings on the relationship between acute and chronic disease and the definition of byssinosis.

At the public hearing, Dr. Hans Weill, a member of the Committee, discussed the findings of the Committee as they related to the standard. He said:

> The NAS Committee on Byssinosis considered that its primary responsibility was to evaluate the scientific evidence regarding the respiratory health effects of cotton dust exposure. This in no way leads to the conclusion that the important social issues which relate to occupational health must not often be addressed in the absence of convincing scientific evidence. The committee felt that they must indeed be dealt with in a timely and equitable way. The need for additional studies to clarify the dust-chronic airways effect relationship or the findings of some investigators that uncharacterized mill factors may influence byssinosis risk are *not* attacks on the present or, for that matter, any cotton dust standard. We specifically stated that "The committee does not intend to imply that the need for such studies precludes the need for maintenance of adequate dust controls in the working environment". As regards chronic pulmonary disease, we said that such a disease outcome is plausible and may have been a consequence of the exposure. We simply find that the evidence needs strengthening.
>
> Rational public policy must be based *in part* on valid scientific evidence while consideration is given to nonscientific issues. The process is appropriately a phased one, accomplished without losing the necessary rigor of the scientific evaluation. Once done, social decisions are made in the broader context, with input from all interested parties. Worker interests are best served when the acquisition of knowledge (research) and analysis and interpretation of results are free of pressures resulting from these wider public concerns since understanding and prevention of workplace-induced diseases depends on this unencumbered process. (Ex. 192-7)

The issue of disease prevention programs in the face of information gaps was also addressed by Dr. Harold Imbus. Dr. Imbus, testifying at OSHA's request, also attested to the benefits of acting to prevent lung impairment even though some questions remain to be answered. He stated:

> * * * I agree with those who say that we do not need to have all the answers in order to set up prevention programs. Nothing illustrates this more dramatically than the cotton dust issue.
>
> Here we have a substance capable of causing lung disease. We do not even know what the agent in the substance is.
>
> * * * However, by establishing preventive programs with the philosophy that we will try to prevent all lung disease irregardless of its cause, we have been able to show a remarkable reduction in prevalence of lung disease in the cotton textile industry. This has offered a great deal of protection for employees from both occupational and non-occupational lung disease. (Tr. 89-90)

Dr. Merchant is one of the world's leading experts on cotton dust-related disease. Dr. Weill is a recognized expert on occupationally-related pulmonary disease. Dr. Imbus was medical director of Burlington Industries for many years and was responsible for programs of medical surveillance and dust control which substantially improved the health of Burlington employees in the 1970's.

OSHA also received reports from the ATMI summarizing medical surveillance data from a large number of textile workers. The "Imbus Report", prepared by Dr. Harold Imbus of Health and Hygiene, Inc., (Ex. 175-60) covered approximately 41,000 workers and the summary prepared by ELB Associates (Ex. 187-17) covered 52,000 employees. In addition to their summary, ELB Associates also provided the raw data on workers from 23 of the companies (Ex. 271).

These data indicated that the prevalences of byssinosis and bronchitis have been dramatically reduced in the textile industry. The overall prevalence rate for byssinosis was less than 1.0%, and the bronchitis prevalence rate ranged from 6.0% to 7.0%. In their testimony, Dr. Merchant and Dr. Imbus attributed the reduction in respiratory disease in these workers to a combination of dust control and medical surveillance (Exs. 192-9, 192-2). In addition, Dr. Merchant pointed to the prescreening of new employees and the retirement of older employees as factors contributing to the decreased prevalence of respiratory disease (Ex. 192-9). He stated:

> It is my opinion that at least three processes have played an important role in reducing the prevalence of health effects in the textile industry. First, and most important, is improved dust control through improved machine design, plant design, use of effective exhaust ventilation. Technological feasibility was demonstrated at the time of the original cotton dust hearing, and these observations have now been largely validated by the record the industry has established with substantial compliance with this standard—well before the date they were required to meet the dust control provision. It is important to note these industries have done this while improving efficiency and remaining competive in the world market.
>
> Secondly, the medical surveillance program has played an important role in identifying those affected by cotton dust and transferring them to lower risk areas, thereby reducing exposure and health effects in this manner.
>
> Another selection process which has no doubt played an important role in producing a healthier workforce has been the widespread use of medical criteria for hiring in this industry.
>
> * * * This together with retirement and sometimes compensation of older and disabled cotton textile workers has produced a highly selected and relatively healthy workforce in these companies.

Although the Imbus and ELB surveys were not formal epidemiological studies and did not employ all techniques traditionally used in such studies (control populations, for instance), they provided the Agency with the most current medical surveillance data on a very large number of workers. They provide a very encouraging picture of the health of textile workers today and the success of the cotton dust standard in improving the health of textile workers.

Significant Risk Analysis

The cotton dust standard was based on data demonstrating significant excess risk of byssinosis and other respiratory symptoms in workers exposed to cotton dust in the early 1970's and earlier. Those data also showed that reductions in exposure substantially reduced the risk. Both the Court of Appeals and Supreme Court upheld OSHA's analysis of the studies and OSHA's conclusion that the standard was needed to substantially reduce a significant risk of disease. Indeed the Supreme Court said of OSHA's analysis, "It is difficult to imagine what else the agency could do to comply with the Court's decision in *Industrial Union Department* v. *American Petroleum Institute*." (The "benzene decision" where the Supreme Court set forth the significant risk requirement.) *ATMI* v. *Donovan*, 452 U.S. 490 (1981). As just discussed the two recent sets of studies essentially confirm the need for and success of the cotton dust standard. The Yale study indicates that high exposures over a period of time lead to chronic lung disease that may be irreversible. The Imbus and ELB surveys indicate that the

reductions in exposure, the institution of medical surveillance programs, and other protective measures required by the standard have substantially improved the health of the workforce.

OSHA requested three leading experts in byssinosis and occupationally-related pulmonary disease to give their own views on the standard and subsequent developments. In their statements cited above they agree that the Merchant data were valid and that they accurately represented the conditions of textile workers subject to uncontrolled exposures preceding the early 1970's. They also agree that the standard's requirements for reducing exposures with dust controls and for medical surveillance have substantially improved the health of the work force today as indicated by the new surveys. There is some disagreement about the relative importance of medical surveillance and dust control, but all agree both are needed.

There was no serious challenge during this proceeding to OSHA's original conclusion and these opinions. There was some disagreement on the applicability of the results of the Yale study to today's workforce, and the National Cotton Council submitted a brief two paragraph criticism of the applicability of the standard to weaving operations but provided no detailed analysis (Ex. 276, p. 20). The American Textile Manufacturers Institute concluded in its post hearing brief:

> In sum, the respiratory health of cotton textile workers today has improved markedly over what was reported in past decades; based on the Imbus and ELB surveys, it compares favorably to the respiratory health of workers who are not exposed to cotton dust. However, there continues to be controversy and uncertainty over the extent to which these favorable respiratory health findings are attributable to the reductions in dust levels mandated by the present standard, as opposed to the implementation of medical surveillance programs and the use of respirators and employee transfers in appropriate cases.
>
> Whatever the reason, the fact is that, in combination, these elements of the Standard appear to be having the desired effect. Moreover, most of the capital expenditures needed to achieve the PELs specified in the present Standard have already been committed, and with the exception of the processing of coarse count ring spun yarns, the vast majority of cotton textile operations have largely been brought into compliance with these PELs. For these reasons, the PELs of 200 $\mu g/m^3$ in yarn manufacturing and 750 $\mu g/m^3$ in slashing and weaving should remain unchanged in the revised standard. (Ex. 280, p. 11)

OSHA's original analysis of the need for the cotton dust standard to substantially reduce significant risk of disease was upheld by the Supreme Court. It is confirmed by subsequent studies discussed above, and the opinion of leading experts and relevant unions and trade associations just quoted. The standard has substantially improved the health of cotton textile workers as intended. Therefore there is no need nor purpose in engaging in additional significant risk analysis for employees in the textile industry.

OSHA concludes that the evidence clearly documents the need for a cotton dust standard in this industry. Furthermore, the new evidence demonstrates the effectiveness of the standard in dramatically reducing the prevalence of byssinosis, bronchitis and loss of lung function in cotton textile workers and the standard has indeed substantially reduced significant risk. OSHA commends the textile industry's actions to reduce cotton dust exposure, to institute medical surveillance and to comply with the other requirements of the cotton dust standard.

III. Occupational Health Implications and Significant Risk Analysis From Exposure to Cotton Dust Exposure in the Nontextile Industries and Scope of Coverage

A. Introduction

OSHA issued a standard in 1978 covering most users of cotton. When the final standard was published in 1978, the permissible exposure limits for lint-free respirable cotton dust divided the covered industries into three segments: yarn manufacturing (200 $\mu g/m^3$ 8-hr TWA); slashing and weaving (750 $\mu g/m^3$ 8-hr TWA); and all others including knitting (500 $\mu g/m^3$ 8-hr TWA). The industries covered by the 500 $\mu g/m^3$ PEL came to be called the nontextile industries. This led to the rather confusing designation of the knitting industry as a nontextile industry, nomenclature which is retained in this document.

The scope of coverage of the 1978 standard in the nontextile industries was determined by the evidence in the record and by policy views. The Agency concluded that evidence of adverse health effects in the nontextile industries could be reinforced by the strong evidence in the textile industry and stated:

> Although these studies of nontextile industries do not provide precise dose-response data, this data clearly establishes that exposure to cotton dust in these industries, regardless of the stage of processing in which the dust is generated, results in byssinosis and other respiratory diseases qualitatively indistinguishable from those arising in the textile industry. (43 FR 27382)

As the regulatory history states, this rationale was accepted by the Court of Appeals for cottonseed processing and classing and warehousing. The decision stated:

> The exact nature of the health hazard posed by cotton dust remains subject to medical debate. The agency had before it conclusive evidence that dust found in textile mills causes debilitating disease; it also had some evidence of related, though less severe, health impairments among workers in nontextile industries. Although petitioners point to differences among the industries, OSHA's mandate requires it to protect workers in all industries. We find that OSHA fulfilled this mandate by reasonably relying on medical evidence from the textile industry and evidence of health impairments among nontextile workers. The differences in the industries that were cited by petitioners do not undermine the agency's determination. (617 F. 2nd 636 (1979) p. 666–7)

The knitting industry did not legally challenge OSHA's findings concerning this industry, and although the waste processing industry did challenge the standard, no judicial decision has been made in this case.

Following publication of the final standard in 1978, new studies were completed by NIOSH and other investigators which examined the health of nontextile workers exposed to cotton dust. Based on the new studies, the unsettled legal status of most of the nontextile segments, and the different composition of the dust in different processes, OSHA concluded that data for each segment should be reviewed. OSHA also concluded for these reasons that this review should give the greatest weight to the studies from each particular segment in determining whether regulation was needed for each segment.

OSHA issued an ANPR on February 9, 1982 requesting new information on the health of exposed workers in the nontextile industries (47 FR 5906). On June 10, 1983, OSHA proposed to amend the 1978 cotton dust standard. The Agency proposed to exclude classing, warehousing, knitting, and cottonseed processing from both 29 CFR 1910.1000 and 29 CFR 1910.1043. OSHA proposed to exclude waste processing from 29 CFR 1910.1043 but did not propose to exclude this industry from 29 CFR 1910.1000. Commenters were invited to present evidence and testimony on this subject.

B. Knitting

The 1978 standard set a permissible exposure limit of 500 $\mu g/m^3$ lint-free respirable cotton as an 8-hour TWA for cotton knitting operations which include the knitwear and hosiery industries. No

direct evidence of adverse health effects was cited for knitting, and these operations were covered by the 1978 final standard based on evidence from other sectors.

The first detailed analysis of the status of the respiratory health of knitting workers exposed to cotton dust was submitted to OSHA in January of 1982. This interim report was entitled "Analysis of Pulmonary Function Data of Knitting Industry Workers" and is often referred to as the Boehlecke/Battigelli report. Drs. Brian Boehlecke and Mario Battigelli of the University of North Carolina prepared the report which was submitted to OSHA by the National Knitwear Manufacturers Association (NKMA) in support of its petition for a stay of enforcement of the standard (Ex. 174). A final report was submitted in July of 1982 (Ex. 183).

This report has been discussed in detail elsewhere (47 FR 35255; 48 FR 5268; 48 FR 26967). Briefly, the report found that the respiratory health of the knitwear and hosiery workers studied, specifically the prevalences of chronic cough, chronic phlegm, mild dyspnea, and byssinotic symptoms, were similar to a group of blue-collar workers not exposed to respiratory hazards. The authors did report that 14.6% of the participants showed an overshift decline in FEV_1 of 5% or greater. They state that a similar percentage of workers in wool and synthetic operations showed such a decline. A deleterious effect of smoking was seen. Average dust levels were well below the 500 $\mu g/m^3$ PEL, ranging from 30–443 $\mu g/m^3$ for knitwear plants and 38–269 $\mu g/m^3$ for hosiery plants. The authors compared the plants represented in their report with the industry as a whole and concluded that the study group was representative of the industry.

Based on the information in the report, OSHA published a notice of proposed stay of enforcement of the cotton dust standard for the knitwear and hosiery industries (47 FR 35255) and requested comments. Twenty individuals or groups responded to the notice with written comments. Eighteen of these comments were in support of the stay but did not provide any detailed comments on the Boehlecke/Battigelli report.

Both NIOSH (Ex. 182–20) and Mr. Andy Oberta, president of Environmental Resources Group, Inc. (ERG, Inc.), (Ex. 182–1) provided specific comments on the report. Mr. Oberta stated that ERG, Inc. provides medical exams and exposure monitoring to the knitting industry. He further states that the results of the medical examinations cited in the report were "consistent with those which we have obtained from our own testing of approximately 400 workers in knitting and hosiery mills." (Ex. 182–1) He called attention to the 14.6% of workers with an overshift decline in FEV_1 and was critical of the lack of dose-response information. NIOSH reviewed the report at the request of OSHA and provided detailed comments (Ex. 182–20). It pointed out, among other things, the limited control that the authors had over the selection of the study population and suggested that there may be some evidence of a dose-response relationship that should be followed up. Both NIOSH and Oberta cautioned against the generalization of the results of this study to the entire industry. Mr. Oberta suggested that OSHA consider data from other sources before making a final decision.

Although some commenters pointed to shortcomings in the report, none of the comments disputed the basic findings of the study, namely that there was no excess of chronic respiratory disease in knitting workers at the exposure levels studied. Based on the analysis of the report and a review of the comments, OSHA reached a conclusion that the Boehlecke-Battigelli report provided sufficient information to extend the stay until the review of the standard was completed and published a notice to that effect in the **Federal Register** on February 3, 1983 (48 FR 5267)

As part of the proposed amendments to the standard, OSHA proposed that the entire knitting industry, including knitwear and hosiery manufacturers, be excluded from coverage from both the 1978 standard and the earlier cotton dust standard and requested comments on this proposal (48 FR 26980). Following the publication of that proposal, a number of commenters including the National Knitwear Manufacturers Association and the National Association of Hosiery Manufacturers wrote in support of exempting the knitwear and hosiery industries from coverage under any standard for cotton dust (Exs. 187–4, 187–7, 187–10, 187–11, 187–18, and 187–21). They based their recommendations on the results of the Boehlecke/Battigelli report and on their contention that OSHA had not made a threshold finding of significant risk for workers exposed to cotton dust in this industry. Other commenters, including NIOSH and the American Public Health Association (APHA), cautioned OSHA against exempting the knitting industry because they contended that those workers who were at risk from exposure to cotton dust would be unprotected (Exs. 187–14, 187–8, 187–23, APHA unnumbered comment).

OSHA requested that Dr. Brian Boehlecke testify as an expert witness on the status of the health of knitting workers at the public hearings held in Washington, D.C. in September 1983. In his testimony, Dr. Boehlecke discussed the report that he coauthored with Dr. Battigelli. He also described the sponsorship, sources of medical surveillance data, the blue collar comparison group and the authors' requests for additional data on work histories. He then restated the conclusions of the report:

> In these data, chronic loss of lung function and increased prevalence of respiratory symptoms were clearly associated with cigarette smoking. After controlling for the effect of smoking, we were unable to demonstrate a significant chronic effect of knitting room dust exposure on pulmonary function.
>
> The small acute decrement in lung function over the workshift in these workers was no greater than that reported in workers exposed to dust from synthetic fibers or wool, and may represent a nonspecific effect of knitting room dust.
>
> The prevalence of nonspecific respiratory symptoms in the knitting workers was not increased over that reported in nonexposed blue collar workers and the prevalence of byssinotic symptoms was similar to that of workers exposed to dust from synthetic fibers or wool.
>
> The consistency of results among several types of analysis supports the conclusion that knitting room work was not associated with important adverse effects on the respiratory system in the workers in this study. Although we have presented some information suggesting that the study group was a reasonably representative sample of workers in the knitting trades, additional information would be useful before forming a final judgment on this question. (Tr. 54–55)

Although Dr. Boehlecke stated that the results support exempting the knitting industry from a PEL and exposure monitoring, he expressed reservations about ending medical surveillance requirements based solely on the results of this report and suggested that additional medical surveillance data be collected. He went on to add:

> • • • I believe that consideration should also be given to requiring medical monitoring of workers each two years for a limited period of time to gather information to confirm the conclusions of our report and to ensure adequate protection of the health of current workers should some exceptions to these conclusions be found.
>
> I cannot say with certainty what period of time might be necessary to provide adequate corroboration of our conclusions, but suggest that at least four years of information, that is two follow-up examinations, would be needed to obtain sufficient data. (Tr. 55–56)

In response to a question, Dr. Boehlecke said:

* * * I think that surveillance should be considered every two years in this particular industry, as I said for a limited period of time.

If after that period of time no evidence is forthcoming that suggests an important risk to health, then surveillance would not necessarily be mandatory in my opinion. (Tr. 59)

Mr. Robert Blanchard, president of the National Knitwear Manufacturers Association (NKMA), testified that it was the opinion of his organization that there had been no evidence presented which disputed the findings of the Boehlecke/Battigelli report and that the NKMA supported a total exemption of the knitting industry from the cotton dust standard. In response to questioning, he stated that he was unaware of any operations in the knitting industry with exposures exceeding 500 $\mu g/m^3$. In answer to a question as to whether the industry would commit itself to do the additional medical surveillance recommended by Dr. Boehlecke, Mr. Blanchard stated:

I think I understand Dr. Boehlecke as a medical doctor and as a human being; I think that I would like to have everybody checked every month or two to make sure that everybody was in excellent health. However, I feel there's really no justification for his action in this particular case. As I've said before, I think most industry people understand good health is good for their business and obviously it's good for their employees. I see no justification for it, no. (Tr. 756)

He did agree, however, to discuss this matter of continued medical surveilliance with his members and submit their response in a posthearing comment.

Following the hearing, Mr. Blanchard responded by letter to the question. He replied in part:

After investigation, I was able to determine, as I testified, that almost all of the companies represented in the "Analysis of Pulmonary Function Data of Knitting Industry Workers" are continuing to do some type of testing to meet their individual needs; however, such testing is not necessarily the same as done for Dr. Boehlecke's study.

* * * If OSHA wishes to consider monitoring in two and/or four years, we suggest it fund an epidemiological study by NIOSH. Our members, the past knitwear participants, would not hesitate to consider opening their plants for such work. (Ex. 228)

Mr. Sid Smith, president of the National Association of Hosiery Manufacturers (NAHM), concurred with the testimony of Mr. Blanchard when he stated:

* * * The record now contains substantive and technically acceptable data that shows that there is no prevalence of byssinosis symptoms or other respiratory difficulties evidenced in the knitting and hosiery industries based on the number of years worked in knitting, even though the use of cotton yarns is in evidence.

* * * Based on the aforementioned information and data submitted, we concur with the conclusion reached by both OSHA and NIOSH that the workers in the knitting and hosiery industries appear to have no significant risk of impaired health and that, therefore, the industry should be excluded from coverage from CFR 1910.1043 and CFR 1910.1000. (Tr. 762)

In response to a question concerning dust levels, Mr. Smith said: "My recollection is that the majority of those are in the very low end of that range, in the 100 to 200 [$\mu g/m^3$], maybe 250 [$\mu g/m^3$] range." (Tr. 767) He also agreed to contact his membership to determine whether they would be willing to conduct the additional medical surveillance examinations recommended by Dr. Boehlecke.

In one of their posthearing comments (Ex. 231), the NAHM expressed the opinion that it had provided OSHA with full justification for excluding the hosiery and knitting industries from all provisions of the standard including the medical surveillance provisions. They concluded by saying:

If, following total exemption from the cotton dust standard for the knitting and hosiery industries, OSHA would like to make a specific proposal on various issues, we would certainly be open to discussing the matter. (Ex. 231)

OSHA wrote to Mr. Andy Oberta of ERG, Inc. and requested that he provide "any data or other relevant information concerning the health of either knitting or hosiery workers or both" that he had not previously supplied to the record (Ex. 246). For reasons of client confidentiality, Mr. Oberta was unable to provide specific results of medical examinations but he did supply comments on the Boehlecke/Battigelli report based on his company's experience in the knitting industry (Ex. L–1). He stated that dust levels obtained in surveys conducted by ERG, Inc. were "considerably higher than those reported in the B/B [Boehlecke/Battigelli] report." He also reported that when hosiery and knitwear workers were analyzed separately that more hosiery workers than knitwear workers showed evidence of decreased lung function (Ex. 182–1).

Drs. Boehlecke and Battigelli responded to Mr. Oberta's criticism in their posthearing comment (Ex. 274). They stated that their study group was "reasonably representative of the industry as a whole" and that the relatively small difference in the dust levels between their report and the ERG data (less than 75 $\mu g/m^3$ for knitwear and less than 60 $\mu g/m^3$ for hosiery) did not suggest that the plants studied were unrepresentative of the industry as a whole. They agreed that OSHA should be cautious in generalizing their findings, but they did not feel that Mr. Oberta's comments provided "any further insight into the validity of our findings." (Ex. 274)

OSHA requested that NIOSH review and comment on the information submitted by ERG Consultants, Inc. In its posthearing brief, NIOSH repeated its earlier caution about possible selection bias in the study since the study was performed using information submitted voluntarily by employers. These facilities might be expected to have lower dust levels than the industry as a whole. However, NIOSH cautioned OSHA about making comparisons between dust levels in the Boehlecke/Battigelli report and those submitted by ERG Consultants, Inc. They were unable to determine exactly how the mean dust levels were calculated by Mr. Oberta, and whether they were directly comparable with those in the Boehlecke/Battigelli report. NIOSH also pointed out that there are problems comparing the pulmonary function data from the two reports since Mr. Oberta did not take into consideration the smoking status of the two populations and there are no objective indications of the technical quality of the ERG, Inc. data. They did say that further analysis of the data submitted by ERG, Inc. could prove useful (Ex. 285).

The post hearing statement of the ACTWU provided the most detailed critical analysis of the Boehlecke/Battigelli report that was submitted to the record (Ex. 279). They state that a single negative study cannot form the basis for valid conclusions on the health risk to a human population and that the report does not satisfy established criteria for evaluating a negative study. Specifically they questioned the representativeness of the sample, the exposure data and the reliability of work histories. They also contend that one of the tables in the report (Table 22) provided evidence of a dose-response relationship.

Conclusion and Significant Risk Analysis

The state of the health record for the knitting industry has been reviewed above. Within the context of this health record for the knitting industry, OSHA has three decisions to make. Should the exposure limit and related provisions of the section 6(b) cotton dust standard be revoked for the knitting industry? Should the medical provisions of that

standard be revoked for the knitting industry? Should the exposure limit requirements of the 6(a) standard of § 1910.1000 be revoked for the knitting industry? These issues are addressed serially.

It was definitively established by the Supreme Court in *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute* 448 U.S. 607 (1980). (*IUD* v. *API*), that when OSHA issues a new health standard under section 6(b) of the Act which sets a lower exposure limit, the Agency must demonstrate that a significant risk exists which will be substantially reduced by lowering the exposure limit. OSHA has explained its overall approach to significant risk determinations in the context of two final standards and several proposed standards. In the case of carcinogens, these explanations were included in the final standards for inorganic arsenic (48 FR 1864–1899; Jan. 14, 1983) and ethylene oxide (49 FR 25734, 29763–66; June 22, 1984).

OSHA's overall analytical approach for setting worker health standards is a four-step process consistent with recent court interpretations of the OSH Act and rational, objective policy formulation. In the first step, risk assessments are performed where possible and considered with other relevant factors to determine whether the substance to be regulated poses a significant risk to workers. Then, in the second step, OSHA considers which, if any, of the proposed standards being considered for the substance will substantially reduce the risk. In the third step, OSHA looks at the best available data to set the most protective exposure limit necessary to reduce significant risk that is both technologically and economically feasible. In the fourth and final step, OSHA considers the most cost-effective way to achieve the objective.

It is appropriate to consider a number of different factors in arriving at a determination of significant risk. The Supreme Court gave some general guidance as to the process to be followed. It indicated that the Secretary is to make the initial determination of the existence of a significant risk, but recognized that "while the Agency must support its finding that a certain level of risk exists with substantial evidence we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations." (IUD v. API, 448 U.S. 655, 656, n. 62). In order for such a policy judgment to have a rational foundation, it is appropriate to consider such factors as the quality of the underlying data, the reasonableness of the risk assessment, the statistical significance of the findings, the type of risk presented and the comparative significance of the risk relative to the risk in other occupations.

The first issue to be faced in the context of the above facts, law and OSHA policies is whether there is a significant health risk at the current 6(a) exposure limit in knitting justifying a lower exposure limit and the other provisions of § 1910.1043 (excluding the medical and monitoring provisions). OSHA concludes that there is insufficient evidence to meet this test. There is no study in this industry segment demonstrating risk. The one study available indicates no excess risk of byssinosis and similar pulmonary function compared to suitable blue collar controls. The study is substantial in size and of overall high quality. The fact that this study has, like all studies, some areas which could be strengthened and the general scientific principle that a single study does not prove a negative are not bases for determination of significant risk.

Proven risk in one segment may, in appropriate circumstances, provide a basis for determining risk in another segment because of chemical similarity, confirmatory evidence, or other good reasons. However, these factors are much less relevant in the case of the knitting segment because the composition of the cotton dust varies from segment to segment, the exact etiologic agent is unknown and there is no confirming data of risk in the knitting segment. Therefore, the strong evidence of significant risk in yarn production and slashing and weaving is not a sufficient basis for concluding there is significant risk in the knitting industry. The lack of the factors mentioned for extrapolating risk is the basis for OSHA changing its earlier policy for cotton dust of applying risk data in one industry to another.

As can be seen, there is not sufficient evidence indicating risk to justify a lower exposure limit. Therefore there is no need to inquire into the further stages of analysis which OSHA would go through to make a significant risk determination.

The second issue is whether the medical surveillance requirement in § 1910.1043 should be revoked for the knitting industry. OSHA has determined not to include a medical surveillance requirement for the knitting industry for the reasons discussed but NIOSH will perform a follow up longitudinal study. The general principles for retaining medical surveillance are discussed below in the discussion for the cotton seed processing industry.

First, as discussed above, the one study available on knitting, indicated that employees had no greater incidence of nonspecific pulmonary symptoms, lung function declines or byssinosis that control groups. The study was of reasonable quality and large scale.

Second, the knitting employees studied had low exposures, on average, well under both the old (making reasonable hypothesis between total and respirable dust) and the new exposure limits. However, there is evidence in the record that knitting operations are not dusty and that exposures would not rise if there were no limits. Therefore, OSHA has some evidence to support its belief that exposures will rise above current levels.

Third, Dr. Boehlecke, who was one of the authors of the report on knitting employees discussed above, recommended continuing medical examinations every two years "to confirm the conclusions of our report and to insure adequate protection of the health of current workers should some exceptions to the conclusions be found." ACTWU argued that a single negative study can not be the basis for valid conclusions on health risk and that the Boehlecke/Battigelli study did not meet appropriate criteria for evaluating a negative study. As discussed, representatives of the knitting and hosiery industries believed that total exemption from regulation including medical surveillance was called for in light of the Boehlecke/Battigelli report.

Dr. Boehlecke's recommendation that a confirmatory study would be useful and ACTWU's argument that a confirmatory study is appropriate can be met by a prospective study. Unlike NIOSH's earlier cross sectional studies, this study is a longitudinal study. Such a study, unlike routine medical surveillance, can be specifically designed with criteria appropriate for testing a negative hypothesis and can follow employees longitudinally, including employees who quit. In addition, such a study can act as a "backstop" to determine whether the health of employees has been maintained after the elimination of an exposure limit. Of course, if such a study indicated that employees have not remained healthy, OSHA will consider whether further regulation is appropriate.

Accordingly, beginning in Fiscal Year 1987, funding will be provided to initiate a NIOSH study to determine the potential for risk of workers exposed to cotton dust in certain nontextile

industries (knitting, classing, and warehousing). It is expected that the study will survey and track a representative sample over an 8 year period.

The third issue presented is whether OSHA should exempt the knitting industries from the 1971 cotton dust standard of 1000 $\mu g/m^3$ (1 mg/m^3) total dust contained in § 1910.1000, Table Z–1. That standard was issued pursuant to section 6(a) of the OSH Act which states:

Without regard to chapter 5 of title 5, United States Code, or to the other subsections of the section, the Secretary shall, as soon as practicable during the period beginning with the effective data of the Act and ending two years after such date, by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard, unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees. In the event of conflict among any such standards, the Secretary shall promulgate the standard which assures the greatest protection of the safety or health of the affected employees.

The 1000 $\mu g/m^3$ standard was an established Federal standard under the Walsh Healy Act applying to government contractors and was adopted in 1971 pursuant to section 6(a). Prior to its adoption the American Conference of Governmental Industrial Hygienists (ACGIH) had adopted that level as a recommended threshold limit value for cotton dust.

In the June 10, 1983 **Federal Register** notice, OSHA proposed to exempt the knitting industry from coverage under the 6(a) standard. OSHA stated:

As discussed above, the 1978 cotton dust standard has never gone into effect for any of the nontextile industries. It has been OSHA's position, however, and the case law indicates, that the 1971 standard (29 CFR § 1910.1000 Table Z–1) which was adopted pursuant to section 6(a) of the Act, covers the nontextile segments. The 1971 standard would therefore, remain in effect for the nontextile segments unless OSHA revokes the standard for nontextile industries.

Based upon the present record, OSHA proposed to exclude the classing, warehousing, cottonseed processing and knitting industries from coverage by § 1910.1000 Table Z–1. OSHA believes that since there is evidence of safe working conditions in the classing, warehousing and knitting industries, it will better effectuate the purposes of the Act to exclude those industries from coverage. Resources spent protecting employees under the existing standard would be better spent on health and safety in other areas. (48 FR 26968)

Several legal tests have been suggested as the basis for revoking 6(a) standards. Section 6(b)(8) of the Act states:

Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard.

Any action to eliminate coverage for the knitting industry requires promulgation of a rule and this section gives guidance as to the legal test to be met to revoke a standard. However, the cotton dust standard was technically an established federal standard and not a national consensus standard.

In comments, several representatives of the nontextile industries have stated what they believe to be the proper test for revoking 6(a) standards. These were most specifically stated in comments submitted on behalf of the National Cotton Batting Institute and the Textile By Products Association. They stated:

OSHA proposes to maintain the "status quo" by keeping the one milligram standard in place for the garnetting industry. There are two reasons, however, why it cannot do so. First, like other section 6(a) regulations, the one milligram total dust standard was never intended to be a permanent standard, but was always intended to be an interim standard, to be supplanted by a regulation promulgated pursuant to section 6(b). Second, and more fundamentally, since 1976, when OSHA first proposed a permanent standard for occupational exposure to cotton dust, this proceeding has been conducted under section 6(b) of the Act, 29 U.S.C. 655(b). Whenever OSHA undertakes a rulemaking pursuant to section 6(b), it is obligated to adhere to the standards set forth in the benzene case. Thus, in determining whether or not to regulate this industry, OSHA had two choices: (1) Either determine that there is a significant risk at current dust levels and promulgate a standard or (2) determine that there is no significant risk and not promulgate a standard. The Act does not allow OSHA to fall back on an interim standard whenever it determines that it cannot meet the "significant risk" requirement. (Ex. 284, p. 2). (See also the National Association of Bedding Manufacturers comments, Ex. 187–22.)

The AFL–CIO also submitted a posthearing comment on this issue. It stated:

As discussed, the "threshold finding" of a significant risk of harm that must be made before a permanent standard is adopted to reduce exposure levels simply has no purpose to serve under the statutory scheme where all that is at issue is the retention of an existing established Federal standard. For Congress saw no need to subject consensus standards and established Federal standards to the kind of analysis that is embodied in the significant risk test, recognizing as Congress did that these standards represented only a "minimum level of health and safety," and that established Federal standards had "already been subjected to the procedural scrutiny mandated by the law under which they were issued" and "in large part, represented the incorporation of voluntary industrial standards."

To be sure, because consensus standards and established Federal standards generally "represent merely the lowest common denominator of acceptance by interested private groups." Congress recognized that OSHA would ultimately have to improve upon such standards through rulemaking under section 6(b) of the Act: "it is essential that section 6(a) standards be constantly improved and replaced as new knowledge and techniques are developed." But it would be contrary to every documented indication of congressional intent to hold that by allowing section 6(a) standards to be improved through section 6(b) proceedings, Congress meant to provide that as a condition of being retained as standards they would be subject to a "significant risk" requirement. Rather, the test should remain as stated in section 6(a): unless it is shown that an established Federal standard "would not result in improved safety or health for specifically designated employees, the need for the standard is not a matter of dispute." (Ex. 278 pp. 7–8. Quotes are to the legislative history or the Act and footnote citations are omitted)

The AFL–CIO added:

Indeed, even putting aside the language of section 6(a), under general principles of administrative law it is the proponent of a rule or order who has the burden of proof in administrative proceedings. *IUD* v. *API, supra.*, 448 U.S. at 653 (plurality opinion). Section 6(b) of the Act indicates that the same procedural principles apply to an agency proposal to "modify" or "revoke" a standard as would apply to a proposal to "promulgate" a standard; and any possible suggestion that OSHA does not bear the burden of proof when it proposes to weaken an existing standard has been put to rest by the Supreme Court's recent decision in *Motor Vehicle Mfrs. Assn.* v. *State Farm Mut. Auto. Ins. Co.*, 103 S. Ct. 2856, 2856–66 (1983). (Ex. 278, pp. 9–10, Footnote omitted)

OSHA believes that when it proposes to eliminate a class from either a 65(a) or 6(b) standard on health grounds, the evidence must affirmatively indicate that significant risk is unlikely to exist for that class at exposures likely to exis after the standard has been eliminated.

The reasons are that this would lead to consistency in eliminating both 6(a) and 6(b) standards and permit OSHA to apply the significant risk test of *IUD* v. *API* to both. An action to eliminate either a 6(a) or 6(b) standard is also a 6(b) rulemaking with the same procedures and same standard for review. OSHA must be able to support with substantial evidence any change it is propounding. The requirements of section 6(b)(8) are applicable whether

OSHA strengthens or weakens a regulation.

However, lack of evidence of risk is not a basis by itself for eliminating a 6(a) standard. The absence of evidence of risk could merely mean that the 6(a) standard (which has been in effect for 13 years) is working and the work force is healthy as a result of compliance with the 6(a) standard. Consequently there is no worker population to study at higher levels. It does not necessarily mean that with uncontrolled exposures there would not be significant risk. Of course, there might be no significant risk at the current exposure, but significant risk may be present at higher exposures which could not be demonstrated because the 6(a) standard is in force.

OSHA believes the AFL–CIO formulation in one respect is incorrect. OSHA believes that Congress did not intend for the Agency to apply different criteria to eliminate a 6(a) standard than to eliminate a 6(b) standard. Also if a different standard applied, this would mean that the guidance of the Supreme Court in *IUD* v. *API* would apply to eliminating some health standards and not others.

The nontextile sector has argued that OSHA must either determine that there is a significant risk at current exposures and promulgate a standard or determine that there is no significant risk and not promulgate a standard. They further argue that OSHA cannot retain a 6(a) standard unless it can affirmatively show there is significant risk at the 6(a) level. This later argument is incorrect. This would mean that when a 6(a) standard has eliminated significant risk which would exist at higher levels, OSHA would have to eliminate that 6(a) standard. Then OSHA would have to wait until employees developed the risk that the 6(a) standard protected against before OSHA could issue a new standard.

It is necessary to apply the test to the facts. As discussed above, there is no evidence of risk in this segment. There is a good quality report which indicates no risk at the rather low levels studied, and little basis for extrapolating the studies in the textile industry to this sector. There is some, though not overwhelming, evidence that exposures will stay low if the segment is exempted from the 6(a) limit. OSHA believes that these factors provide substantial evidence to indicate that no significant risk will exist at the exposure levels likely to prevail if the 6(a) standard is repealed for this segment.

In addition, as OSHA stated in its proposal, it would better effectuate the purposes of the OSH Act if these segments were removed from coverage of 6(a) because resources spent on carrying out the 6(a) standard would be better spent on health and safety in other areas.

The facts present in the knitting industry, also meet the test for repeal propounded by the AFL–CIO. Retaining the 6(a) standard for knitting employees "would not result in improved safety or health" for knitting employees because exposures are likely to remain low and evidence indicates no risk at the lower levels studied.

C. Cottonseed Processing

The 1978 standard set a PEL of 500 $\mu g/m^3$ for cottonseed processing. This was based on health studies in the textile industry and on studies of the health of cottonseed processing workers in the United States, Egypt, and Australia. The record for the 1978 standard contained several studies on the health of workers in this industry (Exs. 6–68, 6–70, 128k, and 128m) and they are discussed in the June 10, 1983 proposal (48 FR 26966–7).

In response to an ANPR published on February 9, 1982 (47 FR 5906), additional information on the health of these workers was submitted to OSHA by NIOSH (Ex. 175–56) and by Dr. Robert Jones, representing a group of investigators at Tulane University (Ex. 175–12). The Procter & Gamble Company, whose workers participated in the Tulane study, also submitted comments and information, some of which was identical to that in Ex. 175–12 (Ex. 175–48). The Tulane and NIOSH studies have been discussed elsewhere (48 FR 26966–7). Briefly, the four cross-sectional studies conducted by the Tulane group showed that effects on lung function, most commonly a decline over the work shift in the forced expiratory volume, were related to length of employment in a cottonseed mill, to jobs in early processing steps, to general allergy, to allergy to cottonseed linters and to smoking, but not to dust levels. The prevalences of byssinosis and chronic bronchitis were lower than those usually observed in textile workers, but the dust levels were higher than those found in textile mills. No long term effects were demonstrated, but the follow-up period which averaged 23 months was very short (Ex. 192–5).

The NIOSH study, entitled "Respiratory Disorders and Dust Exposure in Sectors of the Cotton Industry of the United States. Part 3: Cottonseed Oil Mills," compared cottonseed processing workers with a nonexposed blue collar comparison group. They demonstrated a significant effect on ventilatory changes and chronic cough in cottonseed oil mill workers who smoke, indicating an additive effect with tobacco smoke. The study did not show an increase in the prevalence of byssinosis of chronic bronchitis in these workers (Ex. 175–56).

The National Cottonseed Products Association did not submit any new health studies but rather argued that conditions in foreign mills were very different than conditions in the United States (Ex. 175–38). They offered a detailed critical analysis of both the foreign studies and some of the earlier Tulane studies and concluded that: "The only available evidence regarding cottonseed oil mills establishes that there is no significant risk of material health impairment among oil mill workers."

Based on the evidence and comments in the record, OSHA reached the preliminary conclusion in the June 10, 1983 proposal (48 FR 26968) that workers in the cottonseed processing industry appeared to have no significant risk of impaired health as a result of their exposure to cotton dust and proposed excluding this industry from coverage under 29 CFR § 1910.1043. In the discusson of 29 CFR 1910.1000, OSHA noted that the cottonseed industry was not in compliance with the PEL (1000 $\mu g/m^3$ total dust 8-hr TWA) and that compliance with the PELs specified by either § 1910.1000 or § 1910.1043 could cause severe economic disruptions in the industry. OSHA proposed to delete this industry from coverage under 29 CFR 1910.1000 but requested:

> . . . comments on alternative approaches to protecting worker health in the cottonseed processing industry which would be economically feasible. (48 FR 26968)

In commenting on the proposal, NIOSH disagreed "with OSHA's conclusion that workers in this industry appear to have no significant risk of impaired health as a result of their exposure to cotton dust." (Ex. 187–23) They reinterated the conclusion of their own study in this industry and described the findings of other investigators. They concluded:

> The findings of excess symptoms and adverse ventilatory effects in cottonseed oil mill workers suggest biological activity of these dusts. These effects warrant a standard applying to cottonseed oil mills, in particular, a requirement to provide medical surveillance to identify signs or symptoms of exposure. (Ex 187–23)

Both the National Cotton Council (Ex. 187–18) and Proctor & Gamble (Ex. 187–20) commented in support of OSHA's proposal. Proctor & Gamble restated positions taken in earlier comments that neither acute nor long term health

effects have been shown from exposure to cottonseed linter dust and that cottonseed linter dust is different from cotton dust.

OSHA requested that Dr. Robert Jones, a coauthor of the Tulane University studies on cottonseed processing workers, testify at the public hearings as an expert witness on the health of cottonseed processing workers. Dr. Jones described the four cross sectional studies conducted between 1975 and 1980 by the Tulane group. He also described and commented on the Australian and Egyptian studies and the NIOSH cross sectional study. Dr. Jones concluded from the results of these studies "that the dust in the cottonseed crushing mills has some biologic activity of a kind similar to that found in cotton textile mills," but that the potency of the dust in cottonseed crushing mills is considerably less than the dust in textile mills. (Tr. 205)

Dr. Jones recommended continued medical surveillance for these workers, although he did not recommend setting a PEL. He stated that he did not feel that scientific data demonstrated a dose-response relationship at the dust levels studied in the Tulane and NIOSH studies (0.5 to 2.0 mg/m^3). He did, however, state several reasons why continued medical surveillance for these workers would be appropriate:

> The dust in cottonseed oil mills does have some effect, similar in kind to those seen in textile mills. There is evidence of an interaction of cottonseed linter dust with some factors of host susceptibility; namely, smoking in some studies, and general and specific allergy in our studies.
>
> A medical surveillance program offers two benefits. First, it could allow identification and protection of persons who, for any reason, were unusually susceptible to adverse effects of this dust.
>
> Simple prudence dictates that persons with active airways diseases, such as bronchial asthma, or with advanced and potentially disabling lung diseases of any cause, should not be assigned to particularly dusty jobs.
>
> It is also prudent to reassign away from such jobs if longitudinal surveillance shows the development of respiratory illness in a previously healthy worker. The numbers of employees so affected may be understated by large cross-sectional respiratory surveys.
>
> Second, the presence of industrywide health surveillance allows for continuing reassessment of the true levels of risk associated with work in these mills. While I believe that the scientific literature to date does not support the setting of a low permissible exposure limit, the existence of systematic, ongoing medical surveillance would result in an accumulation of health data that could allow reassessment of the need for exposure regulation on a timely basis. (Tr. 206–7)

In response to a question as to what would be an appropriate medical surveillance program for this high-turnover industry, Dr. Jones said:

> Clearly, the type of surveillance I have in mind involves pre-exposure testing, or preplacement testing. For one thing, I suggest that people who have demonstrable impairments of their lung function not be assigned to high risk areas whether in this or in any other industry.
>
> But, if there is a high turnover, it is . . . translatable ultimately into better worker health, to know why people leave an industry.
>
> Accordingly, I would suggest that in any industry with a lot of labor turnover, where people may possibly be leaving because of perceived symptoms from exposure early in their working career, that a terminal examination—at termination of employment—also be offered, or strongly recommended, in order that we may know why people leave the industry. . . . [I]t's of interest to me as a physician and a scientist to know if people are leaving because they're actually developing troubles. (Tr. 208)

The NIOSH cross-sectional study on the cottonseed processing industry was described by Mr. Richard Lemen testifying for NIOSH. He stated that, although the study did not provide a clear dose-response relationship, the results were consistent with findings of the Tulane group and that:

> Both the NIOSH and the Jones studies show that dust found in cottonseed oil mills is not a mere nuisance. This dust has distinct biological activity, as does textile mill dust, and measures should be taken to protect workers from its effects. (Tr. 401)

Mr. Lemen was accompanied by a panel of physicians and industrial hygienists who had helped to conduct the series of five studies on the nontextile industries. One member of this panel was Dr. Alan Engelberg, a physician and former NIOSH employee who helped to direct and interpret the studies. Dr. Engelberg disagreed with Dr. Jones' conclusion that the available data did not support a PEL for the cottonseed processing industry and stated that some dust control was important because the dust was not simply a nuisance dust (Tr. at 406). He did agree that medical monitoring should be required. Other panel members also reiterated NIOSH's recommendation for a PEL based on health effects and not necessarily on feasibility considerations.

The written statement of the National Cottonseed Products Association (NCPA) discussed the findings of the Tulane study and included a review written by Dr. Robert Jones of a draft report of the NIOSH study. They concluded that the record did not support a threshold finding of a significant risk in the cottonseed industry. (Ex. 213a) Dr. Phillip Wakelyn testified on behalf of the NCPA. He supported OSHA's proposal to exclude the cottonseed processing industry from coverage by the standard and pointed to problems, both economic and technological, that would accompany efforts at dust control in this industry. He stated that data in the record would not "support either the requisite threshold finding of significant risk, or a finding of adverse health effects in cottonseed oil mills." (Tr. 1082)

Mr. T.S. Schuler, president of the NCPA, testified that in his 40 years in the cottonseed industry he had not seen any adverse health effects in workers in his industry (Tr. 1076). In response to a question, Mr. Schuler testified that his company did not have a medical surveillance program and that a requirement for such a program "would present a real problem" to the industry (Tr. 1086). He stated that the rural location of most plants would require transporting workers for long distances to see a physician. This point was reiterated in the NCPA's post hearing brief. (Ex. 281)

OSHA was able to obtain some information relating to this matter of providing medical surveillance to small operations that do not have company physicians. Mr. John Lumsden of ELB Associates, an industrial health and safety consulting group that provides in plant medical surveillance examinations, testified at the Columbia hearings. Mr. Lumsden was asked what his company charged to provide the services required to meet the medical surveillance requirements required by the cotton dust standard to a small employer with 20 employees located about 100 miles from their office. He responded that such an employer was below the minimum so that they would charge "about $400 to do the trip, the testing and the computerized report—annual report." (Tr. 1352)

Dr. James Merchant testifying for the American Thoracic Society joined with the recommendation of NIOSH and the World Health Organization (WHO) for a PEL of one milligram per cubic meter (1000 $\mu g/m^3$) and medical surveillance for the cottonseed industry (Tr. 333).

The National Cotton Council stated that the Tulane study indicated that cottonseed oil mill workers suffered no long term adverse respiratory health effects from their working environment and that the NIOSH study found no acute or chronic problems and no dose-response relationship. Therefore, they concluded that the evidence indicates that no standard is necessary. They

supported OSHA's June 10, 1983 proposal to exclude the cottonseed industry from the standard (Ex. 276).

Conclusions and Significant Risk Analysis

OSHA has carefully considered all the data and comments. The NIOSH and Tulane studies both show no dose-response relationship at the levels studied but they do show that these workers exhibit reactivity to cotton dust. All the medical authorities agree that the dust is reactive though much less so than that seen in textile mills. Based on the data, NIOSH recommended a PEL, exposure monitoring, and medical surveillance. The NCC and NCPA recommended no standard at all. OSHA believes that the data support a middle course. Altering the dust level, at least within the range studied by NIOSH and the Tulane group, does not appear to affect the risk. However, medical examinations will detect reactivity relatively early when it is reversible.

The legal principles and OSHA policies that were discussed under knitting apply equally to cottonseed processing. This section does not repeat that discussion but applies the facts of the cottonseed industry to that analysis.

The first question presented is whether the evidence indicates that a significant health risk exists at the current exposure level which could be reduced by lowering exposures. The evidence indicates that workers exposed at levels equal to ½ to 2 times the present exposure limit do not have an increased incidence of byssinosis or bronchitis compared to controls. It does indicate that there is an excess incidence of overshift declines in FEV_1s but that the decline in overshift FEV_1s is not proportional to dose. Therefore there is little data that reducing exposure would reduce that decline in lung function. (There can be reasons why a dose response relation exists but is masked which are discussed under waste processing, but there is not sufficient evidence to support that hypothesis here.) Dr. Jones has researched this area extensively, and he does not believe an exposure limit is appropriate. As discussed below OSHA does not believe in these circumstances it is appropriate to extrapolate data from the textile industry to this nontextile segment. For these reasons OSHA concludes there is not sufficient evidence of significant risk which could be substantially reduced by lowering exposure limits to justify applying the exposure limit and nonmedical provisions of § 1910.1043 to the cottonseed industry. Accordingly, OSHA is exempting this sector from those provisions.

In 1978, based on the few foreign studies and extrapolating from the textile industry studies OSHA found sufficient evidence to justify a standard in cottonseed processing. That reasoning was upheld by the D.C. Circuit in *AFL–CIO* v. *Marshall*, 617 F. 2d 636, 666 (1979) as applied to cotton seed processing. (The Court reversed and remanded the standard on economic feasibility grounds.)

It is appropriate in these circumstances to explain specifically why OSHA has changed its view. At the time of the 1978 decision, the record in cottonseed processing basically included just the foreign studies, one of which showed risk of byssinosis among cottonseed employees and only one domestic study. Subsequent to that time OSHA has received a series of studies from NIOSH and researchers at Tulane University. These indicate that excess byssinosis and bronchitis are not present among U.S. cottonseed workers.

Secondly, as explained in more detail in the knitting segment, the composition of cotton dust varies from segment to segment and the exact etiologic agent is unknown. Since the composition varies there is less basis for extrapolating risk from the textile industry to the nontextile industry and OSHA believes as a policy matter it should not do so in this instance.

OSHA believes these circumstances, the new studies and a justified change in policy, as well as its overall analysis of the facts, are sufficient basis to justify a change in regulatory requirements. Similar reasoning applies to other nontextile segments though the rationale will not be repeated. OSHA believes that the retention of medical surveillance will provide health protection for cottonseed workers.

The second question is whether medical examinations should be retained for cottonseed processing employees. OSHA has determined that the medical surveillance provisions should not be revoked and should remain in effect for cotton seed processing employees.

The Supreme Court addressed this issue in *IUD* v. *API* when it stated:

> It should also be noted that, in setting a permissible exposure level in reliance on less-than-perfect methods, OSHA would have the benefit of a backstop in the form of monitoring and medical testing.
>
> Thus, if OSHA properly determined that the permissible exposure limit should be set at 5 ppm, it could still require monitoring and medical testing for employees exposed to lower levels. By doing so, it could keep a constant check on the validity of the assumptions made in developing the permissible exposure limit, giving it a sound evidentiary basis for decreasing the limit if it was initially set too high. Moreover, in this way it could ensure that workers who were unusually susceptible to benzene could be removed from exposure before they had suffered any permanent damage.
>
> . . . This is precisely the type of information-gathering function that Congress had in mind when it enacted section (6)(b)(7), which empowers the Secretary to require medical examinations to be furnished to employees exposed to certain hazards and *potential* hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure. See Legis. Hist., p. 147. (Emphasis added) (448 U.S.C. 658).

The Court's analysis is directly relevant. OSHA is revoking most of the new standard for cotton seed processing and as discussed below is exempting the industry from the 6(a) exposure limit of § 1910.1000 as well. Hence no exposure limits will apply. These conclusions are based on "less-than-perfect" evidence. Therefore OSHA needs to retain "a back stop in the form of medical testing . . . so it could keep a constant check on the validity of the assumption made in developing the permissible exposure limit" or as in this case eliminating the limit. The Supreme Court's reasoning seems even more compelling when an exposure limit is eliminated.

It should be noted that OSHA is repealing the majority of a § 6(b) standard and a section 6(a) standard in its entirety. This reasoning is specifically designed to address this situation.

The Noweir study (Ex. 128 k, discussed in the proposal at 48 FR 26967) indicates that byssinosis develops at high exposures in at least one foreign cottonseed processing industry. In that study, conducted in Egypt, exposures were very high, and the NCC states that a different process was used than that used in the U.S. However, a backstop is clearly needed with the elimination of the permissible exposure limit to assure that byssinosis and chronic bronchitis do not develop afterwards. This is especially true because cotton seed processing is a dusty process and the possibility exists that exposures will rise above current levels.

In addition, there is a clear medical need for retaining medical surveillance. There is reduction in overshift FEV_1s among current employees. As Dr. Jones pointed out above, medical surveillance would allow identification of persons "unusually susceptible to adverse effects of this dust" and to identify "persons with active airway diseases

. . . (who) should not be assigned to particularly dusty jobs." (Tr. 206–7). These factors indicate that medical surveillance should be permanently retained.

The third issue presented is whether OSHA should exempt this industry from the 6(a) standard. That is a more difficult question than for knitting. Some data indicate that very high exposures may lead to byssinosis. In addition, the process is dusty, some exposures are already above the 6(a) limit and OSHA cannot have as much confidence that exposures will not rise if the 6(a) standard is eliminated. On the other hand, the studies indicate no bronchitis or byssinosis at current levels some of which are over the 6(a) limit.

In the context of this record, several other factors become revelant. The cottonseed processing industry is very much a declining industry. The number of facilities has been decreasing and many are small businesses. (The 1978 standard has not been in effect during this period. The decline results from market forces.) Employee turnover is 100% per year and the work is often seasonal. The exposed workforce is relatively small, about eight hundred. The data in the record indicate that compliance with 1 mg/m^3 total dust 6(a) standard would be technically and economically difficult, though if interpreted as a respirable dust standard compliance becomes less difficult. (See the discussion under waste processing.)

In the total context, OSHA has determined that the evidence permits it to conclude that a significant health risk will not develop if the 6(a) limit is repealed for this segment. OSHA only makes this determination with the assurance that retention of medical surveillance will provide a backstop if that judgment is incorrect and this surveillance will protect the health of the employees. OSHA believes as indicated in the proposal that, at this point in time, it would better effectuate the purposes of the Act not to require the fairly large expenditures that compliance with the 6(a) standard would require in the face of evidence that byssinosis and bronchitis do not exist at current exposures and the retained medical surveillance provisions will address the issue of overshift FEV_1 declines.

These medical examinations include an initial exam and periodic exams every two years unless the employee falls under the criteria in (h)(3) (i) and (ii). In that case, examinations are required every six months and in some circumstances the employee is to be referred to a specialist for further evaluation.

D. Waste Processing Including Garnetting

The 1978 standard set a PEL of 500 $\mu g/m^3$ for the waste processing industry. This coverage was based on health studies in the textile industry and on studies of waste processing workers in the United States, Britain, and Australia. The record for the 1978 standard contained several studies on the health of workers in this industry (Exs. 99f; 38f; 6–72; 6–71), and they are discussed in the 1978 cotton dust standard (43 FR 27381). An additional health hazard evaluation (Ex. 188–X) was submitted to the Agency following publication of the final standard, and OSHA issued an administrative stay on September 1, 1978 in order to consider this information (43 FR 39087). Following its evaluation of the new information, OSHA concluded that the findings in the 1978 standard were correct and lifted the administrative stay on January 26, 1979 (44 FR 5438).

An early study (Ex. 6–72) of cotton waste mills in the United Kingdom by Dingwall-Fordyce and O'Sullivan found a 30% prevalence of byssinosis, including a 5% prevalence of disabling byssinosis. Bronchitis prevalence was not reported in this study. The authors did not include controls in their study and workers did have some exposure to raw cotton. Chinn and coworkers (Ex. 99f) studied willowing mills in the United Kingdom and found a 53.3% prevalence of bronchitis. A 5% prevalence of byssinosis was reported. In addition, willowers had greater pre-shift and postshift declines in lung function when compared to controls. Simpson measured pre-shift and postshift FEV_1 in six Australian garnetting operations (Ex. 6–71). No control data was reported. About 31% or the workers had postshift FEV_1 declines of 200 milliliters or more.

NIOSH investigators conducted a health hazard evaluation of a U.S. garnetting and mattress-making company in 1973 (Ex. 38f) and in 1977 (Ex. 188–X). No comparison group was included in the studies. In 1973, the bronchitis prevalence was 59% and the byssinosis prevalence was 11.8%. The percentage of workers with a postshift decline in FEV_1 of 5% or more was 20.6%. In 1977 when the cotton dust levels were much lower, the bronchitis prevalance was 34% and the byssinosis prevalence was 1.9%. There was a slight rise in the prevalence of postshift decline in FEV_1.

The ANPR published on February 9, 1982 (47 FR 5906) solicited any additional information on the health of workers exposed to cotton dust in any of the industries covered by the 1978 standard, and OSHA received a study on the waste utilization industry from NIOSH (Ex. 175–56).

The new study from NIOSH was entitled "Characterization of Byssinosis and other Pulmonary Abnormalities in the Cotton Waste Utilization Industry, Part 5" (Ex. 175–56). In 1978 and 1979, NIOSH examined 260 workers in 13 cotton waste utilization plants in the Southeastern United States. A group of 292 blue collar workers employed in non-dusty occupations served as the control group. NIOSH found no significant increase in the prevalence of byssinosis in the cotton waste workers when they were compared to the control group. They did find a significant increase in the prevalence of bronchitis in exposed workers employed in the waste industry for less than two years. This increase was most striking in nonsmoking workers who had been employed for less than two years. In addition, they found that decreases in pulmonary function in some exposed workers appeared to be related to the particular plant in which the individual was employed. No dose-response relationship was demonstrated by this study. The geometric mean dust concentration for many of the plants was around 0.5 mg/m^3.

The National Cotton Council (Ex. 175–47) submitted two critical reviews of the NIOSH study as an attachment to its earlier comments. These reviews noted that no evidence of excess prevalence of byssinosis was seen in the workers. The NCC also said that an association between cotton dust exposure and chronic bronchitis in workers with less than two years of experience could not be made because "chronic bronchitis" is defined as chronic only when persisting for at least two years, so it must have pre-existed the work with cotton-related materials. They also criticized the control group used by NIOSH. These criticisms were repeated in their final posthearing brief (Ex. 276).

At the time that NIOSH analyzed the data for their report, data from only six of the more than 30 comparison plants were available to be used as controls. In order to conform to the "Southeast" location of the waste cotton workers (North and South Carolina, Georgia, Alabama and Florida) and to respond to some comments about the more westerly location of some of the comparison plants, NIOSH reanalyzed the data using only "Southeast" comparison plants. This addendum did not replace the original report but was a further analysis of the data (Ex. 175–56). Using this comparison group, NIOSH

found a significant increase in the prevalence of bronchitis in workers (both smokers and nonsmokers) who had worked in the waste cotton industry for more than two years and in nonsmokers with less than two years in the industry. In addition, workers with less than two years in the waste cotton industry had a significantly greater prevalence of bronchitis than workers with more than two years. There was a significant increase in the prevalence of overshift decrements of FEV_1 greater than 10% in workers with greater than two years service, and there was also a significant increase in the prevalence of overshift decrements of FEV_1 greater than 5% in waste cotton workers compared to controls matched in age and smoking. NIOSH found no significant increase in the prevalence of byssinosis or of workers with an FEV_1 of less then 80% of the predicted value.

OSHA concluded that although the data did not support reducing the permissible exposure limit that there was evidence of risk to workers, and there was no evidence of safety in this industry. Therefore, OSHA proposed to continue coverage of the waste processing industry under § 1910.1000 and to delete the industry from coverage under § 1910.1043.

OSHA invited Dr. Alan Engelberg, formerly of NIOSH and a medical project officer on the NIOSH cross-sectional studies, to testify at the public hearings as an expert witness on the waste processing industry. Dr. Engelberg described the results of the NIOSH study and responded at length to the criticisms of the National Cotton Council concerning the control group. He devoted more than half of his written testimony to responding point-by-point to the criticisms of the study made by the National Cotton Council and others. One criticism of the study made by NCC was that the control group came from a different socio-economic group and the basis for this contention was that the group of control workers received $3.80 to $7.40 per hour while the waste cotton workers received $3.35 per hour, the minimum wage. Although socioeconomic status can be correlated with respiratory health, Dr. Engelberg stated that in none of the studies cited by the NCC was socioeconomic defined by wage differential alone. In the Higgins study, three groups were defined: (1) White collar, (2) farm labor and (3) blue collar, and both the waste cotton workers and the control group in the study belong to the blue collar group. Dr. Engelberg provided similar analyses for the two other papers cited by the NCC on this matter. There was also a criticism of NIOSH's definition of the term chronic bronchitis, and Dr. Engelberg responded that the definition used by NIOSH was consistent with the way chronic bronchitis was defined in the papers cited by the NCC. OSHA believes that Dr. Engelberg has satisfactorily answered the criticisms of the NCC and that the results of the NIOSH study are valid.

Dr. Engelberg also provided OSHA with his recommendations concerning this industry. He agreed that a respirable dust standard, measured by the vertical elutriator would be appropriate. He stated "that OSHA should consider an elutriated dust standard equivalent to the proposed total dust standard, to address the fact that the dust in this industry has similar biological effects as cotton dust in other industries." (1983 Tr. at 65) He further recommended that medical surveillance be continued to detect early stages of respiratory disease (Tr. 65; 141).

Dr. Merchant testified in behalf of the American Thoracic Society on the need to retain regulation of the waste processing industry and the need to retain medical surveillance. That was also his conclusion for ginning and cottonseed processing. He agreed that medical surveillance was sufficient for knitting and classing.) However, he added:

> OSHA is proposing to regulate this industry with a one milligram per cubic meter of total dust PEL only. As has been noted in the textile industry, total dust often does not correlate with health effects; hence, OSHA's proposing to utilize total dust which may or may not contain biologically active inhalable dust. Thus, it risks not providing workers adequate protection on the one hand, and over-regulation of the industry on the other.
>
> A more rational plan, in my view, would be to adopt a PEL for inhalable dust between .5 and one milligram per cubic meter together with medical surveillance. As has been demonstrated in the textile sector, both provisions are important in preventing respiratory disease. (Tr. 331–332)

In their testimony, NIOSH discussed the findings of their cross-sectional studies and made their recommendations concerning the protection of these workers. Mr. Richard Lemen, representing the Institute said:

> In conclusion, NIOSH continues to recommend the provisions of its 1974 Criteria Document as the basis of a Cotton Dust Standard. . . . The Criteria Document recommended reduction of dust concentrations to the lowest level feasible and recommended medical monitoring and employee training. (Tr. 401–2)

The National Cotton Council repeatedly stated in their comments and written testimony that OSHA has not made a threshold finding of significant risk in the waste cotton industry and that meeting a 1000 $\mu g/m^3$ total cotton dust standard is economically and technologically infeasible. Therefore, they concluded that this industry should be totally exempted from any standard. Although they opposed coverage of this industry by any standard, Mr. Frank Mitchner of the National Cotton Council agreed that measuring respirable dust is more appropriate than measuring total dust in this industry. A summary of his statement read into the hearing record stated:

> The vertical elutriator, with all its faults, is vastly more appropriate for measuring dust in nontextile operations, or any operation for that matter, than the personal sampler. (Tr. 977)

Both the Textile Fibers and ByProducts Association (Ex. 210B) and the National Cotton Batting Institute (Ex. 211D) presented their own analysis of the evidence in the record and concluded that the health studies in the record could not be used to support a finding of adverse health effects.

The testimony of the industry representatives on this issue was limited to comments and critical analyses of studies in the record. These studies show that workers exposed to cotton dust in this industry develop adverse health effects. No new studies were introduced to provide evidence of safety. No medical expert testified that the evidence supported the elimination of medical surveillance for waste processing workers. Therefore, the evidence in the record provides no basis for eliminating a permissible exposure limit and medical surveillance for this industry.

Conclusions and Significant Risk Analysis

The legal and policy basis for an analysis of the waste processing segment is discussed under the knitting segment. That general discussion is not repeated. On the facts presented it appears more logical to discuss the issues in reverse order for waste processing.

The first question is then whether there is sufficient evidence to demonstrate that significant health risk is unlikely to exist if the waste processing industry were exempted from coverage of the 6(a) standard. It is clear that the evidence does not demonstrate this. A series of studies indicate substantial excess risk of byssinosis, bronchitis and lung function declines. The NCC pointed out that each study has some weaknesses, but that point does not provide a sufficient evidentiary

basis for eliminating all regulation. Indeed, the fact that a number of studies show substantial excess prevalence of disease tends to overcome the fact that each has weaknesses.

As discussed under knitting the burden of proof in eliminating a 6(a) standard is to show that uncontrolled exposures are unlikely to lead to significant risk, not to demonstrate that significant risk exists. However, if no standard existed and OSHA was undertaking a 6(b) rulemaking to determine whether a standard should be promulgated for this sector, OSHA would find that a significant risk existed at uncontrolled exposures which would be substantially reduced by a standard. Several studies taken together show substantial excesses of byssinosis, bronchitis, and pulmonary function declines at high exposures. This is significant risk of material impairment of health and functional capacity. The most recent NIOSH study shows that lower exposures eliminate byssinosis and reduce pulmonary function declines. Therefore a standard such as the 6(a) standard substantially reduces a significant risk.

Further, waste processing tends to be a dusty operation and some exposures are over the 6(a) cotton dust standard as a total dust level measured by a personal sampler. Both Dr. Merchant and Dr. Engelberg recommended that the 1000 $\mu g/m^3$ PEL be interpreted as a vertical elutriator respirable dust standard rather than a total dust standard. This would to be more consistent with the epidemiological studies and more protective for employees. Representatives of the NCC also agreed that if there were to be a level, it should be a respirable dust level. Accordingly OSHA is changing its interpretation of the 6(a) limit in § 1910.1000 to a respirable dust level as measured by a vertical elutriator which will increase employee protection. A footnote has been added to the cotton dust entry of Table Z–1 of § 1910.1000 to indicate this.

As discussed below in the feasibility section it is substantially easier to achieve a respirable dust level than a total dust level. This change therefore responds to the NCC's feasibility concerns and improves the cost-effectiveness of the standard as well.

OSHA has concluded it is appropriate to narrow the definition of waste processing to the operations of waste recycling (sorting, blending, cleaning and willowing) and garnetting as proposed. However, it is excluding bedding assembly operations. OSHA does not believe that risk was demonstrated in bedding assembly, which is a much less dusty operation. However, if a bedding manufacturer has a garnetting operation, the garnetting part of the bedding manufacturer's operations are covered by the standard.

The next question is whether there is significant risk at the 6(a) level which can be substantially reduced by a lower exposure limit. The recent NIOSH study of the current work force does not demonstrate the existence of byssinosis, and the excess incidence of pulmonary function declines and chronic bronchitis does not indicate a dose-response relationship. The ACTWU and Dr. Beck pointed out that a dose-response relationship could be masked when there is an acute reaction which varies among persons. The more reactive employees might transfer to lower dust areas because they could not function in high dust areas, and the less reactive employees willing to work in higher dust because their reaction would not be as great. This would lead to overall excess risk compared to suitable controls but no indicated dose-response relationship (Ex. 279, pp. 113–114; Tr. 1123–5) However, no empirical research is presented to support this hypothesis.

OSHA concludes in light of the absence of byssinosis and demonstrated dose-response that in this particular circumstance there is not sufficient evidence to demonstrate that a lower exposure limit would substantially reduce significant risk. In addition Dr. Merchant, the scientist whose research was a major factor in the development of the cotton dust standard, indicated that it would be a "rational plan" to adopt a 1000 $\mu g/m^3$ respirable dust standard with medical surveillance. This is in essence what OSHA is doing and OSHA believe it will be protective of employees.

The last question is whether medical surveillance should be retained. OSHA concludes it clearly should be retained for waste processing. First, medical surveillance in conjunction with the exposure limit is needed to prevent the development of substantial rates of byssinosis and bronchitis which uncontrolled exposures lead to. Second, the NIOSH study does indicate excess chronic bronchitis and pulmonary function declines at current exposures. Medical surveillance is needed to identify and protect employees who develop these conditions. Third, Dr. Merchant and Dr. Beck testified on the need for medical surveillance. No medically qualified person testified it was unnecessary. Finally, it is a necessary backstop for the decision not to lower exposures to the 500 $\mu g/m^3$ respirable dust level.

E. Cotton Classing

When the 1978 standard was published, OSHA had no direct evidence in the record on the health of workers employed in classing operations. There was, however, evidence that dust levels in some unventilated operations reached 2400 $\mu g/m^3$ and minor changes in the ventilation could reduce the dust levels (43 FR 27369). The Agency included classing operations in the scope of the standard based on indirect evidence from the textile industry.

Following the legal challenges to the standard and the Supreme Court's decision on the Benzene standard, OSHA administratively stayed enforcement of the standard as it applied to cotton classing offices and cotton warehousing because there was a concern that the preamble to the standard had "not adequately describe[d] the rationale for including warehousing and cotton classing operations." (45 FR 50329, July 29, 1980)

Following the publication of the February 9, 1982 ANPR, the American Cotton Shippers Association (Ex. 175–30) commented in favor of excluding classing operation from the standard. They emphasized that there were no studies in the record on the health of classing workers. Because they submitted their comments before the anticipated NIOSH study on USDA classing offices became available, they requested additional time to comment specifically on it. They pointed out that unlike government classing offices, classing associated with merchandizing is more seasonal and cotton classifiers spend only a portion of their workday in this function.

NIOSH submitted a study on the environmental conditions and the respiratory health of workers in 13 USDA cotton classing offices, entitled "Respiratory Disorders and Dust Exposure in Sectors of the Cotton Industry of the United States Part 4: Cotton Classing Offices." (Ex. 175–56) Briefly, this study found that dust levels had been reduced and at the time of the study ranged from 70 $\mu g/m^3$ to 340 $\mu g/m^3$. They found no evidence to suggest an excess prevalence of lung symptoms or diminished lung function in these workers. NIOSH suggested that a second epidemiological study with proper control group be "funded in the near future." (Ex. 175–56)

Based on the findings of the NIOSH study, OSHA proposed to exclude cotton classing operations from coverage by either cotton dust standard (29 CFR 1910.1043 and 29 CFR 1910.1000)

because there was no evidence that workers in classing offices suffer either acute or chronic adverse health effects as the result of their exposure to cotton dust (48 FR 26968). OSHA received very few comments on this issue following publication of the proposal and there was little discussion of this matter in the public hearings.

In their prehearing comments, NIOSH restated the findings of their study and recommended a continuation of dust control (Ex. 187–23). In their testimony and posthearing comments, NIOSH recommended that OSHA adopt the recommendations outlined in the 1974 criteria document. These recommendations included both medical surveillance and the lowest feasible dust level. In posthearing comments, the ACTWU cited a number of reasons that argue against using a single negative study to exclude an industry from the standard but they did not question the findings of the NIOSH study (Ex. 279). The National Cotton Council supported OSHA's proposal to exclude classing from the standard because the record "will not support a threshold finding that . . . classing office workers are exposed to a significant health risk." (Ex. 276)

Conclusion and Significant Risk Analysis

The factual underpinnings are very similar and the analysis identical for the classing segment as for the knitting industry. Therefore, it is only briefly summarized. There is one study in the record which addresses the health of classing workers. This study, conducted by NIOSH, concludes that neither acute nor chronic adverse health effects were seen in these workers, and this finding has not been seriously questioned. There are no studies demonstrating risk in this segment and extrapolation from the textile segment is inappropriate in these circumstances. Therefore, based on the information in the record, OSHA concludes that under current conditions workers in cotton classing offices do not appear to be at significant risk of adverse health effects due to their occupational exposure to cotton dust which could be substantially reduced by a lower exposure limit. Consequently OSHA is exempting the classing segment from all requirements of § 1910.1043.

The employees surveyed in the NIOSH study were working under conditions where the dust levels were being controlled and their exposure were low. OSHA believes exposures will not rise. However, the medical study by NIOSH, discussed above under knitting, will act as a backstop to indicate if the health of the employees remains unimpaired after regulation ceases. Of course, if the study indicates that employees have not remained in good respiratory health, OSHA will consider appropriate regulatory action.

Based on the facts available for classing operations and the analysis presented in the knitting discussion, OSHA also concludes that the evidence demonstrates that a significant health risk will not develop if this segment is not covered by exposure limits. Accordingly, OSHA is exempting this operations from the 6(a) cotton dust exposure limit. This decision will better effectuate the purposes of the Act.

F. Cotton Warehouses

The record for the 1978 standard included a report by Barman of a survey of 70 workers in a single compress/warehouse operation (Ex. 56). In response to the February 9, 1982 ANPR, NIOSH submitted a study of the environmental conditions and respiratory health of workers in this industry. The study was entitled "Respiratory Disorders and Dust Exposure in Sectors of the Cotton Industry of the United States, Part 2: Cotton Compress Warehouses" (Ex. 175–56). The study showed an excess prevalence of bronchitis and decrements in FEV^1 greater than 10%. However, several factors made interpretation of this data difficult. One factor is that a large portion of the study group had been employed in other cotton industries such as ginning. A second factor is that there were a large number of differences between the study group and the control group, specifically racial, geographic and age differences. A third factor is that there was an inverse dose-response relationship between dust levels and decrement in FEV_1. In other words, workers at lower cotton dust levels were more likely to show a decrement in FEV_1 than workers at higher cotton dust levels. The authors suggested that this impairment seen in workers at lower dust levels may have resulted from exposures to other than cotton dust, such as exhaust emissions from idling transport vehicles. At the hearings, NIOSH recommended a standard for this industry that incorporated the recommendations of their 1974 criteria document.

OSHA's proposal to exclude cotton warehousing operations from the standard received few comments, and those received were very general in nature. Commenters either supported OSHA's proposal to exclude warehousing (Exs. 214, 276) or argued that a single negative study was inadequate to exclude an industry from the standard (Ex. 279).

Conclusions and Significant Risk Analysis

The analysis presented for the knitting and cottonseed segments is relevant here. There is only limited data in the record which addresses the health of warehousing workers. The major study, conducted by NIOSH, concludes that there is some evidence of adverse health effects in these workers. The areas where these effects was in the areas of lowest cotton dust exposure. It is not clear, therefore, whether these adverse health effects are due to exposure to cotton dust or to some other factor. There is no evidence in the record that indicates that reducing the dust level will result in a reduction of respiratory symptoms. Therefore, based on the information in the record, OSHA concludes that under current conditions cotton warehousing workers do not appear to be at significant risk of adverse health effects due to their occupational exposure to cotton dust. Consequently, OSHA concludes that the data support deleting cotton warehouse operations from § 1910.1043.

For the same reasons discussed under knitting and classing, OSHA concludes that the medical surveillance requirements need not be retained. However, the medical study by NIOSH discussed above under knitting, will act as a backstop to indicate if the health of the employees remains unimpaired after regulation ceases. Of course, if the study indicates that employees have not remained in good respiratory health, OSHA will consider appropriate regulatory action.

OSHA also concludes that the evidence demonstrates that a significant health risk is unlikely to develop if the exposure limit of the 6(a) standard is eliminated. Exposures tend to be intermittent and operations are usually in open areas with substantial natural ventilation. Therefore, OSHA does not expect exposures or medical conditions to change with the elimination of the 6(a) standard. Accordingly, OSHA is exempting cotton warehousing operations from the cotton dust permissible exposure limit of § 1910.1000, Table Z–1. OSHA concludes that this decision better effectuates the purposes of the Act.

G. Interpretation of Scope and Medical Startup Dates

The 1978 standard applied "to the control of employee exposure to cotton dust in all workplaces" with certain specified exceptions. The National

Cotton Council recommended that OSHA specify exactly where the standard was to apply (Ex. 276, p. 2). This is the approach OSHA took in its proposal and retained in the final. The operations in which the standard is applicable are the operations where coverage is appropriate and justified by health data. This approach makes it clear that the cotton dust standard does not apply to bedding assembly, furniture assembly, tire manufacture and other segments not specified or discussed in this preamble.

The cotton dust standard applies to the operations specified and is not limited to facilities in SIC codes where that operation is the primary operation. For example, garnetting operations are covered by the medical surveillance limit of § 1910.1043 and the exposure limits of § 1910.1000. Bedding assembly is not covered by either standard. Obviously a garnetter using waste cotton is covered as specified, and a bedding assembly facility with no garnetting operations is totally excluded from the standard. However, in a bedding assembly facility which has a garnetting operation, the standard applies to cotton dust exposures in the garnetting area. Similarly, tire production is not covered by either standard. However, if a tire producer has a yarn production operation with cotton dust present, the area of that yarn production operation is covered by the textile standard.

The medical surveillance provisions of § 1910.1043 have been stayed for nontextiles. The medical provisions are being retained as discussed above for cotton seed processing and waste processing and the stays will be lifted. In order to permit time for industries to arrange for medical surveillance in an orderly and efficient manner, a six month period is being permitted before initial medical examination requirement goes into effect. This start up provision is set forth in § 1910.1043(m)(2).

H. Supplementary Submission by Non-Textile Industry After Record Close

The last date for submitting post-hearing briefs to the cotton dust record was December 16, 1983. The record was certified by the presiding Administrative Law Judge on January 12, 1984.

The National Cottonseed Products Association, Cotton Warehouse Association, Textile Fibers and By-Products Association and the National Cotton Batting Institute sent to OSHA on January 2, 1985 a "Supplemental Submission." The Supplemental Submission discussed two matters. First, it discussed the relevance of a case decided November 7, 1984, Forging Industry Ass'n v. Secretary of Labor, 748 F.2d 210 (4th Cir.) to the cotton dust standard. Second, it discussed evidence in the cotton dust record on the relationship between cotton dust-related respiratory disease and smoking.

Initially a panel of the Fourth Circuit in *Forging Industry Ass'n.* held in two to one decision that the OSHA Hearing Conservation Standard, which required medical testing, was invalid because it did not adequately distinguish between hearing loss resulting from workplace noise and hearing loss resulting from aging and noise from non-work-related activity such as target shooting. The Supplemental Submission argued that the case was relevant to providing medical surveillance to nontextile workers because cigarette smoking can aggravate or create some of the pulmonary conditions also caused by exposure to cotton dust.

On April 4, 1985, the Fourth Circuit granted OSHA's petition for a rehearing *en banc* of *Forging Industry Ass'n.* On September 23, 1985, the Fourth Circuit, *en banc*, unanimously upheld all provisions of the OSHA Hearing Conservation Standard. Among other things, the court held that OSHA could require medical examinations to detect conditions which are commonly caused by exposure to harmful agents at the workplace though those conditions may also be aggravated or caused by nonoccupational conditions. In light of the *en banc* decision, the arguments which the Supplemental Submission made based on the initial panel decision no longer have basis.

The Supplemental Submission also made various statements about the interaction between smoking, cotton dust exposure and pulmonary disease and symptoms. It also quoted from various studies on this matter. That discussion should have been submitted no later than the deadline for submission of post hearing briefs and accordingly is late.

However, since it selectively reviews the literature and could be misinterpreted, a brief response is made. OSHA did analyze the relationship between cotton dust and smoking in the preamble to the 1978 standard. OSHA concluded that "presuasive evidence demonstrates the cigarette smoking variable, rather than overwhelming the cotton dust variable is merely related to it." 43 FR 27354 (June 23, 1978). The Supreme Court, of course, upheld OSHA's cotton dust standard for the textile industry which was based on this preamble discussion.

Most of the recent cotton dust studies, including those for nontextiles, control for smoking. When these studies report an increase in pulmonary symptoms for smokers, they are comparing a group of smokers who are not exposed to cotton dust to a group of smokers who are exposed to cotton dust, and the cotton dust exposed workers had the greater response. Similarly in matched pair analysis, exposed workers are matched with controls who have the same smoking history. So if there is an excess of pulmonary symptoms in the group exposed to cotton dust, smoking has been controlled for and that excess is due to cotton dust exposure.

For example, the NIOSH study of the waste utilization industry (Ex. 175–56) indicated a significant increase in bronchitis for smokers employed more than two years and all nonsmokers. It also showed a significant decline in lung function for all exposed workers. Similarly, the NIOSH study of the cotton seed processing industry showed a significant decrease in lung function of exposed workers who are smokers compared to smokers who are not exposed to cotton dust.

Medical exams for cotton dust exposed employees are directly relevant to protecting employees from the effects of cotton dust in textiles, cotton seed processing and waste processing. If an employee (smoker or nonsmoker) is revealed by the initial medical exam to have low lung function, or to have a substantial decline of lung function after the employee's first day on the job, then it is necessary for the employee's health for a physician to review the employee's condition. The physician needs to make a recommendation on whether continued exposure to cotton dust will impair the employee's lung function. A similar review is needed if these conditions develop after a number of years of employment. A few employees will react to cotton dust at very low levels of exposure. Consequently, physicians have not recommended low level exposure cut-offs for medical examinations.

Based on all the evidence in the record as briefly summarized in this discussion, OSHA continues to conclude that medical examinations directly provide some health protection to employees exposed to cotton dust in textiles, cotton seed processing and waste processing from illnesses and declines in lung function resulting from cotton dust exposure. This protection benefits both nonsmokers and smokers. The cotton dust exposure creates additional health problems for smokers different from or greater in extent than the problems caused by smoking alone.

IV. Amendments to the Standard for the Textile Industry

This section of the preamble provides an explanation of amendments to § 1910.1043 as the standard applies to the textile industry. Each amendment to the standard is explained separately or if no amendment was made, as in paragraph (J) "Signs", then this has also been indicated. This explanation also refers to operations other than textiles, where such references are appropriate. For instance, the frequency requirements for medical surveillance in nontextile operations are discussed under paragraph (h) "Medical Surveillance".

A few minor grammatical changes have been made to the language of the standard. These changes are not intended to alter the requirements or otherwise affect the intent of the standard and they are not discussed in the preamble.

A. Scope and Application

OSHA made no proposal to amend the scope of this standard as it applies to yarn manufacturing and slashing and weaving. Indeed, the record, discussed at length in Section II. Occupational Health Implications of Cotton Dust in the Textile Industry and Significant Risk Analysis, documents that a standard is not only necessary to protect workers in the textile industry but also that it has been very effective in reducing the prevalence of respiratory disease. Therefore, OSHA concludes that the evidence continues to support the Agency's earlier conclusions that the application of the cotton dust standard to yarn manufacturing and slashing and weaving operations is necessary to substantially reduce a significant risk that would be present if the standard was not in effect and that there is no basis to change the standard in this area.

In the proposal, OSHA proposed to maintain the scope of coverage for the textile industry but limited the coverage of this segment to yarn production and to slashing and weaving. Most textile mills also have a waste house where soft and hard cotton wastes are collected and baled. These waste products are collected from all phases of the production process and in many cases are removed from the production areas by the ventilation equipment and other engineering controls installed to maintain the PEL. Most textile mills have made a good faith effort to comply with the 1978 standard in their waste house operation (Ex. 280, pp. 106–109). Due to an oversight, the 1983 proposal did not discuss the textile mill waste house operations and this omission left the status of these operations unclear.

It is clear that cotton dust exposure in textile mill waste houses is not directly comparable to exposure in other waste cotton operations not directly associated with a textile mill. First, there is a potential for the exchange of air between the production areas and the waste house. Second, there is the likelihood that waste house workers will spend some of their time in production areas which will affect their risk. Third, compliance with the standard may be made more difficult for the employer when there are a group of workers who do not receive training and are covered by some but not by all of the provisions of the standard. For these reasons, OSHA will continue to require that all provisions of § 1910.1043 apply to waste house operations. That is, the PEL (500 $\mu g/m^3$) will continue to apply as well as all other provisions of the standard.

OSHA has clarified its definition of "washed cotton" and evidence has been presented that commercially viable washing processes are now available. Although, at present, "washed cotton" is not prepared commercially, such commercial preparation is likely to begin in the near future. Although the Washed Cotton Task Force made many recommendations concerning washing methods, the Task Force made no specific recommendations on the protection of employees engaged in the washing process (Tr. 893–894). Evidence and testimony presented by the Washed Cotton Task Force indicated that initial stages of cotton washing (bale opening and mechanical cleaning) are identical to the initial stages of yarn manufacturing (Tr. 893–894). OSHA concludes that there is a significant risk of adverse health effects for workers engaged in these initial processes in cotton washing. (These risks have been discussed in another section of this preamble, Section II. Occupational Health Implications of Cotton Dust Exposure in the Textile Industry.) Therefore, OSHA concludes that the standard § 1910.1043 applies to all employee exposure to cotton dust generated by cotton washing operations from opening until the cotton is thoroughly wetted when the likelihood of a release of cotton dust is virtually eliminated. The standard applies to all employees exposed to this dust regardless of the job that the employee is performing.

As a matter of format, OSHA is omitting the paragraph designated (a)(3) in the 1978 standard. No change in meaning is intended. That paragraph refers to all the types of variances for which employers may apply. Employers have those rights because of the statute, and they are applicable for all standards. However, OSHA does not cross reference the variance provision in any other standard. Therefore, this paragraph is being omitted to maintain consistency of format among all standards. Employers still may apply for and have the same right to receive temporary and permanent variances as provided for by sections (6)(b)(6)(A), 6(b)(6)(C) and 6(d) of the Act and 29 CFR Part 1905.

B. Definitions

1. "Blow Off/Blow Down"

The 1978 standard did not define the term "blow off" and defined the term "blow down" as "the cleaning of equipment and surfaces with compressed air." Limitations were placed on blow down in paragraph (g), which prohibited compressed air blow down cleaning where alternate means were feasible. That provision also required employees performing the blow down to wear respirators and required employees who were not needed for the blow down to leave the area. Comments in response to the February 1982 ANPR indicated that the industry used both terms ("blow down" and "blow off") and that confusion was created by the single definition. In addition, it was pointed out that "blow off" of individual machines was the generally appropriate method of cleaning, and because of its limited nature, required fewer restrictions.

To eliminate confusion as to work practice requirements for compressed air cleaning, OSHA proposed to define "blow down" as the "general cleaning of all pieces of machinery in a processing area by the use of compressed air" and to define "blow off" as "the use of compressed air for cleaning of short duration and usually for a specific machine or portion of a machine." (48 FR 26980) Paragraph (g) of the proposal banned blow down if alternative means of cleaning were feasible, required that employees not needed for blow down leave the area, and required that respirators be used for employees performing either blow off or blow down. (48 FR 26982)

Relatively little testimony was offered relating to this change. Mr. Carroll Bailey, a certified industrial hygienist with the South Carolina Department of Labor, testified as to the need for a provision that would distinguish between "blow down" and "blow off" to eliminate inconsistencies in enforcement. He stated:

The inclusion of a definition for the terms 'blow off' and 'blow down' is long overdue. The lack of this * * * resulted in inconsistency in enforcement * * *

It has not been appropriate to require that a whole area be evacuated during operations that are now defined as "blow off". The wearing of an approved respirator during both operations is certainly essential to the protection of the employee's health. (Tr. 1140).

In his testimony, North Carolina Labor Commissioner John Brooks also endorsed the proposed change of definition, and recommended that "blow down" be defined to "include cleaning of an entire area, walls, ceiling, ventilation duct work and so forth, as well as the machinery." (Tr. 1278).

In prehearing comments, the American Textile Manufacturers Institute (ATMI) supported a provision which would distinguish between "blow down" and "blow off", but offered substitute language, as follows:

Section 1910.1943 (b) under the rulemaking proposal defines 'blow down' as 'the general cleaning of all pieces of machinery in a processing area by the use of compressed air.' In fact, 'blow down' (as opposed to 'blow off') involves the general cleaning of an *entire room* rather than simply 'pieces of machinery' within the room. In order to more accurately reflect this distinction, the definition of 'blow down' should be revised as follows:

Blow down means the general cleaning of an entire room by the use of compressed air." (Ex. 187–17)

ATMI further recommended as a general "rule of thumb" that nonessential employees should be cleared from the room when compressed air is being used to clean an entire room. They further note that often it will not, in their view, be necessary to evacuate the entire room, and that instead an industrial hygienist or "other qualified professional" should determine "which portion of the room needs to be cleared of nonessential employees * * *" (Ex. 187–17).

ATMI's views on "blow off" cleaning are that since a much more limited area is involved, "the area that should be cleared of employees who are not performing the 'blow off' can be defined in terms of a one machine buffer zone in each direction surrounding the machine that is being cleaned. In some cases, however, the 'blow off' operation is so limited in scope * * * that no significant elevation in dust levels occurs in the area surrounding the machine. In such instances, there is no need to clear the area of production employees." (Ex. 187–17).

Not all testimony, however, supported the proposed distinction between "blow down" and "blow off". Objections centered on workers' perception that current requirements were not being implemented by employers. Paul Restivo, a representative of the ACTWU, stated:

OSHA's proposed change related to "blow off" and "blow down" with compressed air is one of the most callous changes which OSHA has proposed. Not only will workers be exposed to excessively high levels of cotton dust during these periods and have to stay in the high dust concentration areas, but the levels will not even accurately be reported.

Under the proposed change, an employer could require employees to stay on the job no matter how high the dust level during periods when one machine is being blown off. A distinction is made between "blow down", blowing several machines, or the general area, and "blow off", blowing one machine.

(Our members) * * * felt their employer would simply have compressed air cleaning conducted in a manner in which only one machine is being cleaned at a time, so that workers wouldn't be able to get out of the dusty area."

Under the present work practices provision, many workers have indicated * * * that their employers give employees who get out of the dusty area during compressed air cleaning a hard time. In fact, some supervisors have gone so far as telling workers that they did not have the right to leave the area during compressed air cleaning." (Tr. 1485–6).

Mary Fowler, a textile worker and a member of ACTWU, voiced her concerns on this matter:

Now, to make things worse, I am told I'll no longer be able to vacate the area where blow offs do occur if this proposed change goes into effect.

At the present time, on each spool you have A-side B-side. If "Blow off" occurs on A-side, the dust comes over the machine, under the machine, and so far we have been able to leave the area and wait until the dust has been removed: then return to work. This has been a plus in my opinion for the workers.

I don't think it's right to tell a worker they cannot get out of that cloud of dust * * * " (Tr. 1514).

Subsequent testimony reiterated these points, and provided some further discussion of the difficulty of defining the area which should properly be evacuated in a limited compressed air cleaning operation. (Tr. 1531–49).

In their posthearing submissions, however, both the Amalgamated Clothing and Textile Workers Union (ACTWU), and ATMI agreed on the following points:

1. OSHA's proposal for definition of "blow down" focused "unduly" on the cleaning of *machinery*.

2. "Blow down" means the "general cleaning of an entire room by the use of compressed air."

3. Work practice requirements in the proposal are appropriate, specifically the provisions that require employees performing the "blow down" or "blow off" to wear suitable respirators, and to require employees whose presence is not required to perform the "blow down" to leave the area during the cleaning operation.

4. The work practice provisions should be understood to require also that employees leave the immediate area affected by the "blow off" even if they do not evacuate the entire room.

5. Depending on the scope of the cleaning involved, it may be appropriate to evacuate an entire room, a portion of a room, or only the area affected by the cleaning of a single machine.

6. To implement this understanding, the standard should contain the following:

Employees whose presence is not required to perform "blow down" or "blow off" shall be required to leave the area affected by the "blow down" or "blow off" during the cleaning operation. (EX. 279, p.64; Ex. 280, p.64).

In light of this record, OSHA is retaining the proposed distinction between "blow down" and "blow off". The definition of "blow down" has been changed to put emphasis on the area affected, as was recommended. "Blow off" is often needed to clean a machine but a wide evacuation is not needed. "Blow off" will, therefore, not apply to cleaning major parts of a room, since that would generate a large amount of airborne dust, making the operation equivalent to a "blow down".

2. "Cotton Dust"

In the ANPR (47 FR 5907), OSHA raised the issue of whether the term "cotton dust" could be more narrowly defined. Few comments were received in response to this issue. Some suggested the exclusion of non-cotton materials such as oil mist, mineral dust, and synthetic fiber dust. Additional information was needed to determine whether and how the 1978 definition should be changed. However, none of the comment provided an adequate evidentiary basis for proposing a change in the definition. Thus, in its June 1983 proposal, OSHA requested comment on the "definition of cotton dust as the total particulate collected by the vertical elutriator." (48 FR 26963).

In the 1978 Standard, OSHA defined cotton dust as:

"* * * dust present in the air during the handling or processing of cotton, which may contain a mixture of many substances including ground up plant matter, fiber, bacteria, fungi, soil, pesticides, non-cotton plant matter, and other contaminants which may have accumulated with the cotton during the growing, harvesting, and subsequent

processing or storage periods. Any dust present during the handling and processing of cotton through the weaving or knitting of fabrics and dust present in other manufacturing operations or processes using new or waste cotton fiber or cotton fiber by-products from textile mills are considered cotton dust." (43 FR 27395).

OSHA explicity recognized that cotton dust is a "heterogeneous mixture", and that the proportion of the various components in that mixture could vary depending upon the type of plant, harvesting and storage methods, and cleaning operations at various stages of processing (43 FR 27354).

Because of uncertainty as to the identity of the specific causative agent(s) of byssinosis, OSHA chose the strategy of regulating total respirable, lint-free dust, rather than promulgating specifications for each component, or for various combinations of components. (43 FR 27355). This approach is consistent with the pioneering work of Drs. Shilling and Roach in Britain, and in research conducted by Dr. James Merchant and others, which underlies the 1978 standard, as well as much research conducted since 1978.

Some investigators have attempted to determine whether the concentration of a specific fraction of the dust could be correlated to the prevalence of respiratory disease. In their pioneering work in the Lancashire cotton industry, Roach and Schilling attempted to correlate dust measurement with prevalence of byssinosis. They found a strong linear association ($r=0.93$) between gross dust level and prevalence of byssinosis. In addition, they also fractioned the dust based on aerodynamic diameter ($<7\mu$, 7μ–2mm, >2mm) and on chemical composition (cellulose, protein and ash). Using the fractionated material, they found a strong linear association ($r=0.94$) between the prevalence of byssinosis and the protein fraction of the medium size dust particles (7μ to 2 mm). All fractions, whether based on size or chemical composition, were in some degree associated with the prevalence of byssinosis. In recommending a samplying method, the authors stated:

> For routine measurement of dust it is necessary to have a method in which the sampling equipment is simple and the assessment of the samples is rapid. As total dust concentration is easy to measure and correlates closely with the prevalence of byssinosis ($r=0.93$), our permissible levels of dustiness are expressed in terms of total dust. (Ex. 6–1)

The installation of exhaust ventilation following the study resulted in a dramatic reduction of the coarse dust particles and a less dusty appearance to the card rooms (Ex. 6–4). However, the reduction in gross dust levels did not solve the problem of byssinosis, and investigators began to question whether monitoring total dust was the most appropriate method. Further investigation indicated that fine dust ($<7\mu$) could account for most of the byssinosis seen in the textile industry (Ex. 6–4, 6–51, 6–66).

This early work set the stage for the work of Merchant and his coworkers. They used a Lumsden-Lynch vertical elutriator which collects particles with a mass median aerodynamic diameter less than 15μ. This dust fraction accounts for all of the fine particles and the lower range of the medium particles. The samples were collected in the work area, and all particles less than 15μ present in that area, regardless of origin, were collected by the vertical elutriator and were taken into account in the dose-response calculations. The result was a strong linear association between dust level measured by the V.E. and prevalence of byssinosis in cotton preparation and yarn area workers ($r=0.99$) and in weaving and slashing workers ($r=0.93$). Some difference in the potency of the dust was noted, however, and the slopes of the two curves were different. In addition, a no-effect threshold was seen for slashing and weaving workers. The authors suggested a possible explanation for the two different dose-response curves:

> . . . Preparation and yarn processing areas are justifiably combined since the dust is of the same composition, the dose-response curves for each area are similar, and the areas are frequently contiguous. When the yarn arrives in slashing department, sizing is added to the yarn and has been found consistently to increase the concentration of lint free dust in the slashing and weaving areas. Therefore, the biologically active airborne material in these workrooms is diluted with biologically inert sizing, making it necessary to consider this dust separately when considering these significantly different dose-response relationships. (Ex. 6–51)

OSHA accounted for the contribution of sizing to the overall composition of the dust when it set a separate permissible exposure limit for weaving and slashing operations. The exact contribution of some of the other materials present during Merchant's study such as soil or mineral dust is not known, but it is clear that the dose-response calculations take these materials into account. Any deletion of these materials from the definition of cotton dust would require additional dose-response studies and would result in a lower permissible exposure limit to maintain the same degree of protection (reduction in risk).

The justification provided for choosing this approach was documented in the preamble to the final standard:

> OSHA has concluded that the weight of evidence in the record requires the implementation of a standard based on "cotton dust" as broadly defined . . . The continuing scientific debate over the identity of the specific agent does not detract from the conclusion that "cotton dust" as defined and regulated by this standard has been shown to cause a constellation of respiratory illnesses . . .
>
> . . . the value of dust composition data alone is extremely limited in assigning risk to various concentrations of dust. Where medical research is available, physical and chemical data is less acceptable. (43 FR 27355)

Thus, dose-response relationships were calculated using total lint-free respirable dust as a basis, and the permissible exposure limits were derived from them. Differences in physical composition of the cotton dust at different stages of processing were accommodated through variations in the permissible exposure limit (PEL) at various stages of processing (43 FR 27355).

This strategy is feasible as a basis for regulation, and according to evidence presented in the record, it has been effective in reducing the prevalence of byssinosis in the textile industry. It has withstood legal challenge and has been affirmed by the Supreme Court.

In the comments presented in response to the proposal, three dust components—mineral dusts, synthetic fiber dust, and lubricating oil mist—were suggested for exclusion from the definition of cotton dust by several parties. A fourth component, pure cellulose, was put forward for exclusion only by the National Cotton Council (Ex. 276). Lubricating oil, humidifier mineral solids and synthetic fibers are present in the air during the handling and processing of cotton, and mineral solids and synthetic fibers were in the environment where early cotton dust sampling and research was conducted. Thus, these substances are reflected in the data used to set dose-response curves, and they are incorporated in the PELs. For this reason, actions taken to exclude them at this time must be based not only on their possible role as agents of byssinosis but also on evidence that they were not properly reflected in the PELs because their quantity in the workplace has changed since the research used to set the PELs was completed.

a. *Lubricating oils.* In the early 1970's when Dr. James Merchant and his associates were conducting their research, typical weave rooms in cotton textile plants had Draper looms, shuttle-

type weaving machines that emitted little lubricating oil (Tr. pp. 693 and 1162). In particular, the Burlington Industries weave rooms used in Merchant's study were equipped with Draper Looms (Ex. 187–27; Ex. 233, Item 1). Since that time, however, throughout the industry many of those machines have been replaced with modern equipment, notably the Sulzer shuttleless loom. Sulzer looms are much more productive than the older machines and are expected eventually to replace them in most operations. Some Sulzer machines emit relatively large quantities of lubricating oil in normal operation and the oil mist contaminates air samples taken in weave rooms equipped with these machines. (Ex. 187–27 Appendix A). This issue was raised in the ANPR of February 9, 1982) (47 FR 5908) but few comments were received. Additional information was requested in the June 10, 1983 proposal (48 FR 26969).

Evidence compiled in testimony and through public comment indicated that the quantity of oil mist collected now in sampling is now much greater than would have been present in earlier years. According to ATMI, as much as 86% of a vertical elutriator sample weight may be oil mist (Ex. 187–17, p 34). ATMI also notes with supporting factual analysis, that the Sulzer looms and the accompanying oil mist were not present in the mills where Merchant's research was done. This position is reiterated in ATMI's and ACTWU's posthearing submissions to the record (EXs. 280, p 32–42; 279, p 32–42), and in the submissions by Georgia Textile Manufacturers, et al. (Ex.187–16 p. 6–10) and by J.P. Stevens & Co. Inc., (Ex 187–28A)

ATMI notes that (1) oil mist from Sulzer looms would be present regardless of the type of fiber being woven; (2) oil mists have not been associated with byssinosis; (3) OSHA already has an oil mist standard (29 CFR § 1910.1000) and, (4) any further regulation of oil mist should be achieved through amendment of that rule rather than through the cotton dust standard.

The National Cotton Council also recommends exclusion of oil mist, and provides two methods of calculating the quantity of oil in air samples. (Ex. 216, p 24).

Dr. John Neefus, speaking as Corporate Industrial Hygienist for Burlington Industries addressed the question of sampling for oil mist in testimony on October 4, 1983. (Tr. 1154–1157) Dr. Neefus noted that the method which involves infra-red absorption analysis has been in use at Burlington for more than 5 years. The method is described at length in Exhibit 233, Item 4.

Not all evidence supported exclusion of lubricating oil mists. NIOSH recommended against exclusion on the grounds that the epidemiologic studies from which the assessment of significant risk was determined "included many 'extraneous' materials in the samples from which dust concentrations are calculated and to which workers are exposed." (Ex. 187–23, p. 18)

NIOSH stated that if OSHA wished to exclude oil mist from the definition of cotton dust, a "practical evironmental sampling method" must be developed "other than or in addition to the vertically elutriated particulate." Subsequent to the NIOSH statement evidence was submitted demonstrating that a method was available to separate out oil mist and that oil mist was not present in major part in the dust samples collected by Merchant and his colleagues.

In response to a question regarding acceptable testing for oil mist, NIOSH representatives noted that a proper evaluation of the desirability of excluding oil mist from the definition of cotton dust would involve not only sampling and analytical methods, but also evaluation of health hazards presented by the oil mist itself. (TR. 455)

This reservation was reiterated in the testimony of Dr. Morton Corn, who agreed, however, that the absence of oil mist from the environments sampled in the Merchant studies would have a bearing on conclusions as to whether it could be a causative agent of byssinosis. (Tr. 511.)

OSHA has decided, based on the record, to exclude oil mist from the definition of cotton dust. The evidence is now clear that oil mist was not included in any significant quantities in the samples measured in the Merchant studies, and thus it was not included in the dose-response relationships. The oil mist now present comes from machinery that was not widely used, if at all, in U.S. mills at the time of the Merchant studies. Therefore, excluding oil mist will not increase risk rates and including oil mists may result in feasibility problems in certain areas. There is no independent evidence that oil mist contributes to byssinosis directly or nor was it part of the total sample on which Merchant's findings were based. Further, both ACTWU and ATMI recommend its omission (Ex. 279, p. 42; Ex. 280, p. 42). Oil mist continues to be regulated independently by 29 CFR 1910.1000 Table Z–1.

b. *Mineral Dusts.* The presence of mineral dusts in the air of workplaces affects the weight of vertically elutriated samples. Since the cotton dust standard calls for gravimetric measurement of dust levels, the added weight of mineral dust from humidification water may be included in the air samples taken in some textile mills. Such mineral dust can be simply removed by demineralization of the humidification water before the dust reaches the mill atmosphere. There may also be mineral dust present in the sample which arises as the result of the way the cotton is grown, harvested, ginned and baled.

Little comment was received as to the inclusion of mineral dust in response to the Advance Notice of Proposed Rulemaking. The issue was raised for further public comment in the proposal published June 10, 1983, although no proposal was made to exclude mineral dusts from the definition of cotton dust. Some comments were received in response to the proposal.

The Georgia Textile Manufacturers argue that there "is no evidence from the Merchant studies that oil mist or mineral dust made any measurable contribution to the filter weight". They note that "dissolved solids in a city water system may also make a significant contribution of filter weights; yet there has been no showing that the dissolved solids pose any significant risk to health." (Ex. 187–16, p. 8–9.) The National Cotton Council also made this point in its August 9 submission. (Ex. 187–18, p. 2)

J.P. Stevens & Company also supported exclusion of "dissolved water solids" and stated that they can "contribute up to 90% of the 'dust' on the elutriator filter" in some textile plants. (Ex. 187–28a, p. 3.) J.P. Stevens acknowledged that the original cotton dust studies did not take dissolved solids levels into account as a separate contaminant, but argued that they were easily identifiable and could be subtracted from the weight of filters. J.P. Stevens did not, however, present evidence that the levels of dissolved water solids were for any reason different than they were when the major studies were conducted.

In posthearing comments, the National Cotton Council provided citations of methods to differentiate between mineral particulates and other components of cotton dust, and recommended their exclusion on the grounds that they should instead be regulated under OSHA's standard for nuisance dust. (Ex. 216, p. 23, 24.)

The American Textile Manufacturers Institute's posthearing comments (Ex. 280, p. 109) reiterate the National Cotton Council's points, and recommend that employers be permitted to make at least "a partial adjustment in apparent cotton

dust measurements in those cases where inorganic mineral dust represents a very substantial percentage of the vertical elutriator reading." The effect of such subtractions on permissible exposure levels are not addressed.

ATMI acknowledges, however, that "the level of dissolved solids in the humidification water at the plants studied by Dr. Merchant is not known, but it is highly unlikely that Dr. Merchant's measurements reflected as high a mineral dust component as measurements in many textile plants today". (Ex. 280 p. 112.) The basis for this assertion is not identified, and consequently, it is not possible to compare typical current levels of dissolved solids with those in the environments where research was conducted. There is no evidence in the record that mineral dust levels were not in fact typical with regard to mineral content of humidification water, nor that the plants surveyed by Dr. Merchant included workplaces with exceedingly high or low levels of mineral dust.

Objection to any allowance for mineral dusts in the calculation of total cotton dust exposure came from the Amalgamated Clothing and Textile Workers Union, Labor Commissioner John Brooks of North Carolina, and from NIOSH. The ACTWU objection was based on the fact that mineral dust was already accounted for in the standard's permissible exposure limits, which were based on dose-response relationships including such dust (Ex. 279, p. 119). The union noted also that no evidence was presented to show that mineral dusts of the type found in textile mills were independent of the health effects found there. (Ex. 274, p. 120.) Commissioner John Brooks also testified against changing the definition of cotton dust (Tr. 1287), and noted that the total dust sampling method had not hindered compliance with the standard (Tr. 1280).

NIOSH also recommended against changing the definition of cotton dust, noting that more definitive information is needed about the causal agents of byssinosis. They noted a strong correlation between total respirable dust concentrations and byssinosis (Ex. 187–23, p. 2–4). While NIOSH noted that differences in dose-response relationships may possibly be attributed to differences in dust composition in various workplaces, they concluded that the existing OSHA definition of cotton dust is the best practical definition and should be retained for compliance purposes (Ex. 187–23 p. 7). They reached this conclusion because the dose-response calculations and, consequently, the risk assessment were based on dust samples containing all the materials present in the mill atmosphere.

OSHA did not propose to amend the definition of cotton dust to exclude mineral dusts, and it has concluded that the definition should remain unchanged with respect to mineral dust. Unlike oil mist, mineral dust was clearly present in the atmosphere when the epidemiology studies were performed. No empirical evidence was present that more or less mineral dust from humidification is present in workplaces now than was the case when the research supporting the 1978 standard was performed.

The comments did not present evidence to indicate that equivalency could be established between exposures and health effects for samples with and without mineral dusts. Since such mineral dusts were present during Merchant's research, PELs which were based on his data would have to be recalculated at lower levels than are provided in the present standard to achieve a similar level of worker protection.

For example, assuming that such mineral solids constituted 25% of the weight on a sample filter, and the same percentage applied to Merchant's sample, deletion of the dust would require that the permissible exposure limit be reduced accordingly to maintain the same level of employee protection. This would mean a reduction of the PEL to approximately 150 $\mu g/m^3$ in yarn manufacturing operations and 562.5 $\mu g/m^3$ in weaving operations.

OSHA concludes that it is inappropriate to amend the definition of cotton dust to exclude mineral dust which is present in the mill atmosphere. The epidemiology studies which established the clearest relationship between byssinosis levels and dust in the mills measured total respirable dust present including mineral dust. Therefore, OSHA adopted this approach for regulation and it was upheld by both the Court of Appeals and the Supreme Court. It has proven to be feasible to comply with this definition.

Most importantly, this approach to regulation has been successful in substantially reducing levels of byssinosis and other pulmonary disease among cotton workers. This empirical and objective evidence that the standard works far outweighs theoretical arguments that mineral dust by itself may be inert and therefore it should be subtracted from the sample. No studies have been presented demonstrating that mineral dust in conjunction with cotton dust is inert or comparing response rates with mineral dust included and excluded.

Further excluding mineral dust from samples would lead to the standard's permitting a higher level of cotton present at the existing exposure limit. This would result in a higher level of byssinosis and other pulmonary disease at the current exposure limits. It is inappropriate to permit a higher incidence of disease when controls to achieve a lower incidence of disease have proven feasible. Therefore the approach of excluding mineral dust would require OSHA to set lower exposure limits to prevent the level of disease from increasing. Data and studies to permit determination of the appropriate level to set are not available.

c. *Synthetic Fibers.* Synthetic fiber is present in the air of textile mills which produce cotton blend fabrics. It may be present at all stages of processing, from opening through weaving. Although it does not enter the mill with the cotton, synthetic fiber may be mixed in an "intimate blend" at the opening process, or combined with cotton fibers at later stages of processing. Thus, it is covered by the definition of "cotton dust" which, as noted above, includes "* * * any dust present during the handling and processing of cotton * * *" (43 FR 27395). Little evidence on this topic was presented on this matter in response to the ANPR. In its June 10, 1983 proposal. OSHA proposed no specific change in the definition of cotton dust which would exempt synthetic fibers, but requested that additional information be submitted (48 FR 26969).

In prehearing comments, the American Textile Manufacturers Institute proposed that OSHA establish an adjustment factor to reflect the processing of synthetic blends with varying percentages of cotton, or alternatively, a simple baseline exclusion for operations "in which cotton constitutes less than a specified percentage of the fiber processed during a given period". A 20 percent cotton fiber content was suggested as a threshold and was reiterated in ATMI's post hearing comments (Ex. 280, p. 113). They also noted that the "weighted-average proportion of cotton processed at the 5 plants studied by Dr. Merchant was 89 percent", a proportion higher than many blend mills customarily process.

Burlington Industries presented comments on synthetic fiber dust (Ex. 187–27), including further elaboration on the proportion of cotton fiber being used in the areas studied by Dr. Merchant. They stated that, "Dr. Merchant's

original study was performed in two 100% cotton plants * * * and three blend plants with 75%, 71%, and 50% cotton * * * Weighting these by the number of employees, the average proportion of cotton processed was 89% in both preparation/yarn and slashing/weaving areas * * *"

Burlington argued that because "a large portion of textile plants are processing more than 11% synthetic fiber, the standards set under prevailing conditions of 1970 must not apply uniformly to all cotton processed * * * Burlington strongly supports exclusion of polyester dust fraction from measured respirable dust before applying both the action level and the permissible exposure limit".

Burlington's exhibit also included appendices prepared by Dr. Moon Suh which addressed the issue of synthetic blends from an analytic and statistical viewpoint. Dr. Suh suggests alternative methods of calculating exposures and lower PELs for pure cotton dusts, and suggests variable PELs based on various blend ratios (Ex. 187–27, Appendix B, p. 10). However, he acknowledged the problem with the method that he used. The method is based on the "assumption that dust levels measured under 100% cotton and 100% polyester operations were entirely due to cotton and polyester only. The assumption is not valid if the samples also include minerals, sizing compounds, and/or oil mists which as discussed elsewhere they do. It is difficult, however, to estimate the proportions, of these substances in the Merchant dose response study. (Ex. 187–27, App. B, p. 12).

Burlington also supplied a further analysis using data from 24 cotton and cotton/polyester blend plants (1974–1977) which provided more estimates of the changes in dust levels associated with various percentages of cotton content. This study, however, noted that:

> The estimated R values are too large for the present operational environment where dust levels seldom exceed 500 micrograms in preparation/yarn areas.
>
> An additional analysis can be made using the same statistical model but by applying more recent data. Such as analysis requires considerable amount of time for data acquisition and hence could not be incorporated in this reported at this time. (Ex. 187–27, App. B)"

Thus, the research contributed by Burlington to the record may be useful as a starting point in determining the relation of particular blend percentages to dust levels. The data provided, however, are not sufficient for widespread application, and thus they cannot serve as a basis for exclusion of synthetics from the definition of cotton dust.

Burlington also notes that in slashing and weaving areas, adjustment for mineral dust and other compounds must be made before deriving a variable PEL at different blending ratios. Burlington notes, however that "while chemical assay and other laboratory procedures may provide a guideline for dust apportionment into component fractions, the economic burden for performing such an analysis, even when it becomes feasible, makes it impractical to require it as part of the dust standard. This means that statistical/mathematical techniques must be given a serious consideration in resolving the issue * * *" (Ex. 187–27, App. B, p. 17)

The Amalgamated Clothing and Textile Workers Union testimony objected to this mathematical approach, and took the position that no changes should be made in calculations to allow for synthetics without epidemiological data to support them. (Exhibit 280, p. 119) No new epidemiological studies that address this matter have been submitted to the record. ACTWU notes that because existing PELs were based on data which included synthetics, the existing standard already includes an appropriate allowance for blended fiber operations.

NIOSH strongly recommended the existing definition of "cotton dust" which includes dust from synthetics present be retained because it "is the best practical definition" (Ex. 187–23, p. 4). The basis for NIOSH's recommendation was the strong linear correlation between byssinosis rates and the amount of respirable dust including synthetic dust present in cotton operations. NIOSH pointed out that Merchant's data demonstrating the relationship between byssinosis and total respirable dust included values obtained from mills with up to 50% synthetics present. NIOSH also referred to the impracticality of separating out synthetics.

The Commissioner of Labor for the state of North Carolina also recommended that the definition of cotton dust remain unchanged. (Tr. 1287). Much of the textile industry is located in that state.

OSHA concludes that the evidence in the record does not support excluding synthetics from the definition of cotton dust for reasons similar to those for mineral dusts. The Merchant studies demonstrating byssinosis included a mill with 50% synthetics and there was clear dose-response with samples which contained synthetics. OSHA did not exclude synthetics from the definition of cotton dust for this reason and this decision was upheld by the Supreme Court. The standard has proved feasible.

Most importantly this approach has substantially improved the health of texitle workers in blend mills as well as 100% cotton operations. This empirical and objective evidence far outweighs theoretical arguments not supported by epidemiological studies that some percentage of synthetics should be excluded. No studies have been presented demonstrating that synthetic dust in conjuction with cotton dust is inert or comparing response rates with varying amounts of synthetic dust in the cotton dust.

Further, the whole percentage of synthetics present could not be excluded since synthetics were included in the Merchant studies and are incorporated in his dose-response curves. Consequently excluding the total amount of synthetics present would clearly raise the health risk of the exposed workers at the current exposure limits. Therefore, the approach of excluding synthetics would require OSHA to set lower exposure limits to prevent the level of disease from increasing.

Data are not available to determine what percentage could be excluded without raising the dose-response rate, since the percentage in the dust does not correlate with the percentage of synthetics in the blend. Specifically, there appears to be no reliable way to make a proportional allowance for the amount of synthetics in a particular blend. Burlington has presented limited data which indicates, under certain circumstances, the proportion of polyester dust at various blend levels. However, even at the 10% cotton level, approximately 30 percent of the dust in yarn preparation phases of processing comes from cotton (Ex. 187–27, p 16). There are no epidemiology studies available which have tested such an approach.

d. *Cellulose.* In posthearing comments, the National Cotton Council provided a summary of several studies which indicate that pure cellulose powder cause little or no respiratory response in humans or mammals. (Ex. 276, p. 25) It argued that cellulose should be excluded from the definition of cotton dust. No other party to this proceeding made that argument. OSHA neither proposed to exclude pure cellulose from the definition of cotton dust nor did it raise the issue in the proposal. Other interested parties would not have had adequate notice of this novel concept which was a major departure from other approaches. Indeed, the NCC presented no scientists at the hearing to discuss

this approach, which would have been appropriate because of its novelty.

Cellulose is a major constituent of cotton fiber, comprising approximately 96% of its weight (Ex. 276, p. 25). It was certainly a component of the dust samples in cotton dust research such as the Merchant study which determined the dose-response curve. While the cellulose itself, stripped of other materials found in cotton dust conceivably may present no health risk, it is inherently present in cotton dust. No dose response relationships have been established for cotton dust without cellulose content. No studies have been performed that demonstrate that cellulose does not interact with the other components of the dust and thereby effect the risk.

Removing cellulose would dramatically increase the risk rate at current exposure levels thereby raising risk rates from a lower level which has proven feasible. No mechanism has been suggested by the NCC on how to lower the exposure limit to adjust for this factor.

As also discussed above, cellulose was included in the definition of cotton dust in the standard which was upheld by the Supreme Court, which has proved feasible, and which has substantially improved the health of cotton textile workers. These facts and all the evidence demonstrating a dose-response relationship based on dust samples containing cellulose far outweighs the argument advanced only by the NCC. Its argument that the whose concept of regulation be changed from measuring total respirable lint-free dust to measuring only cotton dust stripped of cellulose (what might be called cotton trash) is a concept unsupported by evidence in the proceeding. It would require a substantial body of scientific studies and expert opinion to justify changing in total concept a regulation which has successfully improved the health of employees, and little evidence has been presented in support of this novel concept. Therefore, OSHA concludes the evidence does not justify excluding cellulose from the definition of cotton dust.

C. Permissible Exposure Limit/Action Level

OSHA proposed to incorporate an "action level" into the cotton dust standard in its June 10, 1983 proposal as discussed at 48 FR 26970. An action level is an exposure level below the permissible exposure limit, above which some provisions of the standard begin to apply and below which fewer provisions of the standard apply.

The 1978 cotton dust standard does not include an action level. Engineering controls and respirators are required only if exposures exceed the permissible exposure limit, but in general, all the other provisions of the standard are required if there is any cotton dust exposure no matter what the level.

The specific proposal OSHA made was to set an action level at 50% of the permissible exposure limit (PEL). Consequently the action level proposed was 100 $\mu g/m^3$ for yarn production and 375 $\mu g/m^3$ for slashing and weaving. The proposal provided that when exposures were under the action level the frequency of medical surveillance could be reached from once a year to once every two years. Periodic monitoring would cease if two consecutive measurements were under the action level until such time as product or process changes indicated that further monitoring was needed. In addition the proposal eliminated the requirement for annual retraining for employees whose exposures were below the action level.

OSHA, after reviewing comments to an advance notice (discussed at 48 FR 26970–1), explained the reasons why it believed an action level was justified. First, it will improve employee health by encouraging employers who can reasonably do so to lower exposure from the PEL to below the action level. These lower exposures are likely to improve employee health. In some cases, the action level both increases the safety factor and results in a lower adverse health response rate for workers whose exposures are reduced below the action level. This health benefit of lower exposure is likely to outweigh any consequences resulting from the reduction of industrial hygiene provisions. OSHA reasoned that retention of the medical surveillance provision for employees exposed under the action level would detect those employees who showed symptoms of byssinosis in time to reverse the symptoms.

Second, OSHA believes the action level substantially increases the cost-effectiveness of the standard. Employers who are in positions to devise ways to reduce exposures of their employees will be able to realize substantial cost-savings from the elimination of some industrial hygiene provisions while improving the health of their employees. The action level improves the flexibility and performance-orientation of the standard by giving the employer a greater choice in adjusting compliance responsibilities to the specific factors present in the workplace while still maintaining health protection.

Third, OSHA has had successful experience with an action level provision for a number of other toxic substances, including nonthreshold substances. In each case the provision was included based on full analysis of the record and the provision has proven successful in practice. The choice of an action level at one-half the PEL was based principally on OSHA's successful use of that level in other standards though the proposal also discussed some statistical literature.

A number of participants addressed OSHA's proposal both in prehearing and posthearing comments and testimony. The ATMI supported OSHA's proposal to incorporate an action level into the standard and OSHA's justification. It concluded:

> In sum, the action level concept proposed by OSHA will make the standard more cost-effective without in any way compromising the protection of employee health. As OSHA points out, similar provisions incorporated in other standards (including standards dealing with carcinogens) "have proven successful in practice." There is every reason to believe the action level concept will be successful in the context of the Cotton Dust Standard as well." (Ex. 187–17, pp. 59–60.)

Carroll F. Bailey, a certified industrial hygienist working for the South Carolina Department of Labor, agreed with the efficacy of incorporting an action level. He stated that an action level will improve employee health by encouraging employers, who can reasonably do so, to lower exposure from the permissible exposure limit to below the action level. (Tr. 1135.) He also pointed out that employers who are in a position to devise ways to reduce exposures to their employees will be able to realize substantial cost savings from the elimination of some industrial hygiene provisions while improving the health of their employees (Tr. 1135–6).

Commissioner Edgar McGowan, Commissioner of Labor for the State of South Carolina, supported the concept of the action level so long as medical surveillance was retained because it encouraged the achievement of a dust level below the PEL. However, he proposed that it be called an "incentive level." (Tr. 1185.)

Dr. James Merchant supported the concept of an action level. He agreed that when exposures were below the action level then medical examinations could be given once every two years "without material increased risk of not detecting significant health effects" (Tr. 293. The words at line 15 "by annual level" should read "biennially."). However, he believed that annual training and monitoring should be

retained even for employees exposed under the action level.

The ACTWU initially opposed the action level as specifically proposed by OSHA (Ex. 157–31, pp. 40–42). Testifying for the ACTWU, Dr. Morton Corn reviewed the initial reason for developing the action level and criticized the inclusion of an action level in the cotton dust standard (Tr. 490–491). He stated that the action level concept was originally created for threshold toxins and that he believed it was not appropriate for nonthreshold substances such as cotton dust. Dr. Corn also reviewed the literature on monitoring which indicated that for environments with low exposure variability a 50% action level gives reasonable confidence that exposures on a given day will not exceed the PEL, but that this is not so for substance with high exposure variability. He indicated this was a reason for not eliminating periodic monitoring when exposures were below an action level.

Dr. Neil Schachter was also critical of incorporation of an action level. He argued:

> In summary, current knowledge suggests that achievement of action levels will not eliminate byssinotic symptoms or ensure against chronic lung disease secondary to cotton dust exposure in workers. Given the unpredictability of individual workers and the potential toxicity of even low dust levels, reductions in monitoring, particularly medical surveillance, may adversely affect the health of workers sensitive to cotton dust. (Tr. pp. 529–530.)

After reviewing the record, in their post hearing comments, both the Amalgamated Clothing and Textile Workers Union (Ex. 279) and American Textile Manufacturers Institute (Ex. 280) made identical recommendations to OSHA on the action level. They recommended that an action level be incorporated into the cotton dust standard at one-half the PEL and that the frequency of medical examinations be reduced to biennially for employees exposed below the action level. However, both parties recommended that annual training and exposure monitoring be retained for exposures below the PEL, including areas below the action level.

Both ATMI and ACTWU supported their views in identical language. They stated:

> In sum, when properly designed, an action level creates incentives to provide greater protection for the health of employees; makes the Standard more flexible, performance-oriented, and cost-effective; and enhances the efficiency and effectiveness of the enforcement program. By making the Standard more rational and sensible to those to whom it applies, the action level is likely to elicit a greater degree of voluntary compliance * * * For these reasons, action levels have 'been in use in other standards covering exposure to toxic substances for several years . . . [and have] proven successful in practice.'
>
> Several witnesses at the hearing initially expressed uncertainty as to whether the rationale for an action level logically applied to substances without dose-response threshold * * *
>
> Regardless of whether a health effects threshold exists, a reduction in exposure levels will lower the health risk and increase the level of health protection. As noted by Carrol Bailey, if the reduction in exposures brings them below a threshold level, the safety factor will be increased, while a reduction in exposures that does not cross a health effects threshold will nonetheless result 'in a lower adverse health response rate' among the workers exposed at lower levels. Moreover, relaxing certain administrative provisions of the Standard (thereby permitting a cost saving) when exposures are reduced below the action level creates a logical incentive for employers to reduce dust levels, thereby increasing the level of health protection for employees. Indeed, the prospect of realizing some significant cost saving is likely to be the principal incentive for an employer to reduce exposures below the action level.
>
> Furthermore, there is nothing at all novel about OSHA's use of an action level for a non-threshold toxic agent . . . [A]ction levels have been incorporated into OSHA standards dealing with acrylonitrile, vinyl choride, inorganic arsenic and benzene, which OSHA considers to be carcinogens for which no health effect threshold is deemed to exist." (Ex. 279, pp. 46–48; Ex. 280, pp. 46–48).

Both ACTWU and ATMI agreed that employee health would be protected if medical examinations were every two years for employees exposed below the action level. (See the discussion at Ex. 279, pp, 49–50; Ex. 280, pp. 49–50) They pointed out that with the exception of Dr. Schachter, all the physicians who testified, [Dr. Merchant (Tr. 293), Dr. Boehlecke (Tr. 57–58); Dr. Imbus (Tr. 96–97) and Dr. Dr. Weill. (Tr. 133)] agreed on this point. For example, Dr. Weill stated that:

> [O]ne could safely have a monitoring program of lung function and other indicators of respiratory health that was instituted for individual workers every second year. (Tr. 155)

OSHA has reviewed the comments and concludes that the evidence supports the inclusion of an action level at one-half the PEL in the cotton dust standard and the reasoning stated in the proposal. An action level improves employee health while improving the cost-effectiveness of the standard. Employee health is improved because employers who can do so will be encouraged to lower exposures to one half the PEL. This improves the health of the employee whether the substance has a threshold or not. For threshold substances it increases the safety factor and for non-threshold substances it reduces the incidence rate. This reasoning has been accepted by ACTWU and ATMI as discussed above.

As the ATMI points out, the action level increases the cost-effectiveness of the standard. Employers who devise innovative ways to reduce exposures below the action level will have their medical surveillance costs reduced. This encourages the employer to reduce exposures and is likely to reduce the net costs of the standard.

OSHA concludes that medical examinations conducted once every two years will be protective for employees exposed below the action level. At those low exposure levels, relatively few employees will develop lung function decrements. The biennial examination will be sufficiently frequent to identify such conditions before they become serious and while they are still reversible. If such symptoms do develop, the standard still requires that semi-annual medical examinations be instituted. As discussed, the appropriateness of biennial examinations for employees exposed below the action level was supported by all but one of the physicians who testified.

As mentioned in the proposal, OSHA has successfully utilized the action level a number of times before, including for carcinogens which were believed to be non-threshold substances. These include inorganic arsenic (§ 1910.1018(b)), vinyl chloride (§ 1910.1017(b)), and acrylonitrile (§ 1910.1045(b)). It is not correct, as one or two commenters initially believed, that OSHA had only incorporated action levels for substances with clearly defined thresholds. Section 6(b)(5) of the OSH Act specifically states OSHA shall take into account "experience gained under the (law)".

As stated in the preamble, OSHA proposed the action level at 50% of the PEL principally because of its past success in utilizing that level in the regulation of the substances mentioned above. As discussed in the proposal, there is literature which indicates that when there is no wide daily fluctuation of exposure, a 50% action level gives a reasonable degree of confidence that the PEL will not be exceeded on individual days. Dr. Corn points out that if there is a wide daily variation in exposure, one cannot have that degree of confidence that some daily exposure will not occasionally exceed the PEL. However,

the principal reason OSHA is adopting the 50% action level is its prior experience.

Second, OSHA is adopting the joint ACTWU–ATMI recommendation that annual exposure monitoring be retained when exposures are under the action level. Third, the final standard retains the provision that employers must remonitor areas including those under the action level when product or process changes or other reasons may lead to increased exposure. (§ 1910.1043(d)(3)(iii)). These latter two provisions should meet some of the concerns expressed by Dr. Corn and Dr. Merchant.

As indicated, OSHA initially proposed to eliminate periodic monitoring when exposures were under the action level (§ 1910.1043(d)(3)(i)). As just discussed, ATMI and ACTWU recommended that yearly remonitoring be retained. Retaining such monitoring meets the concerns of Dr. Merchant and at least in part the concerns of Dr. Corn about undetected increases or large fluctuations. In addition, the development of alternative monitoring devices to the vertical elutriator which are easier to use and the improved provisions of the standard which make it more certain and less complicated to certify alternate monitoring devices, make periodic remonitoring much simpler and quicker. For these reasons OSHA accepts the ATMI and ACTWU recommendation to retain annual monitoring in areas below the action level.

Finally, ACTWU and ATMI both recommended that annual training be retained for employees exposed below the action level (Ex. 279, p. 54; Ex. 280, p. 54). Additional training will to some degree increase the employee's ability to assist in keeping his own exposure low and be aware of the hazards. In addition, the identical recommendations of ACTWU and ATMI are entitled to considerable weight. Consequently, OSHA is adopting this recommendation and retaining annual retraining as specified in the 1978 standard for all employees exposed to cotton dust and not adopting the 1983 proposal to eliminate retraining for employees exposed under the action level.

For the reasons discussed, OSHA is making the following amendments to § 1910.1043. A new paragraph (c)(2) is inserted setting an action level of 100 $\mu g/m^3$ for yarn manufacturing, 250 $\mu g/m^3$ for waste houses in textile mills and 375 $\mu g/m^3$ for slashing and weaving operations. Paragraph (h)(3)(i) is amended to indicate that medical surveillance must be repeated every two years for employees exposed below the action level unless certain medical conditions exist. The June 1983 proposals to amend paragraph (d)(3) to end monitoring and paragraph (i)(1)(ii) to end annual training below the action level were not supported by evidence and comments in the record and were not adopted.

OSHA did not specifically propose to retain a permissible exposure limit or to set an action level for waste houses in textile mills or for certain cotton washing operations. As discussed under the scope section, comment indicates that the 500 $\mu g/m^3$ level should be retained for wastehouses. Accordingly it is appropriate to have 50% action level (250 $\mu g/m^3$) for this area for the same reasons a 50% action level has been instituted in other areas.

As discussed in the washed cotton section, OSHA has expanded the processes which come under the various exemptions for washed cotton. This may encourage the use of those processes. The early stages of the washing processes present the same hazards as yarn manufacturing and accordingly similar regulatory provisions including action level provisions are appropriate.

D. Exposure Monitoring

The 1978 standard requires initial exposure monitoring to determine those areas that exceed the PEL. The standard further requires periodic monitoring in order to identify those areas where exposure levels may require prompt action and specifies the monitoring device to be used, the vertical elutriator (VE). OSHA's 1983 proposal addressed a number of issues related to exposure monitoring that became apparent after the standard became effective in 1981. Proposed amendments were made to address these problems and to make the standard more cost-effective. Specific changes were proposed to decrease the frequency of exposure monitoring and to amend the time for and method of employee notification. Although no changes to the VE equivalency protocol were proposed, OSHA indicated that an equivalency protocol was being developed and would be available prior to the public hearings. The changes that were incorporated into the final standard are discussed below by topic.

1. Criteria for Establishing Equivalency to the Vertical Elutriator

The standard sampling instrument for determining employee exposures to cotton dust specified by the 1978 standard is the Lumsden and Lynch vertical elutriator. This device was used in the epidemiological studies which established the dose-response curve and which served as the basis of the 1978 standard. However, the VE is a relatively awkward monitoring device requiring a substantial amount of industrial hygiene resources.

In its June 1983 proposal, OSHA noted that in addition to the VE, new dust measuring devices are available which are simpler to operate and incorporate more sophisticated technologies, and other devices may be developed. The criteria in the 1978 standard for determining an alternative instrument's equivalency to the VE are not as specific as they could be and are too descriptive in nature. For example, the guidelines do not specify sample size. Thus, the sample size can be arbitrarily set making it difficult to make a statistical statement about the population from which the sample is drawn.

Paragraph (d)(1)(iii)(c) of the 1978 standard specified that it shoud be demonstrated that an alternative sampling device is "equivalent within an accuracy and precision range of plus or minus 25% for 95% of the samples . . ." OSHA received ANPR comments on this criterion. Several commenters stated that this language created a possible ambiguity. For example, K.Q. Robert of USDA (Ex. 175–57) commented that an "accuracy and precision range of ±25% is ambiguous. Precision deals with the reproducibility of a measurement independent of the true value of the measured quantity. Accuracy, on the other hand deals with the difference between the average measured value and the true value."

Therefore, OSHA contracted with Dr. Harrison Wadsworth of Georgia Institute of Technology and Dr. Howard Rockette of the University of Pittsburg to design equivalency testing protocols. The purpose of the protocol would be to resolve the possible ambiguity and create a specific and statistically valid method of determining whether other instruments are equivalent to the VE. Their report, entitled "Revised Proctocol for Establishing Equivalency of Sampling Devices", was submitted jointly by Drs. Wadsworth and Rockette in August 1983 (Ex. 186–5).

This protocol requires a total of 100 samples be collected from at least 10 sites in a mill. That means there should be 10 replicated readings at each of the 10 sites. The dust levels at these sites should vary from one-half to two times the permissible exposure limit. The samples are to be collected using two vertical elutriators and one or two alternative sampling devices. These instruments are arranged close to each other in such a way that they are measuring essentially the same dust levels.

The results of these readings of the vertical elutriators and the alternative device are then computed. These are then used in two statistical equations to determine a critical value which provides the basis for determining whether or not the alternative device is equivalent to the vertical elutriator.

The reason for specifying the specific sample size, the conditions under which the samples are to be collected, the number of sampling instruments to be used, and the statistical equations used is that one can then be 95% confident that at least 90% of the measurements of the alternative device are within 25% of the corresponding vertical eluriator reading. This is a reasonably high degree of confidence that the alternate device is equivalent to the vertical elutriator.

Dr. Rockette testified at the Columbia, S.C. hearings and responded to questions about the protocol. Dr. Rockette was asked whether the Rockette-Wadsworth protocol can be interpreted to demonstrate "the general equivalency of an alternative device" and whether it is reasonable that the ten sites he refers to in the protocol be located in different processing areas. Dr. Rockette responded that in fact he was proposing that this protocol be "the method by which the device be shown to be equivalent [to the VE]" (Tr. 1303), and both he and Dr. Wadsworth feel that different processes should be selected so that they cover the range of values of the cotton dust in the mill.

The Rockette-Wadsworth protocol requires that dust level measurements be taken over a range of 0.5 to 2 times the PEL. Since March 27, 1984 was the deadline for achieving compliance with the PELs using engineering and work practice controls, it is expected that textile mills will be in compliance with the standard and will not have areas 2 times the PEL. Dr. Rockette testified that he and Dr. Wadsworth had given some thought to this condition and concluded that the "initial testing itself might have to be conducted in some type of a simulated laboratory condition." Based on this testimony, OSHA believes that testing above the PEL in a laboratory or other experimental setting reasonably modeled after a mill is appropriate. Accordingly, the language of paragraph (d)(1)(iii) has been amended by inserting the words "and laboratory" to indicate that laboratory comparison may be utilized for exposure over the PEL if no field situation can be found at 2 times the PEL.

Dr. Moon Suh of Burlington Industries questioned some aspects of the protocol (Ex. 244). In reviewing Dr. Suh's comments, Dr. Rockette discovered that a term had inadvertently been omitted from one formula in the manuscript (Ex. L-2). The error was that the term $\overline{X}_D$ in equation (2) was left out of the formula for the critical value. The critical value formula should be $T=KS_D+\overline{X}_D$, and the corrected protocol is found in Appendix E.

In their post hearing briefs, ACTWU (Ex. 279) and ATMI (Ex. 280) jointly stated that "We believe that this protocol provides an appropriate basis for establishing equivalency between alternative sampling devices and the vertical elutriator." They recommended that OSHA adopt this protocol and make it clear that this protocol need not be revalidated in each plant. The National Cotton Council (Ex. 276) also recommend the adoption of the Rockette-Wadsworth protocol.

NIOSH, in its prehearing comment (Ex. 187-23) noted that it reviewed the Wadsworth-Rockette protocol and had "no potential problem with the statistical assumptions presented." In their post hearing comments (Ex. 285), NIOSH offered modifications to the protocol which require more statistical knowledge and calculations on the part of the user. Although the suggested modifications may provide some fine tuning, it is outweighed by the advantage of having a statistically sound equivalency protocol that it is simple and straightforward to use. Therefore, OSHA concludes no modification is needed and that the Rockette-Wadsworth protocol meets the objective.

Based on evidence and testimony in the record, OSHA has concluded that it is appropriate to amend the cotton dust standard to clarify what criteria must be met in order for an alternative sampling device to be considered equivalent to the vertical elutriator. Therefore, the standard has been amended and the requirements are stated in paragraph (d)(1)(iii)(C).

As discussed the amended language clarifies the possible ambiguity of the earlier language and replaces it with specific criteria which are clear and well defined. Appendix E is the Rockette-Wadsworth protocol, and by incorporating it, OSHA will make clear that equivalency testing performed in conformity with this protocol will be accepted by OSHA as valid. The ATMI, ACTWU and NCC have agreed that the protocol and approach is valid.

Developers of other measuring devices may use protocols other than the Rockette-Wadsworth protocol to demonstrate equivalency. However, they must then demonstrate that the alternate protocol meets the criteria outlined in paragraph (d)(1)(iii) of the standard and thus is valid for demonstrating VE equivalency. OSHA is permitting the use of alternate protocols to increase the performance-orientation of the standard.

Paragraph (d)(1)(iv) provides that the manufacturer of an alternate monitoring device can provide to OSHA the data that an alternate device is considered equivalent and, if this is the case, receive a letter so stating from OSHA. An alternate monitoring device may be used without a letter from OSHA stating that it is an equivalent instrument. The manufacturer can provide the data to the employer for the employer to demonstrate equivalency. If the data meets the standard's criteria in the manufacturer's tests, the employer need not repeat that testing in the employer's facility. Also, an employer may demonstrate equivalency in the employer's facility with the employer's own tests.

As Dr. Rockette stated, it was his and Dr. Wadsworth's intention that the protocol be used to establish that an instrument is equivalent to the vertical elutriator and that these instruments need not be validated in each plant provided the instrument is of the same quality as the model tested.

Although the vertical elutriator uses a gravimetric detection method to measure cotton dust, OSHA does not require that an "equivalent instrument" use a gravimetric detection method. One advantage of the gravimetric method is that the sample can be further analyzed, where appropriate, to determine the contribution of lubricating oil to the overall weight of the sample. This further analysis of the sample may be important in some weaving operations, such as those employing Sulzer projectile looms, where lubricating oil, which is not considered cotton dust, may make a significant contribution to the weight of the sample. In operations such as yarn manufacturing, where an analysis of the sample is unnecessary, a simple determination of respirable dust is sufficient. However, if it is necessary to determine the amount of oil present in the sample, it appears to be necessary to collect a dust sample and then analyze the sample for oil content. The use of the VE is appropriate in all operations where cotton dust is to be measured. The decision to use an "equivalent instrument" in lieu of the VE in areas where the potential exists for oil contamination of the sample will be left to the employer. If the employer chooses to use an alternate instrument which does not provide a sample so that the percent of oil can be determined, then the employer may not exclude the oil

from the sample in determining exployee emposure.

2. The CAM/PCAM Model C

A potential alternative sampling device, the CAM/PCAM Model C, manufactured and sold by ppm, Inc., has been tested with the VE in a number of side-by-side equivalency trials designed to meet the 1978 standard criteria. In 1980, two of these tests were submitted to OSHA for evaluation and acceptance. In January 1981, OSHA stated in a letter to Dr. John Neefus of Burlington Industries that OSHA believes the CAM instrument system (with the gravimetric certification and the equivalency refinement factor procedures as described in the draft paper "Gravimetric Certification and Equivalency Demonstration Protocols for Alternative Samplers to the Vertical Elutriator") is capable of equivalency to the vertical elutriator in reference specifically to Burlington facilities. Subsequently, the CAM instrument was accepted as equivalent to the vertical elutriator in several State Plan States. OSHA does not intend to require that these states change their decision.

In their post hearing briefs, National Cotton Council (Ex. 276), ACTWU (Ex. 279), and ATMI (Ex. 280) recommend that the CAM/PCAM Model C electro-optical sensors be directly identified in § 1910.1043(d)(1) as acceptable alternatives to the vertical elutriator. The manufacturer, ppm, Inc., (Ex. 203–C) stated that the CAM/PCAM Model C has been shown to be equivalent to the vertical elutriator in 20 of 22 equivalency tests and requested the instrument be directly identified in the standard.

While OSHA believes the CAM/PCAM instruments are likely to be equivalent to the vertical elutriator, the documentation which ppm, Inc. submitted to the record (Ex. 235) as evidence of meeting the Rockette-Wadsworth protocol was not sufficient to meet the protocol. The Rockette-Wadsworth protocol requires 100 samples to be taken at 10 sites in one mill with 10 readings at each site; dust levels represent 0.5 to 2 times the PEL and use of two VEs and one or two alternative devices. In the ppm, Inc. submission, a total of 196 samples came from two employers. The first employer had samples taken at only 6 sites, and the dust level did not meet the 2X PEL requirement. The second employer had samples taken at 8 sites of which one site has more than 10 readings but the other 7 sites only have 5 readings each for a total of 49 readings. Thus, it does not meet the requirement of 100 samples taken at 10 sites with 10 samples at each site.

Because the data submitted does not meet the requirements of the protocol, OSHA cannot identify in the standard CAM/PCAM Model C as an acceptable equivalent instrument to the VE in the standard. However, OSHA believes the CAM/PCAM instrument can probably meet the requirement of the Rockette-Wadsworth equivalency protocol. OSHA encourages all manufacturers of alternative sampling devices to submit proper documentation to show their instruments' equivalency to the VE.

3. Frequency of Monitoring

In the June 1983 proposal, OSHA proposed to reduce monitoring frequency from once every six months to once a year for those employees whose exposure is below the PEL. Further, OSHA proposed that monitoring would be eliminated if the initial monitoring or any subsequent monitoring revealed employee exposure to be below the action level, and an additional monitoring in an interval no greater than one year confirmed that the exposure was below the action level.

There were no specific comments in response to the proposal to reduce monitoring from semi-annually to at least annually for those employees whose exposure level is at or above the action level but at or below the PEL. There were a number of comments on this issue in response to the ANPR which were discussed at 48 FR 26972. For example, ATMI pointed out that OSHA in most health standards reduces monitoring frequency for employees exposed below the PEL and that annual monitoring was justified (Ex. 175–41).

Comments were received on OSHA's proposal to eliminate all exposure monitoring for employees exposed below the Action Level. NIOSH noted that discontinuing exposure sampling "can result in high probability of having workers receive excessive exposure without the ability to detect them by sampling" (Ex. 187–23) Dr. James Merchant commented that "OSHA's proposal to eliminate dust sampling if 'two consecutive monitorings are below the action level within a reasonable period,' in my view is unwise." (Tr. 293) He said there are many variables that affect the dust level and not all of them are detectable or measurable. Therefore, at least annual monitoring of dust concentration would be prudent. Dr. Morton Corn concurred with this view (Ex. 198D, Tr. 293–94). Based on Merchant's and Corn's comments, ATMI and ACTWU recommend that "Exposure monitoring should continue to be required semiannually in areas where the PEL is exceeded and should occur annually in all areas below the PEL, including areas that are below the action level." (Ex. 279 and 280)

OSHA is following its proposal and amending paragraph (d)(3) to provide that periodic monitoring need be repeated annually and not semi-annually for employees exposed below the PEL. This will provide protection for employees by identifying unnoticed changes in the work environment which result in exposures above the PEL. (Paragraph (d)(3)(iii) requires remonitoring if product or process changes may lead to higher exposure.) It will improve cost-effectiveness by reducing monitoring exposes for employees and saves valuable industrial hygiene resources for other duties. In addition, OSHA's experience with other health standards indicates it is adequately protective to reduce monitoring frequencies when exposures are under the PEL. As discussed in the proposal, many comments to the ANPR supported this approach.

There were substantial objections to OSHA's proposal to eliminate routine monitoring for exposures below the action level, and OSHA has retained annual monitoring for employees exposed below the action level. This decision is explained in the action level section, is supported by both ATMI and ACTWU and meets the objections to the proposal stated above.

The 1978 standard requires monitoring on each shift because of variations that can occur between shifts in the same area. The ANPR asked whether in certain circumstances the reading on one shift could be used as representative of all shifts in an area. The North Carolina Department of Labor commented that monitoring should continue to take place on each shift. In its experience there was substantial variation from shift to shift in the same area depending on such variables as production quantity, scheduling and employee work habits.

The ATMI commented that in some circumstances monitoring on a single shift can be sufficiently predictive of all shifts to permit single shift monitoring. In support of this point, the ATMI referred to a study by Dr. Moon Suh of Burlington Industries entitled "Statistical Analysis of Shift-To-Shift Dust Variations Measured in Cotton Textile Operations" as part of ATMI's comments to the ANPR. In this study, Dr. Suh details how a single shift monitoring of cotton dust exposure can apply and if a critical value is met, then a "true day average" can be predicted.

Regarding the study, OSHA's proposal stated:

"The method proposed however, would not identify all shifts where exposure in fact exceeded the PEL. Conceivably, an overall "true-day average" estimated to be below the PEL could mask a single shift average which is actually above it. The study leaves unanswered significant questions concerning the procedures used and the assumptions relied upon. The most important involves the representative characteristics of the fifty firms which supplied data. Potential differences in variability between plants is not addressed. In addition, there are serious questions concerning the pooling of variances across dust levels and work areas in cases where there are wide differences in coefficient of variation values. The report must be considered as inconclusive until further explanations are available." (48 FR 36972)

OSHA concluded that it would not propose to amend the standard to permit single shift monitoring because of the uncertainties on shift-to-shift variability. It opened this issue, however, and requested further comment (48 FR 26972).

At ATMI's request OSHA staff held a meeting with Dr. Suh to explain OSHA's questions. Minutes of the meeting and a memo further explaining the comments are in the record. (Exs. 249 and 204B).

Dr. Suh submitted an additional report as part of the ATMI prehearing comments (Ex. 187–17) and testified on his study at the Washington hearings, (Tr. 687) He stated that there could be increased assurance that the PEL is not exceeded on the unmeasured shifts provided that one of two criteria is met. The criteria are that the measurement is made on the shift:

(a) For which the highest readings were recorded on the two preceding measurement dates, or

(b) For which the person responsible for industrial hygiene at the plant identifies as being likely to have the highest dust levels for the particular work area.

ACTWU (Ex. 279) argued that the proposed method of selecting shifts for single-shift monitoring is unreasonable and unworkable. ACTWU argued if one shift is monitored, no readings will be recorded for the other two shifts and in the future, it will be impossible to determine the "shift for which the highest readings were recorded in the two preceding measurement dates."

Data submitted to OSHA indicate that the highest exposure shift is not easily identified for the single-shift monitoring method. ACTWU submitted data for four successive measurement dates of one company indicating the highest level shifts vary among the three shifts (Ex. 279, Ex. 237F). In a summary of some of their compliance activities, the North Carolina Department of Labor noted substantial differences in exposure readings on various work shifts at the same physical location (Ex. 175–80).

Given the data submitted by ACTWU (Ex. 279) and the South Carolina DOL (Ex. 216) which indicated that the shift with the highest exposure level varies among different shifts and the NCDOL's (Ex. 175–80) comment noting substantial differences on various work shifts at the same location in their compliance activities. OSHA is not deleting the multi-shift requirement. However, those employers who can identify highest exposure shifts and believe the single-shift monitoring method is appropriate for their operation may wish to apply for a variance.

4. Employee Notification

In the proposal, OSHA proposed to amend paragraph (d)(4) to extend the period of notification of monitoring results from 5 to 20 working days and require that each employee be notified "individually" in writing. The extension of time was proposed because of known difficulties in providing notification within the 5-day period required by the 1978 standard. Testimony at the hearing confirmed the necessity of an extension of time.

Edgar McGowan, Commissioner of Labor of the State of South Carolina noted that extension of time will allow employers to translate monitoring results into a language more easily understood by employees (Tr. 1187). Carroll Bailey, Health Supervisor for South Carolina Department of Labor OSHA stated that "even in this computer age, it is often difficult to prepare meaningful data that can be fully understood by the employee "(Tr. 1139). ACTWU and ATMI agreed with the proposed extension of time (Ex. 279 and 280).

Most commenters disagreed with OSHA's proposal to require that employers notify employees "individually". The North Carolina Department of Labor (Ex. 175–80) commented that "posting of sampling results is an acceptable means of employee notification." Commissioner McGowan of South Carolina also stated that "in many plants such posted notices are very effective." (Tr. 1187) In their post hearing briefs, both ATMI (Ex. 280) and ACTWU (Ex. 279) recommended that the word "individually" be stricken from the standard.

On the basis of the testimony on this issue, it appears that a 20 day notification period for posting monitoring results is an effective means of notifying employees. OSHA is not adding the word "individually" to paragraph (d)(4)(i) of this action based on the comments and testimony in the record.

E. Methods of Compliance

OSHA also proposed to amend paragraph (e)(3)(vi) which requires employers to update their written program of engineering controls every 6 months. The proposed amendment eliminated the 6 month requirements and requires updates only when necessary to reflect the current status of the program and current exposures. The proposal has been incorporated into the final amendments with a slight language clarification. There is no need to update the written compliance program if all exposures are under the PEL. (Note the explanation of the change in the proposal, 48 FR 26875, had a typographical error mistakenly referring to paragraph (e)(3)(ii) rather than paragraph (e)(3)(vi).)

Paragraph (e)(3)(i) of the 1978 cotton dust standard requires employer to establish a written program to reduce exposure below the PEL. It was OSHA's intention, of course, that this apply only to employers with exposures over the PEL. However, some misinterpreted the language to apply to employers who had no exposures over the PEL. OSHA proposed to clarify the language to indicate that only employers with exposures over the PEL need to have a written compliance program to reduce exposure below the PEL with engineering controls. That proposal has been incorporated in the final amendments. (Note that the provisions of paragraph (g) that requires all employers with cotton dust present to have a written program of work practices and those provisions remain unchanged.)

The 1978 cotton dust standard in paragraph (e)(4) requires that the effectiveness of all mechanical ventilation equipment be checked every six months and within five days after a production change. OSHA proposed to amend the language of the standard to require that the checks be made at "reasonable intervals." The basis for this proposal was OSHA's judgment that it was more appropriate to leave the exact frequency of such checks to the professional judgment of the plant engineer or other such individual designated by the employer to maintain the equipment (48 FR 26974). The proposed amendment drew very few comments. The ATMI endorsed OSHA's proposal to require such measurements be made at "reasonable intervals." It pointed out that the frequency of such measurements would depend on such

factors as the type and age of the equipment, the characteristics of the particular workplace, and no "hard and fast" rule could be established for the variety of circumstances found in the industry. The ATMI also pointed out that such a provision is consistent with the protection of worker health when periodic exposure monitoring continues to be required regardless of the cotton dust level (Ex. 208, p. 104–105). The ACTWU had "no objection to the proposed amendment of paragraph (e)(4) which would allow the measurements of the ventilation system to be conducted at 'reasonable intervals.' " (Ex. 279, p. 121)

Based on the evidence available, OSHA concludes that its proposal to amend paragraph (e)(4) to require that measurements of the effectiveness of the mechanical ventilation equipment be made at reasonable intervals is consistent with the Agency's desire to make the standard more performance oriented without sacrificing the protection of workers' health. Therefore, paragraph (e)(4) is amended to require that such measurements be made at reasonable intervals.

F. Use of Respirators

The standard requires respirators to be used under the following circumstances: (1) During the time period required to install or implement feasible engineering controls and work practices controls; (2) during maintenance and repair activities in which engineering and work practice controls are not feasible; (3) in work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the permissible exposure limit; (4) during work practices of "blow down" and "blow off"; and (5) whenever an employee requests a respirator. The standard further requires that the employer institute a respiratory protection program in accordance with applicable parts of 29 CFR 1910.134 and that the employer select respirators from among those approved by NIOSH under 30 CFR Part 11. The standard also includes a selection table which lists required types of respirators.

1. Changes to the Respirator Table

OSHA proposed no major changes to the respirator use and selection provisions. However, OSHA noted in its June 1983 proposal (48 FR 26972) that since the publication of the 1978 cotton dust standard, NIOSH has retested some "single-use" respirators and approved them as respirators with "replaceable" filters. Based on this action by NIOSH, OSHA proposed a technical change to update the standard and replaced the word "single-use" with the word "disposable" and noted that a "disposable respirator" means the filter element is an inseparable part of the respirator. Because there have been no significant changes in the construction and performance of these respirators according to the 30 CFR Part 11 MSHA/NIOSH respirator testing and certification requirements, OSHA did not propose to change the assigned protection factor of 5 times the PEL.

OSHA also noted in the proposal that because of their weight and bulk, self-contained breathing apparatus (SCBA) and combination supplied air respirator with escape SCBA are impractical and inappropriate for protection against cotton dust where only an air purifying respirator is needed. Their much greater protection factors are not needed because if the cotton dust exposure exceeds the PEL by more than 5 times, the condition is not immediately dangerous to life. However it is permissible to use a respirator providing a greater protection factor. Therefore, the employer could technically supply a heavier and more awkward to wear respirator when only a simpler, lighter one was needed. This is unlikely as a matter of practice because of the greater expense of the heavier respirator. Therefore, it was proposed that these respirators be deleted from Table 1 as required respirators.

NIOSH agreed that the proposed changes to the respirator section were appropriate and stated "at the present time, NIOSH views the changes OSHA has proposed in the respirator provisions of the proposed standard as useful. Users should find the requirements to be clearer." (Ex. 187–13) Carrol Bailey, a certified industrial hygienist and OSHA health supervisor for the South Carolina Department of Labor testified at the hearings that the proposed changes in the standard on the use of respirators "are largely technical in nature and do serve to update the regulations." (Tr. 1139)

Accordingly for the reasons stated the proposed changes are incorporated into the final amendments to the respirator table. To further clarify OSHA's intent, SCABs and supplied air respirators are moved from the body of the respirator table to a note. This does not change the legal situation. They still may be used, but this change is to indicate that OSHA does not believe they will be used very frequently and the OSHA is not, in the case of cotton dust, encouraging their use. (Their greater protectiveness will outweigh their heaviness and awkwardness in situations where there is high exposure to a carcinogen or in situations immediately dangerous to life and health.) However, there may be some situations where a supplied air respirator may be appropriate in the case of cotton dust where the employee does not need to move about. Therefore, the possibility of their use is eliminated.

The Minnesota Mining and Manufacturing Company (3M), a manufacturer of the "disposable" class of respirators, submitted written comments (Ex. 187–12) and testified at the Washington, DC hearings. 3M's representatives contended during the hearings that:

(1) NIOSH recognizes and judges disposable respirators equivalent to respirators with replaceable filters and OSHA should not limit the protection factor of these respirators to five.

(2) OSHA allows use of "disposable" respirators as protection against lead at a level 10 times the PEL. Thus, there is no justification to limit to 5 times the PEL for cotton dust.

(3) Fit tests are available and accepted by OSHA as viable means of assessing the facefit of this type of respirator. OSHA should not use outdated facefit criteria to limit the use of disposable respirators.

(4) The American National Standards Institute (ANSI) has recognized the equivalency of disposable and nondisposable respirators and have incorporated this equivalency in their respirator selection logic in published standards.

(5) Limiting the use of disposable respirators to a protection factor of five would force the cotton industry to purchase more expensive, less comfortable respirators and deprive employees from using the device that is the most accepted by the workers in the industry.

OSHA has carefully reviewed the evidence in the record on the respirator provisions and concludes that there is no justification for changing the protection factor for disposable respirators from 5 to 10 times the PEL. Although it is true that NIOSH recognizes and judges "disposable" respirators equivalent to respirators with replaceable filters, NIOSH's certification test does not test whether a facepiece fits the user and NIOSH does not assign a protection factor in the certification test but tests only filter efficiency and breathing resistance. Consequently, the NIOSH certification does not indicate whether the disposable respirator provides as much protection as a half mask when fit as well as filter efficiency are taken into account.

Lead and cotton dust are different air contaminants and the application and use of respirators for lead and cotton dust are also different. Under the current lead standard, biological

monitoring is required. The biological monitoring required by the lead standard, determining blood lead levels, will give a reasonably direct indication whether the respirator is working from the blood lead levels because it will give a reasonable indication of whether lead is getting into the breathing zone. Pulmonary function testing is not a direct measurement of the efficiency of the respirator because it does not indicate how much cotton dust penetrates the respirator and enters the breathing zone. Furthermore, the lead standard requires the use of respirators with high efficiency filters while the cotton dust standard does not have such a requirement at levels less than 10 times the PEL. The use of dust and mist filters instead of high efficiency filters is only permitted under a current temporary administrative stay of the lead standard.

The ANSI standard "Practices for Respiratory Protection, Z88.2, 1980" did not address the questions on protection factors (PF) provided by disposable respirators. All PF data on air-purifying respirators were developed on quantitative fit testing from respirators equipped with high efficiency filters only. Since there were no "surrogate" disposal respirators available which would not alter the fit characteristics of a disposable respirator, the ANSI respirator protection factor table was developed without any fit testing results from disposable respirators.

To assure proper protection, the facepiece fit must be checked by the wearer each time the respirator is worn. A simple positive or negative pressure test gives a rough indication whether a rigid respirator is working. The employee places his or her hand over the inhalation and exhalation valves and blows or inhales to determine whether air is escaping from the face seal. The disposable dust and mist respirators which are permitted in this standard have neither an inhalation of exhalation valve. Therefore, it is difficult for the user to perform a negative or positive pressure test on this class of respirators in a simple and effective manner to determine whether there is a gross leak.

An alternative to the positive or negative pressure test is to perform a qualitative or a quantitative fit test. Due to the design limitations of these respirators, quantative fit testing is not possible, and OSHA believes it is not appropriate to require the employers to conduct the saccharin QLFT each time the respirator is worn since it is time consuming and because of the nature of the hazard.

For those reasons, OSHA believes that it would be inappropriate to assign a protection factor of 10 to a disposable respirator for cotton dust protection. A protection factor of 5 for the class of disposable dust and mist respirators is the appropriate protection factor to provide an adequate margin of safety to overcome the fitting problem. OSHA further believes that at the present time virtually no employee in the textile industry is exposed to cotton dust at levels greater than 5 times the PEL for an eight hour period. The disposable respirators available in the market today are likely to be the respirator of choice, and the cotton textile industry would not be forced to purchase more expensive and less comfortable respirators.

2. Wage Rate Retention

The 1978 standard [29 CFR 1910.1043(f)(2)(v)] provides that whenever a physician determines that an employee is unable to wear any type of respirator, the employee shall have the opportunity to transfer to another job, if one is available, which involves exposure to cotton dust levels below the permissible exposure limit. In addition, the regulation, as originally issued, required employers to assure that transferred employees would not suffer a loss of earnings, other employment rights or benefits. This latter part of the paragraph is referred to as the "wage rate retention provision".

Both the ATMI and the ACTWU, in their posthearing comments, agreed that the evidence supported the inclusion of a wage rate retention provision in the amended standard. In identical statements, they said:

> As a response to these health-based concerns, it would be appropriate to include in the standard a rate retention provision applicable to employees who are transferred from an area in which dust levels exceed the PEL because of inability to wear a respirator safely and effectively. (Exs. 279, p. 75; 280 p. 75)

In 1981, the Supreme Court, in *ATMI v. Donovan,* 452 U.S. 490 (1981), struck down the wage retention provision of the regulation as promulgated, but left the job transfer provision in effect. The Court held that OSHA failed to provide a sufficient rationale for the wage retention provision because it did not explain how the provision was related to the achievement of a safe and healthful work environment (Id., at 537–538). The Court did not decide the issue of whether OSHA had the underlying authority to promulgate such a provision. The Court noted that there was some evidence on the subject in the record (Id., at 539, footnote 73).

The United States Court of Appeals for the District of Columbia Circuit upheld the validity of OSHA's Medical Removal Protection ("MRP") program for the lead standard in United Steelworkers of America, AFL–CIO v. Marshall, 647 F. 2d 1189 (D.C. Cir. 1980), *cert.* denied, Lead Industries Association Inc. v. Donovan, 101 S. Ct. 3148 (1981). Part of the MRP program for lead involved a wage retention provision for workers who transferred to other jobs or were laid off to avoid continued exposure to unacceptable levels of lead.

In response to the Supreme Court remand in ATMI v. Donovan, the ANPR of February 9, 1982 raised the issue of whether a wage retention provision (47 FR 5406) should be incorporated into the cotton dust standard. Among the comments received, some were in favor of the provision and others were opposed. After consideration of the comments submitted in response to the ANPR on the issue of wage retention, OSHA decided not to include such a provision in the proposed standard because the evidence available at that time was not sufficient to justify it. OSHA stated that the evidence available did not indicate that the provision would have a substantial impact on a significant population of employees and that the evidence then available did not indicate a clearly established link between employee health and the wage retention provision. The Agency also stated that it considered it sound policy not to become involved in determining wages and terms of employment (an area traditionally reserved to employers' personnel practices and the collective bargaining process) unless evidence established occupational health need. As a matter of broad policy, OSHA continues to subscribe to that view.

OSHA has received numerous comments and testimony in response to the proposal. Some evidence presented indicates that exclusion of the wage retention provision could cause workers to withhold information about symptoms of respiratory impairment, thereby posing risks to their health. A number of workers testified that because they have responsibilities which must be met and cannot afford drastic cuts in pay, they would be less likely to report symptoms of disease if they fear losing wages and benefits as a result of a health-related job transfer.

For example, Mr. Reese Boware said:

> I know of workers who have lied on the breathing test and questionnaires just because they feel that if they are transferred because of problems, they will be transferred

to a lower-paying job. Now this is bad for their health because they try to hide their breathing problems. These workers have told me that if their pay was for sure protected, that they would be happy to go to a less hazardous area. Nobody wants brown lung.

However, with prices as high as they are today, no person could afford a drastic pay cut. (TR. 1525–36)

Ms. Derenda Clements testified:

A lot of us are not going to get up there and tell you that they have got a breathing problem, because they do not want to lose that dollar and hour or dollar and a half an hour because they cannot afford it . . . (Tr. 515)

Mr. Samuel Shelton, another worker who testified, said:

If an employee were to be told that he did not have transfer rights with wage retention, they would be more apt not to report all their symptoms to the company, simply because they could not afford to be transferred to another department and take a cut in pay. (Tr. 1166)

Mr. O'Dell Rambo testified to the long lasting effects of wage cuts to older workers who are nearing retirement when he pointed out:

. . . a person's Social Security retirement could be greatly affected because of lower wages during the last five years of work that should have really been the highest earning years of his life. (Tr. 1512)

A number of physicians testified to workers' reluctance to reveal breathing problems. Dr. James Merchant conducted a number of epidemiological studies in the textile industry which involved medical evaluation and interviewing of several hundreds of cotton textile workers and evaluated many textile workers clinically at Duke University Medical Center and at the University of North Carolina. According to Dr. Merchant:

. . . individuals who have impairment who come in for evaluation . . . at least at that time, there was a great deal of apprehension in regard to their continued employment, if their employer was aware that they had obtained this evaluation.

Similarly, we observed on a number of occasions people who were quite symptomatic by observation in terms of respiratory disease, who would give completely negative questionnaires. And I think, in part, that was because of the fear that workers have that if they divulge symptons this in some manner may jeopardize their employment. (Tr. 336)

Dr. E. Neil Schachter stated in his testimony that in an environment where safeguards against job loss or salary loss do not exist, groups of workers in general and individual workers in particular are reluctant to give details of their illnesses. He said:

. . . (B)ased on my experience with clinical examinations of workers with byssinosis and with epidemiologic data available from workers in Columbia, South Carolina, I agree with the assessments made by ACTWU, the Brown Lung Association and Dr. James Merchant, that workers unprotected by rules safeguarding their employment in general and their wages in particular will not be willing to discuss their medical problems openly. These workers will thereby be at risk of having their medical problems worsen without appropriate intervention. (Tr. 530)

Dr. Robert Castellan testified about worker reluctance to participate in the NIOSH-sponsored industry-wide studies because of concern about what impact the results might have on their lives. He stated:

(W)e did have individuals who did show some concern at the beginning of the shift for their pre-shift examination . . . You know, we would discuss with them the situation. They would consent to participate. At the post-shift examination, some of these individuals, we were told by their fellow workers, did leave work without stopping by because they were concerned about what might get placed in their medical record." (Tr. 431)

There were a number of prehearing comments which initially opposed wage rate retention from ATMI and various textile companies. The reasoning was similar to that stated on OSHA's proposal (see Exs. 175–41 p 35, 175–24.)

ATMI and ACTWU have made a series of identical recommendations to OSHA on amendments to the cotton dust standard for textiles. (Exs. 279, pp. 7–76; Ex. 280, pp. 7–76.) These have been discussed throughout this preamble. Among their identical recommendations was that there be a wage retention provision in the cotton dust standard.

In support of its inclusion they stated:

. . . Under the Standard and its supporting rationale, an employee who works in an area where dust levels exceed the PEL is deemed to be facing an unreasonable risk of material impairment of health or functional capacity if he is not effectively utilizing a respirator. To avoid such a result, an employee who is assigned to an area where dust levels exceed the PEL and who is unable to wear a respirator should be transferred to an area in which cotton dust levels are below the PEL.

In order to make this health-based transfer requirement effective, the Standard should assure those employees who are unable to wear respirators effectively that they will not face a substantial economic penalty as a result of disclosing that fact. The Standard requires a physician to make a determination of the employee's ability to wear a respirator and provides for an opportunity to transfer to a position where dust levels are at or below the PEL if the employee is unable to wear any form of respirator. In order to make this determination, the physician must take into account the employee's report of any difficulty in breathing that he experiences when wearing a respirator. Moreover, in some cases, use of a respirator may be counterindicated from a medical standpoint because of other health problems, which may be entirely unrelated to cotton dust exposure. Information of this type must be disclosed to the physician if he is to make a properly informed and soundly based judgment regarding the employee's ability to wear a respirator safely and effectively.

As a response to these health-based concerns, it would be appropriate to include in the Standard a rate retention provision applicable to employees who are transferred from an area in which dust levels exceed the PEL because of inability to wear a respirator. (Ex. 279, pp. 74–75; Ex. 280, pp. 74–75.)

Both data from industry and the Centaur Report indicate that most areas of the industry are in compliance with engineering controls. Therefore, relatively few employees will be wearing respirators. Data which industry supplied indicated that relatively few employees are unable to wear respirators. Consequently a wage retention provision will not create major costs.

Considerable new evidence was presented at the hearing indicating a health need for limited wage retention provision. First, three knowledgeable physicians, as just discussed, testified of some employee reluctance to reveal information necessary for proper health care if the employee feared it might result in transfer to lower paying jobs. Second, the employee testimony brought to OSHA's attention a situation about which it had not been aware. Older employees are concerned that transfer to a lower paid area will not only reduce current pay but will also result in their social security pensions being substantially reduced if their last few years' salary is reduced. It is likely that older workers will comprise a large portion of those employees who would have to be transferred, and it is, of course, important that the health of older employees be maintained through appropriate medical surveillance.

In addition, OSHA believes it is good policy to encourage representatives of employees and employers to develop joint recommendations to OSHA to protect employee health. (OSHA is carrying out policies similar to this in the cooperative assessment agreements for arsenic and lead.) The ATMI and ACTWU have successfully developed identical recommendations of considerable merit supported by the record. The wage rate retention recommendation is an important part of these recommendations. OSHA encourages such joint recommendations for employee health protection and gives significant weight to such

recommendations, especially in areas where employee and employer representatives have considerable experience.

Therefore, because of the new health evidence and the recommendations of the ACTWU and the ATMI, OSHA is incorporating a limited wage retention provision which is sufficient to meet health needs. Paragraph (f)(2)(iv) provides that:

> Whenever a physician determines that an employee who works in an area in which the dust level exceeds the PEL is unable to wear any form of respirator, including a power air purifying respirator, the employee shall be given the opportunity to transfer to another position which is available or which later becomes available having a dust level at or below the PEL. The employer shall assure that an employee who is transferred from an area in which the dust level exceeds the PEL due to an inability to wear a respirator suffers no reduction in current wage rate or other employment rights or benefits as a result of the transfer.

G. Work Practices

The terms "blow down" and "blow off" are discussed in detail in this section under B. Definitions. The addition of the term "blow off" to this standard has necessitated changing paragraph (g)(4) of this section to read, in part:

> Where compressed air is used for cleaning, the employees performing the blow down or blow off shall wear suitable respirators. Employees whose presence is not required to perform the blow off or blow down shall be required to leave the area affected by the blow down or blow off during the cleaning operation.

This makes clear that the degree of evacuation depends on the extent of the cleaning operation. OSHA believes that this change, as supported by ACTWU and ATMI, meets and satisfies the concerns expressed by the witnesses because it makes clear that employees in areas where dust levels are raised by compressed air cleaning are required to evacuate the area. The requirement for appropriate respiratory protection for workers engaged in compressed air cleaning has been retained.

The 1978 standard requires that the work practice provisions of paragraph (g)(1–3) be met regardless of the level of employee exposure. These practices continue to be required because the operations of blow off and blow down, the use of compressed air for cleaning, and floor sweeping all increase the workers' exposure levels. Therefore, overexposure may result even though exposure monitoring may indicate that the PEL is not exceeded. OSHA did not propose to eliminate these provisions, and no comments were submitted recommending elimination.

Paragraph (g)(4) of the 1978 standard required that cotton and cotton waste be handled by mechanical means except where the employers can show that this is infeasible. Shortly after the standard was published, OSHA interpreted this provision by letter to mean that this requirement applied only when exposures were in excess of the PEL (Ex. 239, 240).

As the result of an oversight, OSHA proposed to amend paragraph (g)(4) to require mechanical handling when exposures exceeded the Action Level. The effect was to impose additional requirements on the employer in this area which was not OSHA's intention. Therefore, OSHA is amending paragraph (g)(4) by adding the words, "in areas where employees are exposed to concentrations of cotton dust greater than the permissible exposure limit" to indicate clearly where this provision is required. The net effect is that there is no change in the intent of paragraph (g)(4) from the 1978 standard.

OSHA also proposed to delete paragraph (g)(5) which requires that the employer "inspect, clean, maintain and repair" all engineering controls. Since the standard requires the employer to reduce cotton dust exposure to the level specified by the PEL and to check the effectiveness of the engineering controls at reasonable intervals, OSHA proposed to delete paragraph (g)(5) as a duplicative and an unnecessary specification requirement.

This proposal to delete paragraph (g)(5) was supported by the ATMI (Ex. 280, p. 105–107). They agreed with OSHA's reasoning in this matter and said that, "Where it is necessary to maintain ventilation equipment to achieve this objective, employers will do so" (Ex. 280 p. 105) and that such an incentive is particularly effective when periodic exposure monitoring is continued in all areas.

The ACTWU argued that OSHA should not delete Section (g)(5). They cited the testimony given by Dr. Morton Corn who said that "maintenance for non-productive aspects of the process ae last on the list." (Tr. 495) They also argued that dust levels are subject to variation and that annual or semiannual monitoring might not promptly detect a failure in the ventilation system.

OSHA has considered the comments by the ATMI and the ACTWU in this matter. Although it may be true as Dr. Corn suggests that maintaining non-production equipment generally is not a high priority item, some companies have individuals whose specific job responsibility it is to check and maintain the ventilation equipment (Tr. 522). Furthermore, the goal of the standard is to protect the health of workers by, among other things, reducing the exposure levels to the applicable PELs. Section 6(b)(5) of the Act specifies that "Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired." OSHA concludes that the requirement to meet the PEL provides adequate incentive to the employer to maintain the engineering controls in the proper working order. In addition, the requirement that the effectiveness of the mechanical ventilation be checked periodically will serve to ensure that once the PEL is achieved that it will be maintained and that the health of exposed workers will continue to be protected. Therefore, section (g)(5) is deleted from the final standard.

H. Medical Surveillance

The 1978 standard required that employees be provided with an opportunity for medical surveillance prior to initial exposure and annually thereafter. Employees who experience an FEV_1 decrement of 5 percent or 200 ml. on a first working day, who have an FEV_1 less than 80 percent of the predicted value, or who in the opinion of a physician have a significant change in their respiratory condition [paragraph (h)(3)(ii)] are to be provided with examinations every six months.

In 1983 OSHA proposed that an "Action Level," an exposure level equal to one half the PEL, be included in the standard. Most employees exposed to cotton dust at levels below the Action Level would be provided with an opportunity for medical surveillance once every two years. Regardless of the dust level, employers would still be required to provide an opportunity for medical surveillance every six months for those employees who meet the criteria outlined in paragraph (h)(3)(ii) of the standard.

Most of the physicians testifying at the hearing agreed that for employees exposed to dust levels below the Action Level, medical examinations every two years would be adequate (1983 Tr. at 57–58, 96–97). In response to a question on this matter, Dr. Hans Weill stated "my personal view is that at levels that low one could safely have a monitoring program of lung function and other indicators of respiratory health that was instituted for individual workers every second year." (Tr. 155) Dr. James Merchant, whose studies provided the dose-response relationship upon which OSHA relied, agreed that most workers

exposed to dust levels less than the Action Level "can probably be followed biennially without material increased risk of not detecting significant health effect." (Tr. 293). He did emphasize, however, that those employees who showed a loss of pulmonary function should continue to receive an examination every six months even if they are exposed below the Action Level (Tr. 293).

Dr. Neil Schachter was the only physician to disagree with the biennial medical examination schedule. He recommended annual exams for all exposed workers. However, he did agree that Dr. Merchant was "one of the most knowledgeable people in [the] field" and was "well qualified to render an opinion on that subject." (Tr. 584)

Both ATMI and ACTWU agreed in their post hearing briefs that this reduction in medical frequency was appropriate (Exs. 279 & 280). See also the discussion of the Action Level above.

Based on evidence and testimony, primarily the expert opinion of physicians who are specialists in pulmonary medicine, OSHA concludes that most employees exposed to cotton dust at levels below the Action Level can be followed by medical examinations every two years without increasing their risk of health impairment. Paragraph (h)(3)(i) is amended accordingly. The reduction in the frequency of medical examinations will help to create an incentive for employers to search for ways to reduce exposures to levels below the Action Level. However, employers will continue to be required to provide an opportunity for medical examinations every six months to employees who show evidence of loss of pulmonary function regardless of the dust level to which those employees are exposed.

Evidence and testimony in the record support the need for preplacement medical examinations. The record documents the fact that individuals, with or without prior cotton dust exposure, may have a severe reaction to exposure to cotton dust.

Dr. Robert Castellan, a member of the NIOSH panel, testified on this subject at the 1983 hearings. Dr. Castellan cited his experience with human test panels during the washed cotton studies. He said:

> In those exposures, we need to screen individuals before we allow them to fully participate in our exposures . . . and, what we do initially is screen them with a questionnaire and baseline spirometry . . . We would not allow them to participate further if they had greater than 30% decrement in FEV_1. We had approximately three who had that great a decrement. One of them was a great—somewhere in the upper 60's, a very severe reaction . . . The two [individuals] that I recall very well, because I happened to be there at the time, had no prior exposure to cotton dust. (Tr. 422–3)

Dr. James Merchant testified to the importance of the use of medical surveillance to detect a decline in lung function over time. Based on his experience and knowledge of the literature, he stated that such declines in lung function may occur within a period of a few weeks. Therefore, he emphasized the need for establishing "a baseline that is a pre-exposure baseline . . . and that provision, I think, needs to be maintained." (Tr. 307)

Dr. Robert Jones outlined the ways that pre-employment medical examinations could provide information to assist the employer in making appropriate placements. He outlined the benefits of such a program as follows:

> First, it could allow identification and protection of persons, who for any reason, were unusually susceptible to adverse effects of this dust. Simple prudence dictates that persons with active airways diseases, such as bronchial asthma, or with advanced and potentially disabling lung diseases of any cause, should not be assigned to particularly dusty jobs.
>
> It is also prudent to reassign away from such jobs if longitudinal surveillance shows the development of respiratory illness in a previously healthy worker. (Tr. 206–7)

Based on the testimony of these medical experts, OSHA concludes that the evidence supports the continuation of the requirement that initial medical examinations be provided prior to the initial assignment.

Paragraph (h)(2)(ii) of the 1978 standard requires that the FVC and FEV_1 be measured as part of the medical surveillance program. The amended standard continues these requirements and require that the FEV_1/FVC ratio must also be calculated as well. The information obtained from calculating this ratio will assist the physician in evaluating the health of the exposed worker by providing information specified in mandatory Appendix D III B. OSHA anticipates that the addition of the FEV_1/FVC ratio will provide no additional testing burden since both measurements are required by the 1978 standard. In addition, OSHA also has evidence in the record that this ratio as already provided routinely by consultants conducting medical surveillance (Ex. 271).

Paragraph (h)(2)(iii) has also been modified to make clear when the employee should be tested and to make it clear that the employee's exposure on the test day should be typical of the employee's day-to-day workplace exposure.

Paragraph (h)(3)(i) has been clarified to make it clear that the results of the standardized questionnaire are to be used to update the employee's Schilling byssinosis grade. This record contains evidence that at least the majority of workers are being regraded following each periodic examination. (Ex. 271, Ex. 175–60).

Paragraph (h)(3)(i) has been amended to indicate that periodic medical examinations be made available every two years to employees in cotton seed processing and waste processing unless they meet the criteria outlined in paragraph (h)(3)(ii) which specify more frequent exams if the employee has substantial change in lung function. Section (h)(3)(ii) provides for referral to a pulmonary specialist if the lung function decline is even greater. This is discussed at length in Section III of this preamble.

Paragraph (h)(5)(i)(A) requires that the employer furnish the employee with the physician's written opinion which contains "the results of the medical examination and tests." The final standard clarifies this requirement by specifying that the test results from the FEV_1, FVC and FEV_1/FVC ratio are part of the physician's written opinion.

I. Employee Education and Training

Paragraph (i)(2)(iii) of the 1978 standard requires employers to distribute to employees materials relating to the Act, the regulations, and the Cotton Dust Standard which are made available by the Assistant Secretary of Labor. It further requires that employees be provided with a training program designed to inform them of the health hazards associated with cotton dust, appropriate protective work practices and use of respirators, the basis and nature of the medical surveillance program, and the contents of the Standard and its appendices. Such a training program will ensure that employees are informed about the information they should know in order to work safely in cotton textile plants.

The Agency proposed to eliminate the requirement to distribute materials made available by the Assistant Secretary, on the grounds that "individual workplace conditions vary and employers can best determine the information most applicable to their specific work site." (48 FR 26974) No other provision of this paragraph was proposed to be amended.

The comments to the proposal and testimony presented at the hearings did not reveal a need in the case of this

standard to continue requiring that employers distribute training materials made available by the Assistant Secretary. Both the ATMI (Ex. 280) and the ACTWU (Ex. 279) agreed with OSHA's rationale for deleting this requirement from the standard and that this provision was not necessary to protect workers' health.

Based on the evidence in the record, OSHA concludes that the requirement to distribute OSHA supplied training materials is not necessary for the protection of workers' health. Therefore, the final standard has been amended to remove this requirement.

J. Signs

OSHA has made no changes to paragraph (j) Signs.

K. Recordkeeping

No changes have been made to the language of the recordkeeing provision in paragraph (k) Recordkeeping. However, other changes in the standard have very substantially reduced the number of records to be kept and the recordkeeping burden.

The medical examination frequency has been reduced by one-half from yearly to once every 2 years for employees exposed below the action level. A substantial number of employees are exposed below the action level and this will reduce the number of records which need to be retained for them by half.

Secondly, the monitoring frequency has been reduced from once every 6 months to yearly for employees exposed below the PEL. As virtually all employees are now exposed below the PEL, this reduces the number of monitoring records by 50%.

The Paper Work Reduction Act report submitted to the Office of Management and Budget calculates the reduction in recordkeeping burden hours and cost savings. Overall estimates of the cost savings of these changes are presented below in Section V.(F) of the preamble.

L. Observation of Monitoring

OSHA has made no changes to paragraph (l) Observation of Monitoring.

M. Effective Date/Extension for Ring Spinning of Coarse Count Yarns

1. Extension

The current OSHA cotton dust standard (29 CFR 1910.1043) requires that by March 27, 1984, all operations to which the standard applies must be in compliance with the permissible exposure limit using engineering and work practice controls. In the preamble to the 1978 OSHA cotton dust standard (43 FR 27350, June 23, 1978), the Agency presented a substantial amount of evidence to demonstrate the technical feasibility of the standard in the textile industry based on the evidence then available.

In keeping with the OSH Act's mandate that OSHA set occupational health standards which most adequately assure employee safety and health "to the extent feasible," beginning in 1981 as evidence of actual implementation of the cotton dust standard became available. OSHA undertook a further review of the feasibility of the standard. As part of this review, OSHA hired a consulting firm, Centaur Associates, to examine a number of issues including the current state of compliance and to review the technological feasibility of completing the compliance programs within the March 27, 1984 deadline specified by the standard.

After visiting 15 plants and interviewing numerous industrial engineers and manufacturers of dust control equipment, Centaur reported that textile experts generally consider the requirement (of the 1978 standard) to come into compliance with the engineering control provisions by March 27, 1984 to be feasible. The Centaur Report (Ex. 185) documented that, in 1982, a large percentage of textile operations were already in compliance with the permissible exposure limit. Moreover, as stated by ATMI (Ex. 280, p. 11), "most of the capital expenditures needed to achieve the PELs specified in the present standard have already been committed, and . . . the vast majority of cotton textile operations have largely been brought into compliance with the PELs."

Nevertheless, Centaur found that a problem existed for specific processes in the manufacturing of certain types of yarn to come into compliance with engineering controls by March 27, 1984. These problem areas were concentrated in ring spinning operations for high-cotton-content, coarse count yarn. These yarns are used in denim, duck, heavy terry cloth, and heavy industrial fabrics. Recent experience with these particular ring spinning processes indicates that ventilation systems may not always be effective and that this production equipment cannot generally be isolated.

Although it appeared that it might not be feasible for employers to lower dust levels to the permissible exposure limit by March 27, 1984 for high-cotton-content, coarse count ring spinning operations, it also appeared that these problems could be overcome in several years. Control technology, including open-end spinning, is rapidly advancing and compliance with the standard should be possible in all operations in the relatively near future.

Based on this information, OSHA proposed in its June 10, 1983 **Federal Register** notice (48 FR 26962) to extend the deadline for compliance using engineering and work practice controls found in § 1910.1043(m)(2)(ii) from March 27, 1984 to March 27, 1986. The extension applied only to ring spinning, spooling and winding of coarse (yarn count of 14 or lower), high-cotton-content (equal to or greater than 80%) yarn.

This proposal was discussed at length by some of the commenters and additional evidence and testimony were presented on this issue at the hearings. For example, Percy Thackston, Executive Vice President of the Bahnson Company, a supplier of dust control equipment to the textile industry, testified to the inadequacy of control equipment for these operations. Mr. Thackston indicated that for ring spinning through warping and including winding, twisting, spooling and beaming there has not been a major successful, predictable breakthrough in the dust control technology for these operations (Tr. 676). More specifically, he stated that:

> The experience of air handling equipment manufacturers indicates that the state of the art in machinery development and dust suppression systems does not permit assurance that a 200 microgram per cubic meter exposure limit can be achieved and consistently maintained for these areas when the textile product involves coarse count yarns, particularly of high cotton content. (Tr. 676)

Consequently, Mr. Thackston indicated the unwillingness of equipment manufacturers to guarantee the ability of their installed equipment to meet the PEL in these operations (Tr. 676). Therefore, Mr. Thackston supported a two-year extension of the compliance date for these operations so that textile manufacturers and equipment suppliers might have sufficient time to resolve dust control technology in the ring spinning of coarse count yarns (Tr. 678).

James A. King, Vice President of the Textile Manufacturing Division at Cone Mills Corporation, testified that while facilities engaged in the ring spinning of finer yarn counts have minimal problems complying with the 200 $\mu g/m^3$ PEL, those engaged in the ring spinning of coarser count yarns have a "monumental" problem of compliance (Tr. at 681). He identified three factors which contribute to the differences in ability to obtain the same compliance results when comparing finer and coarser count yarn spinning operations

(Tr. 681–682). First the rate of production of coarse yarns per spindle hour is significantly higher in terms of both length and weight delivered. Second, lower grades of cotton, associated with a higher non-lint content, are generally used in the production of coarser count yarns. Third, "the ring spinning frame does not lend itself to the installation of dust capture devices at these several dust release points. This is more critical in the case of coarse yarn spinning due to the fact that a greater quantity of fiber will pass each release point in a given period of time than is the case for finer yarns." (Tr. 682) Mr. King summarized his testimony by indicating that he was unaware of "technological developments of a feasible nature which can result in compliance with the 200 microgram per cubic meter PEL when spinning coarse count cotton and cotton blend yarns" by the effective date of March 27, 1984 (Tr. 684, 707).

Additional testimony on this issue was provided by Labor Commissioner John Brooks of North Carolina who also identified the spinning of coarse count yarns as an area that may encounter technological difficulty in meeting the PEL (Tr. 1274). During questioning, he stated that these operations were the primary component of spinning areas which are not in compliance with the PEL in the State of North Carolina and concurred that a two-year extension would be reasonable (Tr. 1283).

There are several possible solutions to the dust control problem, including the rapid advent of open-end spinning systems. This relatively new technology reduces the dust levels because the fibers are spun within enclosed rotors and ventilation is designed into the machinery. There are, however, some current problems with open-end spun yarn. Mr. James King testified, for instance, that:

> The coarser count yarns produced by open-end spinning, at this time, are not acceptable for all end use products. Open-end spun yarns are still weaker than the equivalent yarn spun on ring spinning. If high strength is an end use requirement, than it becomes necessary to select cotton fibers which are themselves stronger than those used for ring spinning. Unfortunately, these fibers are not readily available in quantities which would be required for a complete change to open-end spinning for a company such as Cone Mills Corporation or for any other major cotton user in the industry. (Tr. 681)

Thus, open end-spun yarn is currently weaker than ring-spun yarns, and broken ends in weaving operations may sometimes result in negative wear and appearance properties in the finished fabric. These factors have led some garment manufacturers to insist that fabric for their apparel be made with ring-spun yarn.

Despite these factors, open-end spinning appears to be the most promising technological means of achieving compliance with the 200 $\mu g/m^{t13}$ PEL in the spinning of course count yarns. While the primary advantage of open-end spinning has been increased productivity in terms of faster spinning speeds, more recent developments in open end spinning equipment has produced a yarn with greater break strength and fewer imperfections. Mr. King also pointed out that improvements in open-ended spinning have been made which have expanded end use potential for coarse count cotton and cotton blend years (Tr. 684). He also stated that his company was planning to convert from ring spinning to open-ended spinning for a major part of denim yarn production and that such plans would be finalized after the International Textile Manufacturers Association show when the latest technology would be available (Tr. 685). During questioning, Mr. King further acknowledged that open-ended spinning equipment had progressed during the last several years and expected to see further advances in the machinery (Tr. 702).

In addition, an article in *American Textiles* pointed out that rapid advances in open end spinning technology are overcoming these problems. It stated that:

> An an example of how refinements can produce effectively higher speeds, Platt Saco Lowell developed recently a new side feed spinning unit for its Rotospin model 887 and 883 machines. The primary thrust of PSL's research was evidently to produce a yarn with greater breaking strength . . . . They were eminently successful in this (break-strength increased 13 percent), but at the same time the unit produced 70 percent fewer imperfections per 1,000 yards and 17 percent lower coefficient of variation in the yarn parameters. (Ex. 264)

It added:

> * * * improvements in the break strength of open-end yarns have been the main advance that has allowed some denim producers to use [open-end] yarn in the warp and in the filling. Swift Textiles in Columbus, Ga., is doing this along with other companies, and many more are evaluating machines that will spin only warp denim yarns (WestPoint Pepperell's Lindale, Ga., mill). (Ex. 264)

In summary, open-end spinning is more productive than ring spinning operations: new generations of open-end spinning machinery have improved yarn strength and decreased imperfections in finished fabric; and some denim producers currently are using open-end spinning for coarse count cotton yarn with success. Technology is developing rapidly in this area. Consequently, OSHA believes that by 1986 when the extension expires, new equipment will be available to meet the desired wear and appearance properties in the finished fabric and to achieve compliance with this standard.

The posthearing briefs of both the Amalgamated Clothing and Textile Workers Union (Ex. 279) and the American Textile Manufacturers Institute (Ex. 280) recommended, based on the above evidence, that the two year extension proposed by OSHA be granted but with some slight modification to the specifications that OSHA originally proposed for the yarn operations to be covered. For instance, under the proposal, the extension of the compliance date in ring spinning operations would apply where the yarn count is 14 or below and the cotton content is 80 percent or greater. Some commenters felt that these criteria did not encompass the range of ring-spun yarns as to the feasibility problems found to exist and suggested modifications. The testimony of Percy Thackston (Tr. 689) and James King (Tr. 684, 699) pointed out that a somewhat broader range of criteria for the yarn was needed.

Mr. Thackston noted that because the presence of "finishing materials" used on synthetic fibers (or the fibers themselves) may contribute to high dust levels (Tr. 678) and because the analytical method does not distinguish between "cotton dust" and synthetic fibers and/or finishing materials (Tr. 678), the feasibility problems in the processing of coarse count yarns in ring spinning operations are not limited to situations where a high cotton content is involved, but extend to cotton/polyester blends as well. During questioning, Mr. James King similarly stated that Cone Mills had difficulty complying with the PEL in the ring spinning of coarse count yarns in the 50/50 blends in the 13–21 count range (Tr. 699). Therefore, as noted in the ACTWU and ATMI posthearing submissions.

> * * * while the problem is most severe with coarse count yarns having a cotton content of 80 percent or above, the feasibility problems exist in blends having a lower cotton content as well. This is particularly true as the coarseness or the yarn increases. (Ex. 279, 280)

These submissions also pointed out the proposal's exclusion of beaming and warping operations following ring spinning (See discussion Ex. 279, 280, pp. 25–26). OSHA agrees that the feasibility problems associated with controlling dust levels when coarse count yarns are ring spun extends through the beaming

and warping operations and that the exclusion of these operations from the two-year extension of the compliance date was inadvertent.

ACTWU and ATMI concurred that compliance with the 200 $\mu g/m^3$ PEL was generally not feasible by March 1984 in coarse count ring spinning operations. Further, they agreed that the feasibility problems exist in the spinning of cotton/synthetic blends as well as high cotton content yarns. However, at any given yarn count, the feasibility problems become less severe as the cotton content of the yarn decreases. They further suggested that OSHA establish the following sliding scale for the yarn count threshold which would trigger application of the compliance date extension:

- Where the average by weight of the yarn being run is *100 percent cotton*, the extension should apply where the average yarn count by weight is *18 or below*.
- Where the average by weight of the yarn being run is *80 percent or more cotton*, the extension should apply where the average yarn count by weight is *16 or below*.
- Where the average by weight of the yarn being run is *50 percent or more cotton*, the extension should apply where the average yarn count by weight is *14 or below*. (Ex. 279, 280, p. 28)

They also suggested that:

Since it is quite common to run a number of different yarns in the same area, OSHA should provide a method (in an Appendix, if not in the Standard itself) for determining the *average cotton content* and the *average yarn count* of the yarns being run in the relevant operation or monitoring area. The most rational approach to making these determinations—an approach that is consistent with general practice and understanding in the industry—is as follows:

The *average cotton content* should be determined by dividing the total weight of cotton in the yarns being run by the total weight of all the yarns being run in the relevant work area.

The *average yarn count* should be determined by multiplying the yarn count times the pounds of each particular yarn being run to get the "total hank" for each of the yarns being run in the relevant area. The "total hank" values for all of the yarns being run should then be summed and divided by the total pounds of yarn being run, to produce the average yarn count number for all the yarns being run in the relevant work area. (Ex. 279, 280, pp. 28–29)

OSHA believes that these suggestions are well taken for the reasons given. Therefore, it has incorporated these recommendations into the compliance date extension. In addition, for clarification purposes it has incorporated these definitions of average cotton and yarn count in the standard.

In addition to presenting criteria for the basis of the extension of the compliance date in coarse count ring spinning operations, in their posthearing briefs both ACTWU and ATMI suggested that it would be appropriate to require an employer utilizing the extension to comply with additional conditions to provide additional health protection to employees working in those areas covered by the extension. The suggested conditions were as follows:

- An interim PEL 350 $\mu g/m^3$, to be achieved through use of engineering and work practice controls, should apply in areas covered by the extension. Respirators should be worn by employees in such areas where necessary to assure that their time-weighted average exposure to cotton dust does not exceed 200 $\mu g/m^3$.
- Within one month of the effective date of the revised Standard, employers should notify OSHA of the locations of their specific work areas (e.g., ring spinning at a particular plant) that are covered by the compliance date extension.
- Within six months of the effective date of the revised Standard, employers utilizing the compliance date extension should revise their compliance plans, where necessary, to identify the steps they plan to take in order to reduce cotton dust levels to 200 $\mu g/m^3$ through the use of engineering and work practice controls by March 1986.
- Medical surveillance should be provided semiannully to all employees working in areas where the compliance date extension is being applied.
- For areas in which the compliance date extension is being applied, a physician should individually review the test results of employees whose FEV_1 declines more than 10 percent over the work shift or whose FEV_1 is less than 80 percent of the predicted value. (Ex. 279, 280, pp. 30–31)

OSHA has carefully considered these recommendations for the short transitional period before full compliance will be achieved in this sector. As discussed in the wage retention section, OSHA wishes to encourage unions, employers and others to develop cooperative recommendations for OSHA. OSHA gives such recommendations considerable weight and has done so in this document. However, no notice was given to the public of several of these transitional recommendations. In some cases they will divert resources from achieving full compliance, and OSHA believes that they are included already by existing protective provisions of the standard. For these reasons and because such transitional provisions will be in existence for such a brief period, OSHA has not incorporated some of the transitional recommendations into the standard.

The recommendation for a 350 $\mu g/m^3$ interim level had never been proposed nor discussed during any of the hearing process. The recommendation was not made until the last date for post hearing comments limiting the possibility for public comment. In addition, OSHA would have to permit some delay of the effective date of this recommendation as a practical matter, to permit time to install necessary equipment. Consequently, the actual provisions would be effective for a very brief period. Further, as discussed above, new, more efficient and more protective open-end spinning equipment is being developed. OSHA believes employers should be encouraged to install such fully protective equipment as soon as possible and concentrate their engineering and industrial hygiene resources on this goal. It would be counterproductive to encourage efforts and resources to be spent on less protective interim measures. The standard still requires the employees to be protected to the 200 $\mu g/m^3$ level with respirators and engineering controls in the short interim period. Also the interim requirement of the 1978 standard requiring the achievement of 1000 $\mu g/m^3$ with engineering controls is being retained until March 27, 1986. That level is being interpreted as a respirable dust level which is more directly related to employee health. (See the discussion under waste processing.) The specific requirement is now located in § 1910.1043(m)(2)(ii)(E) and not in Table Z–1 of § 1910.1000.

OSHA has adopted the joint recommendation that an updated compliance plan be completed before the March 27, 1986 deadline for installation of controls. First, this will serve to identify the steps that the employer will take to achieve compliance with the 200 $\mu g/m^3$ level by the March 27, 1986 extension date. Second, this will help to ensure that employers meet that date and will encourage employers to utilize their engineering and industrial hygiene resources to come into compliance with the standard. Because of the date which this standard is issued, the date for completing the plan has been set at February 13, 1986 and not the date recommended.

Two of the transitional recommendations suggested changing the medical provisions for employees in the areas covered by the extension. Essentially, these recommendations add one extra medical exam and somewhat decrease the reduction in lung function needed for employees to be referred to a pulmonary specialist. The medical

provisions of the 1978 standard were carefully devised to protect employees: each employee received an annual medical exam; certain decreases in lung function led to semiannual medical exams; and greater decrements in turn, led to referrals to pulmonary specialists. These provisions were devised with the knowledge that many employees would not be protected by engineering controls for up to four years and were designed to protect those employees during that time. The extension essentially extends that period for up to two years for relatively few employees. OSHA believes that the existing medical provisions protect these employees for the reasons stated in the 1978 preamble and that it would create confusion to change the medical surveillance requirements for a few employees for a brief period.

OSHA believes that the recommendation that employers whose operations are covered by the extension notify OSHA of such locations is unnecessary. Most of the facilities affected by the extension are located in North and South Carolina, and both of these states have state plans with cotton dust programs. Furthermore, state officials are already knowledgeable of the kinds of spinning operations located in textile plants in their states. This transitional provision requiring notification would therefore be duplicative paperwork discouraged by the Paperwork Reduction Act.

It should be noted that OSHA granted a temporary extension of the compliance deadlines for the ring spinning of high-cotton-content coarse count yarns from March 27, 1984 to September 27, 1984 to permit the Agency to have time to complete its review of the record and to make appropriate final decisions (49 FR 6717, February 23, 1984). It later extended the stay (49 FR 46737; 50 FR 14698). This discussion represents OSHA's final conclusions.

2. Effective and Start-up Dates

The 1978 cotton dust standard became effective for the textile industry on March 27, 1980 with startup provisions of all paragraphs except engineering controls at various dates in 1980 and 1981. These amendments change none of those startup dates or effective dates, and they are reprinted unchanged to notify employers and the public of the dates that they were required to achieve compliance and of this continuing obligation. Employers were to have achieved compliance with the engineering control provisions by March 27, 1984. That obligation remains unchanged except for ring spinning of high cotton-content, coarse yarns discussed above and is reprinted unchanged to notify employers of this continuing obligation.

The amended provisions of § 1910.1043 take effect on January 13, 1986. On that date, employers are to commence complying with the provisions as amended. Until that date, employers are to comply with the unamended provisions of § 1910.1043 as currently published in the Code of Federal Regulations (1984 and 1985 editions which are identical in this respect) subject to the existing stay for ring spinning of high-cotton content coarse yarns. If the amended provisions are not in effect because of stays or judicial action, then the unamended provisions will remain in effect. It is the intention that there remain no gaps in coverage and that the existing provisions not terminate unless the new provisions are in effect.

There is no separate start-up date with one exception. The one exception is that a startup date six months after the effective date is provided for medical surveillance in cotton seed processing and waste processing. This is discussed above.

N. Washed Cotton

The 1978 standard excluded "washed cotton" as defined from all provisions of the cotton dust standard. Washed cotton was defined as "cotton which has been thoroughly washed in hot water and is known in the trade as purified or dyed." (43 FR 27395) Reasons for this exemption were discussed in the preamble (43 FR 27382). The strongest support for the exemption came from certain studies by Dr. Merchant and colleagues which indicated that cotton which was thoroughly washed, as in preparation for medical uses, was demonstrated to have reduced levels of biologic activity. Specifically, cotton washed in this manner was shown to have little or no effect on the pulmonary function of human test subjects in laboratory trials. It was not determined whether the reduction in respiratory response was due to reduction in the quantity of dust remaining in the cotton, or whether the washing process had eliminated contaminants. Steamed and autoclaved cottons were not exempted because the study indicated that biologic activity remained after cotton was treated with those processes.

The definition of washed cotton provided in the 1978 standard presented two problems. First, it was ambiguous as to the exact washing processes which would produce non-reactive cotton. The only washing process which was clearly covered by it was the severely washed cotton tested by Dr. Merchant, and that yielded fiber which was not suitable for spinning and weaving operations. Second, although "purified or dyed" cotton was exempted, it was not clear what cleansing processes must be included to qualify cotton for exemption.

The promising results of the Merchant studies kindled interest in cotton washing as a potential means of compliance with the 1978 standard. Further research was needed to establish washing parameters which would both protect the health of workers handling washed cotton and yield fiber which could be processed in textile mills.

Consequently, the "Washed Cotton Task Force," formally the "Industry/Government Task Force on Washed Cotton Evaluation," was formed in 1980. It is composed of representatives from the U.S. Department of Agriculture (USDA), the National Institute for Occupational Safety and Health (NIOSH), the Amalgamated Clothing and Textile Workers' Union (ACTWU), the American Textile Manufacturers Institute (ATMI), National Cotton Council (NCC) and Cotton Incorporated. Major funding during the past three years for byssinosis research came from Cotton Incorporated ($5 million), and from USDA ($15 million). Of this total, $6–7 million has been spent on washed cotton (Tr. 828–831). The purpose of the research was to develop processes which would produce cotton which could be worked in textile mills but would not cause the acute symptoms of byssinosis.

The USDA Cotton Quality research facility at Clemson, South Carolina has been the center of the Task Force's human subjects exposure studies. This facility has provided exposure chambers, and monitoring devices for the various trials where human subjects were exposed to cotton washed through various processes to test to see if it created any acute reaction. The cotton was processed there, as it would be in typical mills and also tested for processability.

Cotton procurement and washing has been done through Cotton Incorporated. They have tested various types of cotton on various washing processes. The various washing sites and methods are described fully in the Task Force's statement (Ex. 205B) and oral testimony. (Tr. 833–841)

The method of selecting the human test panels for the washed cotton studies was described as follows:

> Several times since the Clemson cotton dust work was begun, volunteer human subjects have been selected. In general, these selection processes have begun by soliciting

volunteers from the general public and excluding those with respiratory or other medical illnesses which would contraindicate participation. Next, the remaining volunteers have been exposed to cardroom cotton dust (1mg/m³ by vertical elutriator) for six-hour periods. Spirometry has been performed immediately before and after the six-hour exposures, and only subjects who have had an FEV_1 decrement of at least five percent attributable to these cotton dust exposures have been selected to participate in the actual studies . . . In the Clemson experience, approximately 25–30% of exposed volunteers have at least a 5% acute reduction in FEV_1 attributable to six hours of exposure to 1 mg/m³ vertical elutriated cardroom dust . . .

The study subjects are thus not a random selection of individuals. They have been specifically selected to be relatively sensitive to the acute bronchoconstrictor activity of cotton dust (but not so sensitive as to preclude safe participation—a few with very large acute reductions in FEV_1 have been excluded during the selection process). Only about half had ever worked in cotton mills, and very few gave a history of having had classic byssinosis.

The 1982 ANPR (47 FR 5906) requested comments on how washed cotton should be defined, whether a performance standard keyed to respiratory effects was feasible and appropriate, and whether health or economic effects could be anticipated as a result of changing this definition. There was little public comment on these points.

The Amalgamated Clothing and Textile Workers Union (Ex. 175–36) and the Brown Lung Association (Ex. 175–43) generally opposed change in the definition since research was still in progress.

Those persons commenting in favor of changing the definition indicated, generally, that it should be linked to performance, and that it should be more flexible than the existing provision. American and Efrid Mills suggested a separate definition for "raw washed cotton yarn" (Ex. 175–51). The National Association of Hosiery Manufacturers favored the use of standard, accepted terms, such as "dyed" "scoured", and "bleached" as opposed to a performance definition (Ex. 175–49).

The most substantive comments came from the Washed Cotton Task Force (Ex. 175–44). Those comments described research completed, underway and planned, and provided data on human respiratory response to washed cottons. However, that submission did not include the specific recommendations of the Task Force because research had not been completed. They indicated that the washing research and exposure trails are intended to find ways to eliminate *acute* effects of cotton dust exposure. This effort is somewhat complicated by the fact that the causative agent of byssinosis is still unknown and it is also an object of current research.

Thus, comments received in response to the Advance Notice of Proposed Rulemaking showed a need to pursue a better definition of washed cotton, but provided little new information.

When OSHA issued its June 10, 1983 proposal, it had not received the recommendations of the Washed Cotton Task Force. Consequently OSHA was not in a position to expand the definition of washed cotton, to other processes which would be workable and safe for employees. OSHA stated, however, that if it received evidence of such processes during the public comment period it would consider such processes for inclusion in the final standard definition of washed cotton. The definitions proposed in the 1983 proposal were:

(1) Cotton which has been commercially prepared for medical use (by heating to 270°F with 0.6% caustic solution, washed with soap and tetrasodium pyrophosphate, bleached with 0.1% solution of sodium hypochlorite, and scoured with sulfuric acid at pH of less than 2.0, then washed to a pH of 6.0 to 7.0) or

(2) Cotton yarn or thread which has been scoured in a caustic bath and dyed in a hot, water-based solution.

These washing processes were the ones reported by Dr. Merchant, as not causing acute effects. It was hoped that the Washed Cotton Task Force and other witnesses would provide details on additional acceptable washing methods, and that these could be incorporated in the standard.

The Washed Cotton Task Force submitted its recommendations as comments with extensive supporting documentation on August 26, 1983 (Ex. 190–10). This was before the public hearing and gave adequate notice to any interested member of the public. The members of the Task Force were available to answer questions at the public hearings on OSHA's proposal.

The specific recommendations of the Task Force were the following:

I. Since normal scouring, bleaching, mercerizing and dyeing are more severe than the washing procedure evaluated in the "Tripartite Studies," cottons processed by these processes should be considered "washed cotton" and continue to be exempt from the standard.

II. OSHA should consider as 'washed cotton' cottons that have been (1) classed as *low middling* light spotted or better, unless spotted, tinged or yellow-stained (described in The Classification of Cotton. USDA, AMS, Agriculture Handbook No. 556, . . .); and (2) washed on a rayon rinse system or a continuous batt system as used, evaluated, and described . . . in our studies and at least 28°C with a wetting agent and at a minimum 40:1 water to fiber ratio. Precaution should be taken to limit bacterial growth and endotoxin accumulation in all baths. If these cottons are being processed, the only requirement under the cotton dust standard should be medical surveillance, every year. The Task Force also recommends that environmental monitoring be conducted in mills using cotton.

For cottons classed below *low middling* and all cottons classed as spotted, tinged, or yellow-stained, the dust level should be below 500 micrograms/m³, and they should be at a minimum bleached before being considered "washed cotton" and subject to medical surveillance requirements.

The Washed Cotton Task Force's testimony was submitted in written form and summarized orally at a hearing held in Washington, DC on September 23, 1983. As noted above, two general recommendations were presented.

The basis for these recommendations was the testing results from human subject exposure trails. The Task Force tested various grades of cotton, originating from several growing areas. It examined at least four washing systems, using varying wash parameters (temperatures, water-to-fiber ratio, additives, etc.). After washing, the cotton was taken to the USDA Cotton Quality Research Center, at Clemson, South Carolina where it was processed on typical yarn production equipment. The dusty atmosphere thus generated was then blown into the rooms where test panels were exposed to it. The acute reaction of the exposed persons was then measured with pulmonary function tests, and the results were compared to that of control test panels.

For some types of cotton and some washing processes, the test panels had no acute reaction: their pulmonary function was the same as unexposed control subjects. For other tests, their acute response was less than for unprocessed "raw" cotton, but they showed measurable differences when compared to unexposed controls.

The first recommendation was that an exemption be continued for mercerized, dyed and bleached cotton on the grounds that treatments associated with these processes were more severe than washing procedures evaluated by the group (Ex. 205B). In the course of the oral presentation, the Task Force was asked to provide information specifying the parameters for those three processes. That information was submitted to the Docket on October 28, 1983 (Ex. 256).

The Task Force supplied descriptions for typical processes: continuous warp mercerization, reactive dye (hot), vat dye (reduced), vat dye (pigment), and dye (sulfur). Scouring and bleaching

were also described. These are summarized in the following table:

PROCESSING DESCRIPTIONS

Process	Temperatures	Additives
Mercerization	160 °F to 200°F	Caustic soda.
Scouring	200 °F	Alkalr. Soaps.
Bleaching	170 °F to 200°F	"Bleaching Chemicals".
Reactive dye (hot)	120 °F	Dye, soaps.
Vat dye (pigment)	140 °F to 180°F	Dye, soap.
Vat dye (reduced)	140 °F to 180°F	Do.
Dye (sulfur)	160 °F to 190°F	Do.

Note.—All processes are water based. Scouring and bleaching precede all processes.

The bleaching, mercerizing and scouring processes preceding dyeing are extensive, and in terms of the temperature and chemicals applied, they approach the severe washing specifications used in the original washed cotton studies. More important is the fact that they exceed the specifications for successful washing developed through more recent research which resulted in no reactivity. These factors are the basis both for the recommendation of the Task Force that scoured, bleached and dyed cotton and mercerized yarn be exempted from all provisions of the cotton dust standard and for OSHA's conclusion that cotton subject to the processes remain exempted from the standard.

The second recommendation of the Task Force is that certain types of washed cotton be partially exempt from the standard. It is complex, with several variables to be examined. Specifically, cotton grades or classifications, washing systems and bacterial contamination of wash water must be considered in addition to water temperatures, water volumes, and chemical additives.

Cotton Grades and Byssinosis

The USDA establishes a uniform grading system for cotton; it was presented in summary form in the Task Force's testimony (Ex. 187–19, Attachment 2 Table 3). Characteristics of the cotton include average fiber length, micronaire, and color. Bacterial contamination affects cotton color, giving it a yellow cast.

In effect, the panel recommended that a greater degree of exemption for washed higher grade cotton than for washed lower grade cottons. This is based on the acute reaction of test panels exposed to washed cottons of these two types. In both cases, continued medical surveillance is recommended to ensure that no long-term health effect is incurred.

Two studies in the series reported by the Task Force are relevant here. Study number MQ109 tested cottons of varying grades from three growing areas. The lowest grade of cotton, identified as "C43", "T43", and "M43" usually elicited the greatest decrement in $FEV_{1.0}$ among the test panels.

The high variation in pulmonary reaction shown in these tests led the Task Force explicitly to test "worst case cotton"—that is, fiber which was selected for its high levels of bacterial contamination, as indicated by its low grade and growing area, and large decrement in FEV_1. In these tests, large reductions in FEV_1 occurred even where cotton was washed, bleached and scoured on the continuous batt washing system. The minimum reduction in FEV_1 shown (−2.1%) was greater than one type of unwashed California cotton and only slightly less than one type of unwashed Texas cotton. Thus, the study demonstrated that washing even at high temperatures (93°C was used in these trials, with a 40:1 water-to-fiber ratio) does not render certain types of low grade cotton completely harmless. Depending on the specific wash conditions, potency was reduced by at least two-thirds, and by as much as ninety percent. Washing greatly reduces but does not eliminate, this cotton's ability to cause a drop in $FEV_{1.0}$. The residual activity is a matter of some concern, and for this reason, the Task Force recommended that lower grades of cotton be only *partially* exempted from the standard, and that medical surveillance be continued where washed cotton is used.

Washing Systems

The Task Force recommended that exempted cotton be washed on a rayon rinse system, or a continuous batt system. Trials using a wool scouring system were less successful, as were washing tests which employed the batch kier process. (The batch kier system is used in dyeing operations. In the batch kier tests, part or all of the lack of success was attributed to difficulty in sufficiently wetting the cotton. When cotton is dyed in this equipment, it is pre-processed, and there is less difficulty in obtaining uniform wetting).

Tests results reported in Exhibit 187–19 indicate various degrees of effectiveness for the different washing systems under varying conditions. Continuous batt washing consistently was more effective than other methods in eliminating or minimizing reductions in function. However some decreases in FEV_1 in the test panel were still statistically significant for some types of cotton. (They were reported in the series of tests labeled MQ101). The Task Force stated:

> * * * [E]xposure to the hot scoured and bleached cotton * * * again yielded no response. All other washing treatments reduced the bioactivity of card-generated dust and * * * several gave results which were statistically no different than no effect.

Washing on a continuous batt system at high temperatures, with or without scour and bleach, in some cases eliminated all reactivity and in all cases reduced but did not always eliminate the respiratory response. Thus, the continuous batt system provides good results in many tested circumstances, although it has not been documented that it will do so for all types of cotton, nor with every combination of temperature and other variables. In these tests, cotton washed at 60° with a 40:1 water-to-fiber ratio produced responses which were not significantly different from "no response".

The ability of the rayon rinse washing system to mitigate or to eliminate the reactivity of cotton dust was noted in the Task Force's testimony. This portion of the testimony was supported with an extensive study by Dr. Brian Boehlecke, whose research report was included as an appendix to Exhibit 187–19. Dr. Boehlecke tested acute human pulmonary response to cotton washed using the rayon system, and found that, for the test panel as a whole, "exposure to washed cotton dust in concentrations up to 1 mg/m^3 appeared to result in pulmonary function response no different statistically from that to no dust exposure." (Ex. 187–19, Appendix B, page 23) Wash temperature used in this test was 68°C, similar to wash temperatures tested in the continuous batt process.

Washing Temperature

The Task Force recommended a washing temperature of "at least 28°C with a wetting agent and a 40:1 water ratio." The basis for this recommendation in research is not clear. Only one trial was reported in which a 28°C wash was used (MQ79–3). In that trial, a 65:1 water-to-fiber ratio was used.

Eight wash-only trials which used the continuous batt or the rayon rinse system are described in Exhibit 187–19. Of these, none were conducted at a water-to-fiber ratio of less than 40:1. Only three trials produced response-free cotton, i.e., MQ111–B, MQ101, and MQ79–C.

These data are too few to make definitive statements about all combinations of effective washing treatments. Combinations of lower water temperature and lesser water volume may be proved effective, but

they are not described in the Task Force submission nor in other evidence presented for OSHA's consideration.

The single washing experiment at 28 °C does not supply enough evidence to indicate that temperature this low sufficiently eliminates reactivity. The supporting study, appended to the testimony, indicates a slightly higher residue of endotoxin than in cotton washed at higher temperatures. Further research on this 28 °C washing may later lead to an expansion of the washed cotton criteria. For the present, however, the evidence is inadequate to support an exemption of cotton washed at 28 °C with a 40:1 water-to-fiber ratio.

In the Task Force testimony, it is clear that the temperature and the water-to-fiber ratios recommended were to be considered minima, and that minimum levels for each variable should not necessarily be paired in practice. In response to a question during the hearing, Dr. Phil Wakelyn, chairman of the Task Force, said that a temperature of "50 °C or above would be a more prudent recommendation." (Tr. 885) in further response to the question, it was pointed out that the influence of the combination of temperature and water-to-fiber ratio was not known although the water-to-fiber ratio appeared not to be "all that critical", and that the proper ratio might vary with the wash system being used; i.e. higher for the rayon system than the continuous batt.

OSHA concludes, based on reviewing all the data and recommendations, that the minimum criteria for meeting washed cotton requirements of the standard are 60 °C and a 40:1 water to fiber ratio. That is the lowest combination which consistently produced no reactivity in the continuous batt system. Higher temperatures and/or higher water ratios which provide more protection are permitted.

The Task Force also recommended that only the better grades of cotton (low middling, light spotted or better not spotted, tinged or yellow stained) be exempted from the PEL, and that an exposure limit of 500 micrograms be established for bleached, washed cotton of lower grades. OSHA concludes this recommendation takes into account the greater reactivity of humans to the lower grade cottons in most of the washing tests.

The Task Force recommended that continued medical surveillance is needed for washed cotton which is not medical grade or dyed because the tests were just for acute reactivity. Consequently, medical examinations are needed as a backstop to make sure that long term chronic effects do not develop when washed cotton is used. OSHA agrees with this recommendation and reasoning. The Task Force recommends that scoured, bleached and dyed cotton, mercerized yarn and medical grade cotton should be exempt from all provisions of the standard including the PEL and from medical surveillance. OSHA agrees with this recommendation, because the conclusions are consistent with both the earlier and the more recent research, the processes are more severe than those processes where OSHA has created partial exemptions and this is consistent with OSHA's 1978 decisions. There is more long term experience with those processes, and the processes are more severe than other permitted types of washing.

Based on its review of the data, comments and the Task Force's recommendations, OSHA has reached several conclusions. The standard provides for full or partial exemption of washed cotton, in the following cases.

1. Cotton that has been washed and otherwise prepared to meet the requirements of medical grade cotton (USP) use is exempt from all provisions of the standard.

2. Cotton that has been scoured, bleached and dyed and mercerized yarn are exempt from all provisions of the standard.

3. Cotton must be washed in a facility which is open to inspection by the Assistant Secretary and which provides sufficient evidence to demonstrate that approved washing methods were used.

4. If an employer uses cotton that is washed in a facility separated from the facility using the washed cotton then documentation of the washing processes and other relevant information must be available at the worksite. In this case, the washing facility must also be open to inspection by the Assistant Secretary.

5. Cotton that is classed as low-middling light-spotted or better is exempt from all provisions of the standard except the requirements for medical surveillance, medical recordkeeping, and appendices B, C, and D as they apply to employees exposed below the action level if the cotton has been washed on a continuous batt washing system or a rayon rinse system with a wash temperature of 60 °C or higher, and with a water-to-fiber ratio of no less than 40:1. Additionally, the growth of bacteria in wash and rinse water must be controlled to limit bacterial contamination of the cotton.

6. Cotton which is of grades lower than low-middling, light spotted, if washed to meet the requirements specified in paragraph 5 and is bleached in addition is exempt from all provisions of the standard except to the requirements named above for washed cotton of higher grades and is subject to a permissible exposure limit of 500 $\mu g/m^3$. Environmental monitoring is also required.

O. Appendices

Appendices A–D are unchanged. Appendix E has been added to provide an acceptable protocol for demonstrating that a cotton dust exposure measuring instrument is equivalent to the vertical elutriator. The basis for adding Appendix E is discussed in Section IV (D)(1) of the preamble.

V. Summary of Regulatory Impact Analysis

A. Introduction

The Draft Regulatory Impact Analysis was discussed in the preamble to the proposed standard and was available for public review and comment during the rulemaking. The Final Regulatory Impact Analysis (RIA) for this standard, available at OSHA's Docket Office, summarizes the factors discussed in this preamble and the preamble to the proposal that led the Agency to reconsider the status of the 1978 cotton dust regulation; and summarizes OSHA's rationale for making the final regulatory determinations which are discussed and made in this preamble. As does this preamble, the final RIA explains how the decision to review the standard was made. This decision was precipitated both by OSHA's need to determine whether the risk of adverse health effects in nontextile industries met the "significant risk" test set forth by the Supreme Court's "Benzene Decision," and by OSHA's growing awareness that various technical revisions were required in the standard's application to the textile industry. As part of this evaluation, the RIA summarizes those issues also discussed in the preamble that relate to the need for regulation, the feasibility, and the cost-effectiveness of the 1978 and the revised standard. The RIA particularly examines those changes which the Agency believes will make the standard more flexible, and performance-oriented, thereby serving to protect workers from dust-related illness in a more effective and less costly manner. The RIA also includes a detailed discussion of economic and technical feasibility which is summarized below.

B. Technical Feasibility/Textiles

Section 6(b)(5) of the OSH Act mandates that OSHA set standards that most adequately assure employee safety

and health "to the extent feasible." Consequently, in the preamble to the 1978 standard, OSHA presented extensive documentation demonstrating that it was technically feasible to reduce dust levels in the cotton textile industry to the PEL's within a 4-year compliance period. The various production processes were described and their applicable dust control techniques were discussed in detail. Examples of successful innovative control technologies, especially those that sharply increased industry productivity while reducing dust levels were thoroughly examined (43 FR 27361–27367). Both the District of Columbia Court of Appeals and the United States Supreme Court subsequently upheld OSHA's determination that the Cotton Dust Standard is feasible for the textile industry.

As part of its review OSHA contracted with Centaur Associates to survey the current state of technical dust control and to review the technological and economic feasibility of alternative regulatory provisions. Centaur completed a comprehensive report (Ex. 185) based upon visits to 15 textile plants, extensive survey data and interviews with numerous industrial engineers and manufacturers of dust control equipment. Centaur concluded that, with the limited exception of certain processes using high cotton content coarse yarns, it was technically feasible for the industry to come into compliance by the March 27, 1984, deadline. This view was corroborated by evidence that many equipment companies guarantee their dust control systems to maintain dust levels below the permissible limits under most circumstances.

The new less "dusty" technologies are typically based on systems characterized by enclosed automatic feeding, transferring and processing of materials. In addition to emitting substantially less dust than the older equipment, such processes eliminate the need to conduct some of the dustiest operations, such as picking, roving and winding operations, while greatly reducing the amount of manual handling required. Commonly used systems include automatic bale openers and feeders, automatic waste collection with pneumatic transport to the waste house, fully enclosed chutefeed cards, open-end spinning systems, and shuttleless looms.

Industry exposure data confirmed that by 1982 the industry had made substantial progress toward achieving compliance. ATMI's survey of companies employing a total of about 72,500 workers reported that roughly 80 percent of cotton textile employees were exposed below the current PEL, with 78 percent of the employees below in twisting, 66 percent below in winding, and 73 percent below in spooling operations (Ex. 175–60). These estimates were substantially confirmed by Lumsden, whose data from 44 textile plants showed about 84 percent of the yarn manufacturing work areas in compliance (Ex. 186–2); and by John Brooks, North Carolina Commissioner of Labor, whose survey of North Carolina textile mills indicated that dust levels were below the PEL in 83 percent of the spinning operations, 77 percent of the winding operations and 81 percent of the twisting operations (Ex. 186–4).

In their post hearing submission (Ex. 280), the ATMI did not challenge either the technical or the economic feasibility of the cotton dust standard with the exception of the need for an extension of the compliance deadline for processing high cotton-content coarse yarns. They noted:

> Morever, most of the capital expenditures needed to achieve the PELs specified in the present standard have already been committed, and, with the exception of the processing of coarse count ring spun yarns, the vast majority of cotton textile operations have largely been brought into compliance with the PELs. For these reasons, the PELs of 200 $\mu g/m^3$ in yarn manufacturing and 750 $\mu g/m^3$ in slashing and weaving should remain unchanged in the revised standard. (This endorsement of the existing PEL's should be read in conjunction with our recommendations for extension of the compliance date in the case of coarse count ring spun yarns and for the exclusion of oil mist from measurements of cotton dust under the standard. If the existing PELs remain unchanged, adoption of our recommendations on the foregoing points . . . is essential.)

In earlier testimony and comments, several commenters pointed out that the available technology was adequate for all but coarse yarn processing. For example, Burlington Industries, Inc. noted that dust in many fiber preparation areas could be controlled by ventilation even without replacing the old machinery, although this was not always cost-effective. For downstream processes, however, they reported that "Despite research efforts, the textile industry, its suppliers, contractors and consulting engineers have not been able to develop "on-frame" capture plenums or systems capable of reducing dust levels to 200 $\mu g/m^3$ for coarse yarn manufacturing beyond drawing (i.e. roving, spinning)" (Ex. 170–14).

John Lumsden, a co-developer of the vertical elutriator used to monitor cotton dust levels, a participant in the byssinosis prevalence studies conducted by Merchant et al., a former director for North Carolina Occupational Health Programs, and a vice president for a health and safety consulting firm for the textile industry, discussed control technology in his 1982 Congressional testimony (Ex. 186–2). Lumsden confirmed that exhaust ventilation and material handling equipment adequately control dust from the opening to the roving process. He stated, however, that "the machines, or frames, that accomplish spinning, twisting, spooling, or winding have not, to this time, been retrofitted with local exhaust ventilation systems." Because dust control in these areas must be achieved through general dilution ventilation where efficiency is variable, Lumsden found that some yarn manufacturing areas will experience dust levels above the OSHA standard.

During these same House Subcommittee hearings, Percy Thackston, Executive Vice President of the Bahnson Company, a major supplier of dust control systems, appearing on behalf of the American Textile Machinery Association reached essentially the same conclusion and summarized the problems in control technology by explaining that:

> Technology is presently available for controlling dust from opening through the card room by use of modern machinery and equipment. . . . From ring spinning through warping, it is a different story. There has not been a major, successful, predictable breakthrough in the dust control technology for these process areas. (Ex. 186–3)

As the evidence and these comments indicate, compliance with engineering controls is clearly feasible with one current exception. This area is ring spinning, winding and spooling of relatively coarse, high-cotton-content yarns that generally are used in denim, duck, heavy terry cloth, and heavy industrial fabrics. Centaur explained that the processing of coarse yard produces more dust because the dust emission rate varies directly with the production rate and more cotton per hour is processed with the low count (coarse) yarns than with the high count (fine) yarns. Based on technical information obtained from air filtration and dust control contractors, Centaur estimated that the dust release rate of certain coarse yarns with a high cotton content is above the cleaning capability of the available air handling systems. Indeed, Centaur reported that the same air filtration and dust control companies that typically guaranteed compliance with the PEL in other production areas refused to assure compliance for the spinning and winding of high-cotton-content coarse yarns because controls

for these processes were not always successful.

The most promising solution to the problem appears to be the rapid advent of open-end spinning systems. This relatively new technology sharply reduces dust levels because the fibers are spun within enclosed rotors and ventilation is designed into the machinery. Indeed, the proper operation of the equipment requires local ventilation and efficient dust control. Moreover, this equipment, which fortuitously is best suited for the production of coarse yarns, significantly boosts spinning productivity and completely eliminates the roving process. Some U.S. denim plants have already converted their spinning operations to open-end systems to take advantage of the production efficiencies and many others are seriously evaluating the machines (*American Textiles*, Ex. 264). With this technology developing rapidly and its production rates already from 4 to 5 times higher than ring spinning (Centaur, Ex. 185, p. 3–48), competitive pressures will make it increasingly more difficult for firms to avoid this conversion.

Nevertheless, the record indicates that open-end systems have not yet overcome several problems. For example, at the present time, yarn produced by open-end spinning is weaker (has lower tensile strength) than yarn that is ring spun. Also, there are some potential problems with broken ends in weaving, and negative wear and appearance properties of finished fabrics.

Because of these difficulties, OSHA has granted a conditional two-year extension of the deadlines for the installation of engineering control requirements for the yarn processing operations including and following the ring spinning of coarse high cotton-content yarns. The evidence indicates that current problems with open end spinning are likely to be solved by the end of this period. This exemption is fully described elsewhere in the preamble. With this exemption, therefore, the evidence clearly indicates that the cotton dust standard is technically feasible and that compliance has largely been achieved.

C. Economic Feasibility/Textiles

OSHA must also demonstrate the economic feasibility of standards proposed under section 6(b)(5) of the OSH Act. OSHA found that the 1978 standard was economically feasible for the textile industry. This finding was specifically upheld by both the District of Columbia Court of Appeals and the United States Supreme Court.

OSHA hired Centaur Associates to study the costs that had been incurred and the costs that still needed to be incurred to achieve compliance with the standard, and to project the economic impacts of the standard. Their data confirm that the standard, as applied to the cotton textile industry as a whole is clearly economically feasible. Moreover, this conclusion is strengthened because it now appears likely that control costs are about one-half of the estimated costs that served as the basis for the court decisions upholding economic feasibility. In addition, the revised standard makes compliance even more cost-effective by further reducing the costs of the standard while retaining the health protection.

In their post hearing comment, ATMI did not question the economic feasibility of the standard. Moreover, their submission did not present specific evidence indicating that the standard would result in serious economic feasibility problems. Similarly, in their earlier response (Ex. 175–60), ATMI did not assert that the textile industry as a whole would be significantly impaired, although they argued that, "... in a number of cases, the economics of the situation make it impossible to justify the expenditures that would be required to achieve the permissible exposure limit. For that reason, several marginal facilities already have been closed, and one can expect that additional closings will occur in the future." The NCC contended that some plants complied with the standard by substituting synthetics for cotton, resulting in lost revenues to cotton farmers, handlers and processors (Ex. 175–47).

The cost of the cotton dust standard was one of the questions included in an ATMI survey, to which about 50 textile companies employing 72,500 workers responded. These firms reported that they had spent approximately $310 million for capital equipment to comply with the standard up to the end of 1981, and they expected to incur approximately $150 million in additional capital expenditures to meet the 1984 requirements. ATMI speculated that the companies responding to this survey may have been the more progressive firms and stated that, "Consequently, for the industry as a whole, it seems fair to assume that considerably more than one-third of the required capital expenditures remain to be made in the future." The responding companies also calculated that they would spend about $20 million in annual energy costs and $6 million in annual maintenance costs to comply with the engineering control requirements (Ex. 175–60).

Centaur Associates, in its study for OSHA (Ex. 185), estimated that the textile industry has already spent $143.3 million in capital costs that are attributable to the regulation, and still needs to spend an additional $102.2 million. Centaur calculated that the 1978 standard required annual energy costs of $27 million, maintenance costs of $2 million, monitoring costs of $2.5 million, and medical surveillance costs of $6.6 million. The proposed action level was estimated to reduce the monitoring and medical surveillance costs by about $3.3 million per year. The ATMI and Centaur estimates are not strictly comparable because Centaur adjusted for productivity gains by assuming that all of the ventilation costs, but only 17.5 percent of the new production equipment costs, are attributable to the OSHA standard. Both surveys, however, support the view that between one-half to two-thirds of the required capital expenditures had already been made by 1982.

Centaur's 1982 projections indicated that total future capital outlays for dust control equipment for an average size plant would be approximately $300,000 per year during 1983 and 1984. Those firms that have expended little on dust control equipment would face higher costs up to approximately $600,000 per year over the 2-year period for the average size plant. Over 60 percent of these expenditures, however, would be offset by associated productivity gains. The 1982 average revenue per plant was estimated by Centaur to be $10.3 million (Ex. 185, P. 7–13). Because cash flow as a percent of sales in the textile industry has averaged 4.65 percent in recent years, an annual average cash flow of $479,000 could be predicted. For many firms, this amount would be adequate to cover the additional capital outlay without new borrowing.

The textile industry, however, was affected by the depressed condition of the national economy in 1982, and its profitability and cash flow in that year were below levels of recent years. Thus, Centaur reported that the capital requirements to comply with engineering controls by 1984 might be more than some plants could generate from internal cash sources.

Centaur concluded, however, that despite the textile industry's weaker financial position in 1982, it was improbable that conditions were such that the required capital expenditures could not be made (Ex. 185, p. 7–14). Centaur noted that even where cash flow was not sufficient to cover capital expenditures, most firms would have adequate access to financial markets

because the greater part of the required capital outlays would be for new equipment to improve plant production rates. In addition, recent tax legislation has substantially reduced the after-tax cost of new capital investment, and interest rates for business loans have subsided since 1982. Centaur, therefore, found it unlikely that the capital expenditures required for OSHA compliance would significantly contribute to plant closings. Of course the rapid economic recovery since early 1983 will make it easier for even those companies that have delayed installing dust control equipment to afford the balance of these expenses. Both ATMI and the Centaur studies indicate that the industry has indeed made commendable and largely successful efforts to achieve compliance with the standard.

Public comments have not provided substantial documentation to refute Centaur's findings of economic feasibility for the textile industry. For example, John Brooks, Commissioner of Labor for North Carolina, a state producing about one-third of the nation's yarn, found that although a few firms may have economic difficulty, compliance is feasible in almost every instance (Ex. 217 p. 5). While a few comments declared that requiring the industry to shift large portions of its investment funds into "nonproductive areas" would have significant adverse effects on its competitive position in either domestic (NCC, Ex. 275) or international markets (ATMI, Ex. 189–5; NCC, Tr. 980), the industry itself notes that its recent modernization, "has made the American textile industry the most productive in the world" (Ex. 189–5, p. 2). Moveover, a recent report on the OSHA standard prepared for the Office of Technology Assessment, U.S. Congress, concluded that:

> It would be hard to claim that OSHA's cotton dust regulation has in any way seriously damaged industry profitability. Some would say that OSHA has actually enhanced and encouraged profitable activities. Many corporate executives and plant managers, while still objecting to various aspects of the cotton dust rule, admit that in many of the plants which they have modernized (and they must modernize to survive), the existence of the OSHA rule cause them to make a more timely decision, and in many cases, a more systematic decision." (Ex. 233, p. ii–iii)

The same notion was expressed in a 1980 issue of the British publication "Economist" which stated that:

> Tougher government regulations on workers' health have unexpectedly, given the industry a leg up. Tighter dust control rules for cotton plants caused firms to throw out tonnes of old inefficient machinery and to replace it with the latest available . . ." (Exh. 200)

Commenting on this article, Mr. James King, a Vice President of Cone Mills, representing ATMI, agreed that both the OSHA standard and the increased demand for wider fabrics of better quality contributed to the rapid pace of modernization (Tr. 705–706). In response to the question, "I take it . . . you have just said that the OSHA standard has encouraged the American companies which were already modernizing and improving their productivity to do so at perhaps even a slightly faster rate than you had been doing so before?", he replied, "I think that generally could be said . . ."

In addition, ACTWU presented data demonstrating the strong economic performance of seven textile firms that had largely complied with the standard (Ex. 198–B, App. 4). The NCC rejected this finding, pointing out that the profits per dollar of net worth for these seven companies were 20 percent above the industry average in the 4 years preceding 1978, but 2 percent below in the four years subsequent to 1978 (Tr. 658; Ex. 276 pp. 34–36). In response, George Perkel, a consultant to ACTWU, prepared a trend analysis indicating that the companies' profit on net worth declined during the 4 years prior to 1978, but rose at a rate of 9 percent a year during the 4 years subsequent to 1978 (Tr. 658–659).

After considering the positions stated above, OSHA believes that there is overwhelming evidence to support the conclusion that the cotton dust standard is economically feasible for the textile industry. Indeed, compliance has, for the most part, already been achieved without any serious significant adverse impact.

D. Technical Feasibility/Nontextiles

The final amendments to the cotton dust standard exempt the nontextile segments from all sections of the new cotton dust standard § 1910.1043 except for the medical surveillance provisions for cottonseed processing and waste processing. In addition, this final rule exempts all segments of the nontextile industry except waste recycling and garnetting operations from the pre-existing permissible exposure limit of 1000 $\mu g/m^3$ of cotton dust (raw) specified in § 1910.1000 (Table Z–1). The bases for these exemptions are the data on health effects which are discussed in section III of this preamble.

OSHA did not propose and the final rule does not exempt waste processing and garnetting operations from the pre-existing standard in § 1910.1000 of 1000 $\mu g/m^3$ of cotton dust. This decision was also based upon the health studies discussed in Section III of this preamble on health implications and scope of coverage in nontextiles. However, following the testimony of all health experts commenting at these proceedings, OSHA is changing its interpretation of the 1000 $\mu g/m^3$ exposure limit so that it applies to respirable dust as measured by a vertical elutriator or equivalent instrument rather than to total dust. Respirable dust correlates better with the adverse health effects of cotton dust and thereby provides an improved measure of employee exposure to the toxic material. This interpretation is also utilized in the § 1910.1043 standard.

Section 6(b)(5) of the OSH Act requires OSHA to determine that a new standard issued under section 6(b) of the Act is techically and economically feasible. When OSHA issued the § 1910.1043 standard specifying a 500 $\mu g/m^3$ respirable dust PEL for nontextiles, OSHA made a determination of technical and economic feasibility based on data in the record. The knitting industry did not challenge that determination. The agency's conclusion as to feasibility for cotton classing and warehousing was upheld by the D.C. Circuit, but the Supreme Court remanded for consideration on other grounds. The D.C. Circuit upheld technical feasibility for cottonseed processing but held that the agency had not demonstrated economic feasibility. No judicial decision was issued for waste processing, which includes both waste recycling and garnetting processes. No purpose would now be served by reviewing those determinations, since the final rule eliminates coverage of these segments by § 1910.1043 with the exception of the medical provisions for cottonseed processing and waste processing discussed below.

The § 1910.1000 standard which will remain in effect for waste recycling and garnetting operations was issued in 1971 pursuant to section 6(a) of the Act that provides that:

> without regard to chapter 5 of title 5, United States Code, or to the other subsections of this section, the Secretary shall, as soon as practicable during the period beginning with the effective date of this Act and ending two years after such date, by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard, unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees. In the event of conflict among any such standards, the Secretary shall promulgate the standard

which assures that greatest protection of the safety or health of the affected employees.

The feasibility requirements of section 6(b)(5) did not and do not apply to that 6(a) standard and it was not challenged judicially.

The requirements which continue in effect for waste recycling and garnetting operations in addition to the exposure limit of 1 mg (1000 μg)/m³ for cotton dust, that:

> To achieve compliance . . . administrative or engineering controls must first be determined and implemented whenever feasible. When such controls are not feasible to achieve full compliance, protective equipment or any other protective measures shall be used to keep the exposure of employees to air contaminate within the limits prescribed in this section . . . whenever respirators are used, their use shall comply with 1910.134. (§ 1910.1000(e))

From the statutory provisions it can be seen that the decision to retain a 6(a) standard does not place the burden of proof on OSHA to demonstrate feasibility pursuant to section 6(b)(5). In addition, the fact that an existing area in a waste processing operation is over the 1,000 μg/m³ limit does not demonstrate the lack of feasibility of the 6(a) standard. The specific employer may be out of compliance because the employer failed to install a feasible control which is available. Or pursuant to 1910.1000(e), the employer may have determined that there is no feasible administrative or engineering control and is achieving compliance with respirators as is then permitted if that determination is correct.

Evidence on technical and economic feasibility has been introduced to the record for the waste recycling and garnetting processes. OSHA has reviewed this data, and if the data demonstrated serious feasibility difficulties for the existing standard, OSHA would have reconsidered the 1000 μg/m³ standard for waste recycling and garnetting on feasibility grounds. However, the data demonstrate that the standard is technically feasible and, as discussed in the section below, economically feasible.

As discussed in the scope and application section, OSHA is changing for health reasons its interpretation of the method of monitoring for the 1000 μg/m³ standard. The prior interpretation was that the proper method of monitoring was to measure total dust. OSHA is changing the interpretation to respirable dust as measured by a vertical elutriator or equivalent.

This change is relevant to feasibility determinations. The evidence clearly indicates that respirable dust constitutes only one-third or one-fourth of total cotton dust particulate. Various NIOSH studies demonstrate this fact, and were acknowledged by Dr. Wakelyn and Dr. Ethridge, representing the National Cotton Council. Therefore, it is substantially easier to achieve 1000 μg/m³ of respirable dust than that same level of total dust. This must be kept in mind when reviewing data and comments focusing on 1000 μg/m³ of total dust. In addition it should be kept in mind when considering studies directed at the feasibility of achieving compliance with 500 μg/m³ respirable dust level, that it is, of course, substantially easier to achieve compliance with a 1000 μg/m³ respirable dust level than with a 500 μg/m³ respirable dust level.

In general, compliance with the 1000 μg/m³ respirable dust limit does not appear to be a problem for garnetters. Dr. Wakelyn, testifying on the subject of garnetting operations for the National Cotton Batting Institute (NCBI), indicated that technology does not exist to meet a 1.0 mg/m³ (1.000 μg/m³) *total* dust level but agreed that, "It may, however, be possible for many facilities to meet a 1.0 mg/m³ respirable dust standard. . ." (Ex. 210–C). Similarly, the NCC confirmed that, ". . .it may be possible in most facilities to meet a 1 mg/m³ respirable dust standard" (Ex. 276, p. 13). In two of the three plants for which OSHA has exposure data, all processing areas are already below 1,000 μg/m³ of respirable dust (Ex. L–3; Ex. 118X).

Compliance may not be quite as easy for waste recyclers. In its initial response to OSHA's 1976 proposal to limit dust levels, the NCC reported that Pneumafil, a major dust control vendor, believed that the proposed 200 μg/m³ level could not be achieved in waste recycling, but that dust levels could be reduced sufficiently to permit compliance with a 500 μg/m³ exposure limit (Ex. 99E, p. 17). Since that time, however, experience has indicated that there would be some difficulty achieving 500 μg/m³ in all process areas. NIOSH measured dust levels at all 13 waste recycling plants and reported that respirable dust levels in 8 of the plants had overall geometric mean levels below 500 μg/m³ (Ex. 175–56). In response, the NCC pointed out that about 31 percent of the NIOSH dust samples were taken from non-process areas. NCC also noted that 12 of the 13 recycling plants studied by NIOSH had dust levels above 500 μg/m³, and 11 of the 13 plants had levels above 1,000 μg/m³ in at least some process areas (Ex. 211–C). Norman Paschall, representing the Textile Fibers and By-products Association, testified that the Pneumafil Company had tried and failed to lower dust levels to 500 μg/m³ in his plant (Tr. 1031).

OSHA's final rules, however, require these firms to meet only a 1,000 μg/m³ respirable dust PEL. While Mr. Paschall did not indicate whether his plant had succeeded in reducing dust concentrations to this level, a summary table in the NIOSH submission presents dust level means and standard deviations by individual manufacturing processes. These figures clearly imply that every operation must have achieved dust levels well below 1,000 μg/m³ respirable dust in at least several of the recycling plants (Exh. 175–56, Table 5, p. 47). Thus, OSHA believes that engineering controls capable of reducing dust levels in each type of operation to the PEL do exist and are currently in place in some establishments. As discussed above, if it is determined that feasible administrative and engineering controls are not available to bring a specific area below the PEL, the employer may comply by providing respiratory protection.

OSHA is not eliminating the requirement for medical examinations promulgated in 1978 for the cottonseed processing and waste processing industries. The feasibility of this provision was not seriously questioned during the 1978 rulemaking proceedings. However, a few participants at the 1984 hearing claimed that medical examinations were infeasible for the cottonseed industry. T.S. Schuler, president of the National Cottonseed Products Association (NCPA), pointed out that the cottonseed industry is basically a rural operation and argued that "the medical expertise and doctors are just not available to do it." He said that his employees would have to be transported over a hundred miles to receive the required medical examinations. While acknowledging the existence of medical programs in the Procter and Gamble cottonseed mills, he attributed this capability to their unusual size (Tr. 1087–1089). The NCPA also submitted questionnaire survey responses from about 60 percent (36 out of 62) of the nation's cottonseed mills. Fifty-nine percent of the mills replied that they do not have access to a pulmonary function testing service, but even where the required facilities were available, 76 percent of the time they were more than 50 miles away (Ex. 281).

OSHA, however, believes that the exams could be provided in most instances at reasonable cost. The standard does not require the person administering the test to be a physician as long as that individual has completed

a NIOSH approved training course in spirometry and works under the general supervision of a physician. As the textile industry has found, consultative services often are available to provide the requisite medical services. For example John Lumsden, owner of an industrial hygiene consultation service said that his company would provide medical surveillance for a facility with 20 employees up to 100 miles from their headquarters for $400 (Tr. 1352). See also Exhibit 170–11. In other instances, local physician's offices or regional hospitals could be utilized or a nurse or other employee could be trained at modest cost at the two day NIOSH program. The cost of a spirometer is about $1,000 (Ex. 170–11). Once the demand for such tests is established, a local physician or clinic could easily provide the service. OSHA believes, therefore, that the provision of medical surveillance is technically feasible even in rural areas.

E. Economic Feasibility/Nontextiles

The only segments of the nontextile industry to remain covered by a permissible exposure limit are waste recycling and garnetting. As discussed above in the technical feasibility section, OSHA has determined that the pre-existing 6(a) standard should not be eliminated. Therefore the burden of proof is not on the agency to demonstrate economic feasibility. To the extent that any capital expenditures are required, it is not because of a new action by OSHA, but because of a failure to comply with the existing standard over the past 13 years.

Nevertheless, OSHA has carefully reviewed the evidence of economic feasibility for these segments. This includes the data presented prior to the issuance of the 1978 standard and new data supplied by Centaur, the National Cotton Council (NCC) and others. Based on this evidence, OSHA concludes that the evidence does not demonstrate it is economically infeasible for these segments to come into compliance with the existing standard 1000 $\mu g/m^3$, interpreted as a respirable dust standard. Indeed, OSHA concludes that the evidence clearly demonstrates that it is economically feasible to comply with 1000 $\mu g/m^3$ respirable dust for these segments.

Centaur did not collect independent cost data but updated the pre-1978 engineering cost calculations submitted by the NCC to account for price change, reduction in cotton waste generated by textile mills, and current levels of compliance. They did not attempt to evaluate the accuracy of these cost data or to judge whether the lower estimates presented in Research Triangle Institute's 1976 Inflationary Impact Statement were more appropriate. For example, the major dust control vendor relied upon in NCC's study on waste recyclers estimated that the required controls "would necessitate at least a two-thirds increase in existing cfm . . ." The NCC took this to mean a 167 percent rather than a 67 percent increase in the required cfm and calculated the engineering costs accordingly (Ex. 99E, p. 19). Therefore, the Centaur estimates may be considered an upper bound figure. These estimates indicated that to comply with a PEL of 1,000 $\mu g/m^3$ of total dust, the waste recycling industry would incur capital costs of $11 million and total annual costs of $3.2 million, or roughly 10.4 percent of their total revenues. Similarly, Centaur projected that the garnetting industry would incur capital costs of $13 million and total annual costs of $3.8 million, about 1 percent of their total revenues. These annual compliance costs were estimated to amount to about 3.7 cents per pound of cotton waste processed by recyclers and 1.9 cents per pound of cotton waste processed by garnetters. It should be noted that Centaur believed costs would achieve compliance with 1000 $\mu g/m^3$ of total dust, but that OSHA is changing its compliance interpretation to require 1000 $\mu g/m^3$ of respirable dust. As discussed above, this level is 3 to 4 times easier to achieve than a 1000 $\mu g/m^3$ total dust PEL and consequently the cost to achieve compliance would be substantially less.

Centaur found that the selling price of cotton waste sold by textile firms varied substantially by fiber type but averaged about 10 cents per pound. As compliance costs were estimated at only 2 to 4 cents per pound, Centaur determined that the full financial impact on waste recycling companies would be subtantially moderated through the industry's potential to pass back some proportion of the production cost increases to those firms supplying the unprocessed waste materials. Because sales of cotton waste are not a major source of revenue to any one textile mill and mills would have to pay for solid waste disposal if this outlet disappeared, Centaur concluded that textile mills would have no choice but to accept even sharply reduced revenues from sales of waste cotton to keep the market for waste cotton active (Ex. 185, p. 7–17).

Dean Ethridge, Director of Economic Services for the NCC, objected to Centaur's estimates (Exh. 211–E). He argued that their results are presented as applicable to the proposed 1,000 $\mu g/m^3$ *total* dust standard, whereas their cost data are based upon an earlier NCC study that estimated the cost of meeting a 500 $\mu g/m^3$ *respirable* dust standard. He noted that physical evidence demonstrated that the proposed 1,000 $\mu g/m^3$ *total* dust standard was at least 50 percent more severe than a 500 $\mu g/m^3$ *respirable* dust standard. OSHA, however, does not believe that the Centaur estimates, which are based on industry data, are too low because Centaur adjusted the estimates to reflect current dust conditions.

In addition, Dr. Ethridge claimed that much of the technical and financial data used by Centaur to construct their analysis are outdated. NCC conducted a questionnaire survey and received responses from about 60 percent of the waste processing firms (8 out of 13), and about 38 percent of the garnetting firms (30 out of approximately 80). Applying these data to update the original NCC study "using Centaur's method of updating energy and capital costs," NCC calculated that compliance costs per pound of cotton output were 300 percent higher than Centaur's estimate for the waste recycling industry, and 39 percent higher than Centaur's estimate for the garnetting industry.

A review of NCC's analysis, however, shows several deficiencies. For example, their cost calculations for the waste recycling industry indicate that NCC failed to use an appropriate capital recovery formula (Ex. 211–E, p.7). Applying the formula used by Centaur yields $288,204 as the annualized capital costs per recycling plant in need of new controls rather than $399,936. Moreover, NCC assumed that operating costs amount to 2 percent of capital costs whereas Centaur had provided a plausible rationale for believing that 1.3 percent was more realistic. As NCC did not present any new data to support their assumption, OSHA has applied Centaur's 1.3 percent rate, which lowers the NCC figure for operating costs per plant from $29,499 to $19,174.

On the other hand, NCC substantially underestimated annual energy costs as they apparently did not understand that the Centaur procedure would apply the factors to the new 320,640 cubic feet per minute (cfm) required ventilation system rather than to the 192,000 cfm existing operating system. Consequently, the estimated annual energy cost per firm is approximately twice the NCC estimate, climbing from $36,009 to $60,135. This cost is still substantially below the Centaur estimate of $93,000 because Centaur assumed that typical plants operated at about twice the number of

hours reported in the NCC survey. The sum of these corrections yields a total annualized cost of $367,513 for each out-of-compliance plant to meet a dust limit of 1,000 ug/m³ of total dust.

As noted repeatedly by the NCC, however, the ratio of the weight of total to respirable dust is at least three or four to one (NCC, Ex. 211–E; Tr. 1059). Thus, the above estimates may approximate the cost of dust controls designed to achieve a standard at least three times harder to achieve than the final rule. While the extent of the overestimate is not known precisely, the NCC pointed out that ". . . it is common knowledge that constant increments in severity of dust standards result in more-than-proportionate increases in the cost of meeting the standard." Indeed, an assumed three to one dust ratio was the basis for the NCC presumption that "a conservative estimate of the cost for a 1.0 mg/m³ total dust standard would be 50% above that for meeting a 0.5 mg/m³ vertical elutriated standard." (Ex. 211–E, p.3) Estimating the cost of the final standard by applying the identical logic leads to a downward adjustment of the above compliance cost figures by about two-thirds. On this basis, the adjusted annualized cost per recycling plant needing controls is $367,513 divided by 3 or $122,504, which amounts to about 3.1 percent of the average plant's reported gross revenue (NCC, Ex. 211–E, p.5.). Using these same estimates, the cost of dust control per pound of waste cotton processed comes to 1.1 cents, significantly below the original Centaur estimate of 3.7 cents per pound.

Based on the Centaur assumption that 10 establishments would need dust controls, the above calculations imply that the waste recycling industry would incur capital costs of about $4,916,667 and total annualized costs of about $1,225,000 to come into compliance with the final PEL of 1,000 mg/m³ of respirable dust. At the earlier cost estimate of 3.7 cents per pound to achieve compliance. Centaur concluded that 3 to 5 of the 13 waste recycling firms might decide not to continue their operation. OSHA, however, estimates that compliance with the 1,000 ug/m³ respirable dust PEL would cost only 1.1 cents per pound, part of which would be passed back to the textile mills through a lower purchase price. OSHA, therefore, concludes that it is unlikely that any waste recycling facilities would close their recycling operation because of this standard. Thus, OSHA believes that the 1,000 ug/m³ respirable dust PEL is economically feasible for waste recyclers.

The NCC estimate of the compliance costs to be incurred by the garnetting sector also requires adjustment. Applying Centaur's capital recovery formula and operating cost percentage reduces the NCC estimate of annual operating costs per firm from $29,395 to $21,182 and of annual operating costs per firm from $2,168 to 1,409. Moreover, the NCC survey clearly indicates that Centaur had overestimated energy costs for this industry. Centaur calculated that energy costs were 43.3 per cent of annualized capital costs in the waste recycling industry and, in the absence of better data, applied that ratio to estimate energy costs for garnetters. As discussed above, however, the average energy cost per recycling plant is now estimated at $60,135 (still twice the NCC figure) or about 20.9 percent of annualized capital cost. Replacing the 43.3 percentage by the 20.9 rate lowers the NCC energy cost estimate for garnetters from $12,728 to $4,427. This brings the total annualized costs to $27,018 for the average plant with overexposed workers.

Applying the two-thirds adjustment attributable to the change from total to respirable dust yields total annualized costs per plant of about $9,000. The estimated cost for dust control per pound of cotton waste processed amounts to 0.5 cents, also significantly below Centaur's original estimate of 1.9 cents per pound. As noted above, most garnetting plants may already meet this dust level. Nevertheless, if all garnetting establishments had to install such controls, the resulting capital costs would amount to $2,890,800 and the total annualized costs would sum to $720,480.

Even at the earlier 1.9 cents per pound cost estimate, Centaur predicted that no garnetting operations would close, although a few might decide to process synthetic rather than cotton wastes. At OSHA's revised cost estimate of 0.5 cents per pound for the easier to meet 1,000 ug/m³ respirable dust standard, the $9,000 annual cost per facility should be even more manageable as it is less than 0.7 percent of average gross revenue (NCC, Ex. 211–E, p. 9). Consequently, OSHA concludes that the 1,000 ug/m³ respirable dust level is economically feasible for the industry.

As explained above, the final PEL of 1,000 $\mu g/m^3$ of respirable dust in the waste recycling and garnetting industries should be significantly less costly to meet than either the 1971 PEL of 1,000 $\mu g/m^3$ of total dust, or the 1978 PEL of 500 $\mu g/m^3$ of respirable dust. As a result, the costs imposed will be significantly lower than those estimated by Centaur or NCC, and the company's ability to pass back these costs to the sellers of waste cotton would be even greater than Centaur had anticipated. Consequently, OSHA has determined that the standard is economically feasible for the waste processing and the garnetting sectors.

OSHA of course must demonstrate economic feasibility for the new medical surveillance requirements that are issued under section 6(b) of the OSH Act for cottonseed processing and waste processing. Upon review of the rulemaking record, it is clear that the costs of these provisions are so low in relation to the gross revenues of these sectors that the costs are economically feasible. The 1978 standard required medical examinations annually for all exposed employees, but the revised rule requires that each employee in these industries be tested only once every other year. Centaur estimated that the textile industry's outlay for annual medical surveillance and its associated recordkeeping divided by the number of exposed workers averaged $69 (Ex. 185, p. 4–21). As that industry reports a worker turnover rate of about 40 percent (ATMI, Ex. 175–60), the cost per exam may have been as low as $49. The Environmental Resources Group, Inc., (ERG), Inc., a consultant in Environmental Sciences, offers the test for $300 plus $10 per person tested, which amounts to $13 per test if 100 employees are tested and $70 per test if only 5 employees are tested (Ex. 170–11, p. 3). When asked the price to test 20 workers located 100 miles away, John Lumsden, of ELB Associates, reported that his company's minimum fee of about $400 would apply, making the per employee charge about $20 (Tr. 1352). Responses to the NCPA survey of 36 cottonseed mills showed a median price estimate of $60 per test, although the estimates ranged from $11.50 to $237 (Ex. L–4). Overall, therefore, an estimate of $60 per employee exam appears conservative.

In their comments, however, the NCPA disputed the economic feasibility of the medical surveillance provision for the cottonseed oil industry, maintaining that the reported 100 percent rate of worker turnover (166 employees for 82 jobs) would greatly increase its economic burden (Ex. 281; Ex. L–4). OSHA agrees that unusually high turnover rates will raise compliance costs. Moreover, costs for smaller companies without in-house medical staff will rise more than proportionately because new hires would have to travel to a medical facility both before and after their initial work shift. Nevertheless, as the following

calculations indicate, the costs do not appear to be overly burdensome.

On the assumption that newly hired workers would need an additional 3 hours away from work, that lost production amounts to $5 per hour (these employees reportedly receive the minimum wage), and that travel expenses per exam are $4, the full cost of the initial medical test for each new cottonseed mill employee should average about $79 ($60+$15+$4). Thus, assuming a 100 percent turnover rate for the industry, the annual cost of testing 817 new hires (Centaur, Exh. 191, p. 41) would be $79 x 817 employees which equals $64,543. With turnover rates this high, it is difficult to know how many employees would remain for a biennial examination. Dr. Ethridge of the NCC suggests that on average only 6 percent of the workforce remain employed for a full year (Ex. L-4). Even if 25 percent of the employees remain for 2 years, however, this would add only .25 x $60 x 817 employees = $12,255 of medical costs every other year. The annual cost, therefore, consists of half of this value, which is $6,128 plus the $64,543 estimated above. Thus, OSHA estimates the annual cost of medical surveillance for the cottonseed mill processors at $70,671. With 1981/82 revenues reported at $777.6 million (derived from value per ton and number of tons in Centaur, Ex. 191, pp 49, 51), these compliance costs amount to less than one one-hundredth of one percent of industry sales even in that year of low demand. Clearly this requirement is economically feasible for the cottonseed processing industry.

The worker turnover problem appears less severe for the waste processing companies as the NCC survey (Ex. 232-A) implies rates of 40 percent for recyclers and 21 percent for garnetters, not very different from the approximately 40 percent rate reported for the textile sector (ATMI, Ex. 175-60). Therefore, OSHA assumes that these industries would experience biennial medical surveillance costs similar to the $69 per exposed employee reported for the textile sector (Centaur, Ex. 185). Based on 260 recycling employees (NIOSH, Ex. 175-56) and 880 garnetting employees (NCBI Ex 210-13; NCC Ex. 232A), this approach yields annual medical surveillance costs of $8,970 for the recycling industry (½ x $69 x 260 employees), and $30,360 for the garnetting industry (½ x $79 x 880 employees). These costs come to about $690 for the average recycling plant ($8,970/13 plants), or less than 0.02 percent of the average recycling company's 3.9 million gross revenue (NCC, Ex. 211-E, p. 5); and about $380 for the average garnetting plant ($30,360/80 plants), or about only 0.03 percent of the average garnetting company's $1.3 million gross revenue (NCC, Ex. 211-E, p. 9). Compliance costs of such magnitude would have almost no effect on the industry's profitability and thus are clearly affordable.

F. Cost Savings

Estimates of cost savings were derived for such changes as the revised monitoring frequency, the new action level provision, and the exemption of the nontextile sectors from most requirements of the 1978 standard. Some other changes such as eliminating the requirement to check equipment at specified intervals would lead to further cost savings, but data available did not permit quantification of those savings. Other changes had little or no impact on costs.

For the textile sector, OSHA's new action level and reduced monitoring frequency are estimated to save at least $2.7 million per year. This cost saving reflects the change in both the required frequency of exposure monitoring from semiannually to annually where exposures are below the PEL, and the required frequency of medical surveillance from annually to biennially where exposures are below an action level set at one-half the PEL. Such revisions lower the estimated annual cost for medical surveillance from approximately $6.6 million to $5.1 million, and for exposure monitoring from $2.5 million to $1.2 million. Therefore, the total annual cost savings of these changes, compared with the 1978 standard, are approximately $1.5 million for medical surveillance and $1.2 million for exposure monitoring.

The final action exempts all nontextile industries from all but the medical surveillance requirements for cotton seed processing and waste processing of the 1978 cotton dust standard; and all but waste recycling and garnetting operations from the 1971 cotton dust standard. Consequently, the nontextile industries will accrue substantial savings by not having to comply with the deleted provisions of the 1978 regulation. For example, the engineering control savings that will accrue to the waste recycling sector reflects evidence that meeting the final PEL of 1,000 $\mu g/m^3$ of respirable cotton dust is significantly less costly than meeting the 1978 PEL of 500 $\mu g/m^3$ of respirable cotton dust. The estimated cost savings for this sector total $4.9 million in capital costs and $280,000 in associated annual operating costs. For garnetting operations, the final action is estimated to yield capital cost savings of $2.9 million and associated annual operating cost savings of $200,000. The engineering cost savings for the cottonseed oil industry were based on a study by Centaur, which indicated that compliance with the 1978 PEL would cost $49.5 million in capital investment and $22.5 million in associated annual operating and maintenance costs (Ex. 191, p. 43). Since cotton seed mills are no longer subject to a PEL, these amounts are cost savings for this sector.

In sum, the economic savings that would accrue to the nation's cotton-using industries following the enactment of this revised standard are considerable. OSHA estimates that exempting nontextile industries from the 1978 standard would save $57.3 million in capital costs, $3.3 million in annual medical surveillance and monitoring costs, and $22.9 million in other annual operating costs. Within the textile sectors, OSHA's new action level and monitoring frequency are estimated to save at least $2.7 million per year. In total, therefore, OSHA estimates that the final promulgation of this revised standard will save the cotton industries at least $57.3 million in capital outlays and $28.9 million in annual operating expenses. This lowers the estimated capital costs of the 1978 cotton dust standard by 18.4 percent from $310.6 million to $253.3 million (with all but about $100 million already spent as of 1982), and the annual operating costs of that standard by 45 percent (from $64.8 million to $35.8 million).

G. Summary of Regulatory Flexibility Analysis

OSHA also evaluated the cost of compliance for relatively small firms to determine whether the final action would substantially affect the economic viability of most small companies. Although the revised provisions do not explicitly grant concessions based on firm size, OSHA found that they would give significant relief to the many small firms engaged in the processing of cotton.

The new action level and monitoring frequency will especially benefit the smaller firms in the textile sector. The most difficult dust control problem in the textile industry exists in the yarn preparation processes, where economies of scale typically require fairly large-scale plants for efficient operation. Smaller establishments in this sector, however, tend to perform specialty weaving functions, which create less severe dust control problems than their larger counterparts. Since most small firms already operate at low dust levels, the new action level, which reduces

medical surveillance requirements at low dust levels, should reduce the regulatory obligations of many of these smaller textile establishments.

In situations where dust level limits require engineering controls, potential economies of scale in dust control systems become an important competitive factor. If major economies of scale exist, smaller firms would be at a comparative disadvantage because their unit costs would be higher than those of larger firms. Centaur examined each of the compliance activities required by the standard and reported that dust control costs for most of the textile industry were directly proportional to output levels. Consequently, there was little evidence to suggest that the unit costs of compliance with the cotton dust standard varied with plant size for a given product type. Centaur also found, however, that large textile firms (from over $10 to $25 million is assets) were able to finance capital outlays easier because, on average, they had higher profit margins and a higher cash flow as a percent of sales than did smaller firms. Moreover, the larger firms had better access to borrowed capital. Nevertheless, Centaur concluded that the profit rate differentials were not enough to make a substantial impact on the ability of the smaller firms to comply with the standard or compete with larger firms.

Although the precise number of small firms using cotton in the nontextile sectors is unknown, reports indicate that most of these industries have proportionately large numbers of small establishments. For example, the American Cotton Shippers Association estimated that over 90 percent of the companies merchandizing cotton have fewer than 15 employees (Ex. 175–30), and the 1977 Census of Manufactures indicates that over 50 percent of the nation's cottonseed mills employ fewer than 50 employees. For all nontextile firms, the revised standard reduces regulatory burdens as these companies (except in waste processing) are exempted from either all requirements, or all but the medical surveillance requirements.

Within the waste processing industry, which is covered by the 1971 PEL and therefore must institute engineering controls, all but 1 of the 13 recycling plants is a small business with under 40 employees. As in the textile industry, Centaur found few scale economies for the installation of engineering controls. Yet the larger firms tend to operate more than one work shift which enabled them to spread the capital cost of compliance over a greater output. Dun & Bradstreet financial figures, while not specific to those waste processing firms using cotton (Ex. 211–A), indicate that the larger recycling firms earn after-tax profits of about 1.85 percent of sales compared with 1.5 percent for the smaller firms, but the smaller firms return about 15.6 percent on equity compared with about 9 percent for the larger firms. Centaur projected that from three to five of the smaller companies would have difficulty raising the necessary capital to comply with the proposed PEL of 1000 $\mu g/m^3$ of total dust. The revised standard, however, specifies the PEL in terms of respirable dust rather than total dust, which substantially reduces the capital requirement needed for compliance. As discussed above the change to a respirable dust level eliminates that difficulty and those smaller companies can feasibly comply. In addition, the reduced costs for medical and environmental surveillance would effectively moderate the regulatory burdens imposed upon these small firms.

Ventilation systems in the garnetting of cotton waste industries exhibit significant economies of scale, with unit costs for a three-garnett-line less than one-half that of a single line. On the other hand, the independent garnetters, which generally employ less than 20 workers, tend to operate more work shifts than those garnetters affiliated with larger bedding manufacturers. According to Dunn & Bradstreet data, the profits of independent garnetters (SIC 2293) do not vary by firm size, whereas the profits of the mattress and bedspring industry (SIC 2515) acutally showed higher profits for the smaller firms (Ex. 185). Because garnetters can process synthetic as well as cotton waste, Centaur assumed that no small garnetters would be forced out of the waste fiber business. In addition, the revised standard defines the PEL in terms of respirable rather than total dust, requires less frequent medical surveillance and no monitoring burden, and therefore substantially reduces the regulatory costs imposed upon these small firms.

Pursuant to the Regulatory Flexibility Act of 1980 (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601 *et seq.*), the Assistant Secretary has assessed the impact of the revised standard and concludes that the enactment of the new action level, the various exemptions, and the other technical revisions will moderate the compliance costs of many small cotton-consuming businesses, and that the regulatory burden of the revised cotton dust standard should not substantially affect the economic viability of small companies.

H. Environmental Assessment—Finding of No Significant Impact

In December 1977, OSHA published a Final Environmental Impact Statement (FEIS) on the 1976 proposed cotton dust standard. The FEIS concluded that the proposed action would not result in any significant impact to the general quality of the human environment external to the workplace, particularly in terms of ambient air quality, water quality, or solid waste disposal. On June 10, 1983, OSHA published a Notice of Proposed Rulemaking (48 FR 26962–26984) for occupational exposure to cotton dust. At that time, information was solicited from the public on a variety of issues including possible environmental impacts of the proposed revised standard. The comment period for the NPRM ended on August 9, 1983, and no new or additional information was received pertaining to environmental issues. The final rule and its major alternatives have been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321, et seq.), the requirements of the Council on Environmental Quality (40 CFR Part 1500), and OSHA's DOL NEPA regulations (29 CFR Part 11). As a result of this review, the Assistant Secretary has determined that the conclusions drawn in the FEIS remain valid, that no amended impact statement is required, and that the proposed rule will not have a significant impact on the external environment. Impacts on the workplace environment are discussed in other portions of this preamble and in other Agency notices on cotton dust (47 FR 5906–5910, February 9, 1982; 43 FR 27350–27394, June 23, 1978; 41 FR 56498–56527, December 26, 1976).

The preceding paragraphs and the preamble to this Notice serve as the environmental assessment and finding of no significant impact.

VI. Repeal of Standard for Construction Industry and Amendment of § 1910.1000.

A. Repeal of Standard for Construction Industry

The 1978 cotton dust standard was applied to the construction industry by 29 CFR 1910.19(f). In its proposal, OSHA proposed to eliminate coverage of the construction industry by repealing § 1910.19(f). The basis was that OSHA has no knowledge of any exposures in the construction industry. No contrary evidence or comments were received. The construction industry supports the

change. Accordingly OSHA is repealing 29 CFR 1910.19(f) for the reason stated in the proposal.

B. Interpretation of Cotton Dust Entry in Table Z–1 of § 1910.1000

The current entry in Table Z–1 of § 1910.1000 reads "Cotton dust (raw)" and sets an exposure limit of 1 mg/M³ (1000 μg/M³). That limit which has existed since 1971, has applied to all non-textile operations while § 1910.1043 has been stayed as discussed in section I.E. of this preamble above. There is a footnote (with a printer's error in the 1984 ed. of the CFR) stating that "This standard applies in cotton yarn manufacturing until compliance with § 1910.1043 (c) and (e) is achieved."

The table entry remains unchanged. The footnote entry is changed. The current footnote is obsolete and omitted. It indicated that yarn manufacturers were to achieve a 1 mg/M³ PEL with engineering controls until they were required to achieve 200 μg/M³ with engineering controls on March 27, 1984. That date has passed and yarn manufacturers are now required to achieve 200 μg/M³ so there is no purpose in retaining that footnote. (There is an exception for coarse count yarn production discussed in IV.M. above.) The textile industry is now fully covered by §1910.1043 and this entry has no future relevance for the textile segment.

OSHA is exempting knitting, classing, warehousing and cottonseed processing from 1 mg/M³ limit and retaining coverage of the waste processing industry under this limit based on an analysis of the health data. Accordingly a footnote "e" has been added to the "cotton dust (raw)—1 mg/M³" entry. The second sentence of the footnote indicates that this entry applies generally only to the "cotton waste processing operations of waste recycling (sorting, blending, cleaning, and willowing) and garnetting."

In addition health data indicate that this exposure limit will be more protective of workers if interpreted to be measured as "respirable dust as measured by a vertical elutriator cotton dust sampler or equivalent instrument." The first sentence of the footnote indicate that this is the proper interpretation.

The health reasons for these provisions generally are discussed at length in section III. of this preamble, above. The discussion of the interpretation of measuring technique and the retention of coverage for waste processing operations can be specifically found in section III.D. The feasibility implications of these provisions are discussed in section V.D. and E. above.

It is the intention that there remain no gaps in coverage and that existing provisions not terminate unless the new provisions are in effect.

List of Subjects in 29 CFR Part 1910

Occupational safety and health, Health, Cotton dust.

VII. Authority and Signature

This document was prepared under the direction of Patrick R. Tyson, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Ave, NW., Washington, DC 20210. Accordingly, pursuant to sections 6(b), 8(c) and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655, 657), 29 CFR Part 1911 and Secretary of Labor's Order No. 9–83 (48 FR 35736), 29 CFR Part 1910 is hereby amended as set forth below.

Signed at Washington, DC, this 5th day of December, 1985.

Patrick R. Tyson,

Acting Assistant Secretary for Occupational Safety and Health.

VIII. Amended Standards

PART 1910—[AMENDED]

Part 1910 of Title 29 of the Code of Federal Regulations is hereby amended as follows:

1. The authority citation for Subpart B of Part 1910 is revised to read as set forth below, and the authority citations following all sections in Subpart B of Part 1910, except for source citations (FR citations) and Effective Date Notes, are removed:

Authority: Secs. 4, 6, and 8 of the Occupational Safety and Health Act, 29 U.S.C. 653, 655, 657; Walsh-Healey Act, 41 U.S.C. 35 et seq.; Service Contract Act of 1965, 41 U.S.C. 351 et seq.; Pub. L. 91–54, 40 U.S.C. 333; Pub. L. 85–742, 33 U.S.C. 941; National Foundation on Arts and Humanities Act, 20 U.S.C. 951 et seq.; Secretary of Labor's Orders 12–71 (36 FR 8754), 8–76 (41 FR 2505), or 9–83 (48 FR 35736); and 29 CFR Part 1911.

§ 1910.19 [Amended]

2. Paragraph (f) of § 1910.19 is hereby removed and reserved.

3. The authority citation for Subpart Z of Part 1910 continues to read as follows:

Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657; Secretary of Labor's Orders No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), or 9–83 (48 FR 35736), as applicable; and 29 CFR Part 1911.

Section 1910.1000 Tables Z–1, Z–2, Z–3 also issued under 5 U.S.C. 553.

Section 1910.1000 not issued under 29 CFR Part 1911, except for "Arsenic" and "Cotton Dust" listings in Table Z–1.

Section 1910.1001 also issued under Sec. 107 of Contract Work Hours and Safety Standards Act, 40 U.S.C. 333.

Section 1910.1002 not issued under 29 U.S.C. 655 or 29 CFR Part 1911; also issued under 5 U.S.C. 553.

Sections 1910.1003 through 1910.1018 also issued under 29 U.S.C. 653.

Section 1910.1025 also issued under 29 U.S.C. 653 and 5 U.S.C. 556.

Section 1910.1043 also issued under 5 U.S.C. 551 et seq.

Sections 1910.1045 and 1910.1047 also issued under 29 U.S.C. 653.

Sections 1910.1499 and 1910.1500 also issued under 5 U.S.C. 553.

4. In Table Z–1 of § 1910.1000, the footnote attached to the entry "Cotton Dust (raw)" is removed and a footnote "e" is added to the entry "Cotton Dust (raw)" to read as follows:

§ 1910.1000 Air contaminants.

* * * * *

TABLE Z–1

Substance	p/m[a]	mg/m³[b]
* * * * *		
Cotton dust (raw)		1[e]
* * * * *		

* * * * * *

[a] This 8 hour time weighted average is for respirable dust as measured by a vertical elutriator cotton dust sampler or equivalent instrument. This time weighted average applies to the cotton waste processing operations of waste recycling (sorting, blending, cleaning, and willowing) and garnetting.

5. Section 1910.1043 is revised, except for Appendices A–D which remain unchanged, to read as follows:

§ 1910.1043 Cotton dust.

(a) *Scope and application.* (1) This section, in its entirety, applies to the control of employee exposure to cotton dust in all workplaces where employees engage in yarn manufacturing, engage in slashing and weaving operations, or work in waste houses for textile operations.

(2) This section does not apply to the handling or processing of woven or knitted materials; to maritime operations covered by 29 CFR Parts 1915 and 1918; to harvesting or ginning of cotton; or to the construction industry.

(3) Only paragraphs (h) Medical surveillance, (k)(2)–(4) Recordkeeping—Medical Records, and Appendices B, C and D of this section apply in all work places where employees exposed to cotton dust engage in cottonseed processing or waste processing operations.

(4) This section applies to yarn manufacturing and slashing and weaving operations exclusively using washed cotton (as defined by paragraph (n) of this section) only to the extent

specified by paragraph (n) of this section.

(5) This section, in its entirety, applies to the control of all employees exposure to the cotton dust generated in the preparation of washed cotton from opening until the cotton is thoroughly wetted.

(6) This section does not apply to knitting, classing or warehousing operations except that employers with these operations, if requested by NIOSH, shall grant NIOSH access to their employees and workplaces for exposure monitoring and medical examinations for purposes of a health study to be performed by NIOSH on a sampling basis.

(b) *Definitions.* For the purpose of this section:

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee;

"Blow down" means the general cleaning of a room or a part of a room by the use of compressed air.

"Blow off" means the use of compressed air for cleaning of short duration and usually for a specific machine or any portion of a machine.

"Cotton dust" means dust present in the air during the handling or processing of cotton, which may contain a mixture of many substances including ground up plant matter, fiber, bacteria, fungi, soil, pesticides, non-cotton plant matter and other contaminants which may have accumulated with the cotton during the growing, harvesting and subsequent processing or storage periods. Any dust present during the handling and processing of cotton through the weaving or knitting of fabrics, and dust present in other operations or manufacturing processes using raw or waste cotton fibers or cotton fiber byproducts from textile mills are considered cotton dust within this definition. Lubricating oil mist associated with weaving operations is not considered cotton dust.

"Director" means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

"Equivalent Instrument" means a cotton dust sampling device that meets the vertical elutriator equivalency requirements as described in paragraph (d)(1)(iii) of this section.

"Lint-free respirable cotton dust" means particles of cotton dust of approximately 15 micrometers or less aerodynamic equivalent diameter;

"Vertical elutriator cotton dust sampler" or "vertical elutriator" means a dust sampler which has a particle size cut-off at approximately 15 micrometers aerodynamic equivalent diameter when operating at the flow rate of 7.4 ± 0.2 liters of air per minute;

"Waste processing" means waste recycling (sorting, blending, cleaning and willowing) and garnetting.

"Yarn manufacturing" means all textile mill operations from opening to, but not including, slashing and weaving.

(c) *Permissible exposure limits and action levels*—(1) *Permissible exposure limits.* (i) The employer shall assure that no employee who is exposed to cotton dust in yarn manufacturing and cotton washing operations is exposed to airborne concentrations of lint-free respirable cotton dust greater than 200 $\mu g/m^3$ mean concentration, averaged over an eight-hour period, as measured be a vertical elutriator or an equivalent instrument.

(ii) The employer shall assure that no employee who is exposed to cotton dust in textile mill waste house operations or is exposed in yarn manufacturing to dust from "lower grade washed cotton" as defined in paragraph (n)(5)of this section is exposed to airborne concentrations of lint-free respirable cotton dust greater than 500 $\mu g/m^3$ mean concentration, averaged over an eight-hour period, as measured by a vertical elutriator or an equivalent instrument.

(iii) The employer shall assure that no employee who is exposed to cotton dust in the textile processes known as slashing and weaving is exposed to airborne concentrations of lint-free respirable cotton dust greater than 750 $\mu g/m^3$ mean concentration, averaged over an eight hour period, as measured by a vertical elutriator or an equivalent instrument.

(2) *Action levels.* (i) The action level for yarn manufacturing and cotton washing operations is an airborne concentration of lint-free respirable cotton dust of 100 $\mu g/m^3$ mean concentration, averaged over an eight-hour period, as measured by a vertical elutriator or an equivalent instrument.

(ii) The action level for waste houses for textile operations is an airborne concentration of lint-free respirable cotton dust of 250 $\mu g/m^3$ mean concentration, averaged over an eight-hour period, as measured by a vertical elutriator or an equivalent instrument.

(iii) The action level for the textile processes known as slashing and weaving is an airborne concentration of lint-free respirable cotton dust of 375 $\mu g/m^3$ mean concentration, averaged over an eight-hour period, as measured by a vertical elutriator or an equivalent instrument.

(d) *Exposure monitoring and measurement*—(1) *General.* (i) For the purposes of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(ii) The sampling device to be used shall be either the vertical elutriator cotton dust sampler or an equivalent instrument.

(iii) If an alternative to the vertical elutriator cotton dust sampler is used, the employer shall establish equivalency by reference to an OSHA opinion or by documenting, based on data developed by the employer or supplied by the manufacturer, that the alternative sampling devices meets the following criteria:

(A) It collects respirable particulates in the same range as the vertical elutriator (approximately 15 microns);

(B) Replicate exposure data used to establish equivalency are collected in side-by-side field and laboratory comparisons; and

(C) A minimum of 100 samples over the range of 0.5 to 2 times the permissible exposure limit are collected, and 90% of these samples have an accuracy range of plus or minus 25 per cent of the vertical elutriator reading with a 95% confidence level as demonstrated by a statistically valid protocol. (An acceptable protocol for demonstrating equivalency is described in Appendix E of this section.)

(iv) OSHA will issue a written opinion stating that an instrument is equivalent to a vertical elutriator cotton dust sampler if

(A) A manufacturer or employer requests an opinion in writing and supplies the following information:

(*1*) Sufficient test data to demonstrate that the instrument meets the requirements specified in this paragraph and the protocol specified in Appendix E of this section;

(*2*) Any other relevant information about the instrument and its testing requested by OSHA; and

(*3*) A certification by the manufacturer or employer that the information supplied is accurate, and

(B) if OSHA finds, based on information submitted about the instrument, that the instrument meets the requirements for equivalency specified by paragraph (d) of this section.

(2) *Initial monitoring.* Each employer who has a place of employment within the scope of paragraph (a)(1), (a)(4), or (a)(5) of this section shall conduct monitoring by obtaining measurements which are representative of the exposure of all employees to airborne concentrations of lint-free respirable cotton dust over an eight-hour period.

The sampling program shall include at least one determination during each shift for each work area.

(3) *Periodic monitoring.* (i) If the initial monitoring required by paragraph (d)(2) of this section or any subsequent monitoring reveals employee exposure to be at or below the permissible exposure limit, the employer shall repeat the monitoring for those employees at least annually.

(ii) If the initial monitoring required by paragraph (d)(2) of this section or any subsequent monitoring reveals employee exposure to be above the PEL, the employer shall repeat the monitoring for those employees at least every six months.

(iii) Whenever there has been a production, process, or control change which may result in new or additional exposure to cotton dust, or whenever the employer has any other reason to suspect an increase in employee exposure, the employer shall repeat the monitoring and measurements for those employees affected by the change or increase.

(4) *Employee notification.* (i) Within twenty working days after the receipt of monitoring results, the employer shall notify each employee in writing of the exposure measurements which represent that employee's exposure.

(ii) Whenever the results indicate that the employee's exposure exceeds the applicable permissible exposure limit specified in paragraph (c) of this section, the employer shall include in the written notice a statement that the permissible exposure limit was exceeded and a description of the corrective action taken to reduce exposure below the permissible exposure limit.

(e) *Methods of compliance*—(1) *Engineering and work practice controls.* The employer shall institute engineering and work practice controls to reduce and maintain employee exosure to cotton dust at or below the permissible exposure limit specified in paragraph (c) of this section, except to the extent that the employer can establish that such controls are not feasible.

(2) Whenever feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the permissible exposure limit, the employer shall nonetheless institute these controls to reduce exposure to the lowest feasible level, and shall supplement these controls with the use of respirators which shall comply with the provisions of paragraph (f) of this section.

(3) *Compliance program.* (i) Where the most recent exposure monitoring data indicates that any employee is exposed to cotton dust levels greater than the permissible exposure limit, the employer shall establish and implement a written program sufficient to reduce exposures to or below the permissible exposure limit solely by means of engineering controls and work practices as required by paragraph (e)(1) of this section.

(ii) The written program shall include at least the following:

(A) A description of each operation or process resulting in employee exposure to cotton dust at levels greater than the PEL;

(B) Engineering plans and other studies used to determine the controls for each process;

(C) A report of the technology considered in meeting the permissible exposure limit;

(D) Monitoring data obtained in accordance with paragraph (d) of this section;

(E) A detailed schedule for development and implementation of engineering and work practice controls, including exposure levels projected to be achieved by such controls;

(F) Work practice program; and

(G) Other relevant information.

(iii) The employer's schedule as set forth in the compliance program, shall project completion of the implementation of the compliance program no later than March 27, 1984 or as soon as possible if monitoring after March 27, 1984 reveals exposures over the PEL, except as provided in paragraph (m)(2)(ii)(B) of this section.

(iv) The employer shall complete the steps set forth in his program by the dates in the schedule.

(v) Written programs shall be submitted, upon request, to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, and any affected employee or their designated representatives.

(vi) The written program required under paragraph (e)(3) of this section shall be revised and updated when necessary to reflect the current status of the program and current exposure levels.

(4) *Mechanical ventilation.* When mechanical ventilation is used to control exposure, measurements which demonstrate the effectiveness of the system to control exposure, such as capture velocity, duct velocity, or static pressure shall be made at reasonable intervals.

(f) *Use of respirators*—(1) *General.* Where the use of respirators is required under this section, the employer shall provide, at no cost to the employee, and assure the use of respirators which comply with the requirements of this paragraph (f). Respirators shall be used in the following circumstances:

(i) During the time periods necessary to install or implement feasible engineering controls and work practice controls;

(ii) During maintenance and repair activities in which engineering and work practice controls are not feasible;

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the permissible exposure limits;

(iv) In operations specified under paragraph (g)(1) of this section; and

(v) Whenever an employee requests a respirator.

(2) *Respirator selection.* (i) Where respirators are required under this section, the employer shall select the appropriate respirator from Table I below and shall assure that the employee uses the respirator provided.

TABLE I

Cotton dust concentration	Required respirator
Not greater than:	
(a) 5 x the applicable permissible exposure limit (PEL).	A disposable respirator with a particulate filter.
(b) 10 x the applicable PEL.	A quarter or half-mask respirator, other than a disposable respirator, equipped with particulate filters.
(c) 100 x the applicable PEL.	A full facepiece respirator equipped with high-efficiency particulate filters.
(d) Greater than 100 x the applicable PEL.	A powered air-purifying respirator equipped with high-efficiency particulate filters.

NOTES

1. A disposable respirator means the filter element is an inseparable part of the respirator.
2. Any respirators permitted at higher environmental concentrations can be used at lower concentrations.
3. Self-contained breathing apparatus are not required respirators but are permitted respirators.
4. Supplied air respirators are not required but are permitted under the following conditions: Cotton dust concentration not greater than 10X the PEL—Any supplied air respirator; not greater than 100X the PEL—Any supplied air respirator with full facepiece, helmet or hood; greater than 100X the PEL—A supplied air respirator operated in positive pressure mode.

(ii) The employer shall select respirators from those tested and approved for protection against dust by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR Part 11.

(iii) Whenever respirators are required by this section for concentrations not greater than 100 × the applicable permissible exposure limit, the employer shall, upon the request of the employee, provide a powered air purifying respirator with a high efficiency particulate filter in lieu of the respirator specified in paragraphs (a), (b), or (c) of Table I.

(iv) Whenever a physician determines that an employee who works in an area in which the dust level exceeds the PEL is unable to wear any form of respirator,

including a powered air purifying respirator, the employee shall be given the opportunity to transfer to another position which is available or which later becomes available having a dust level at or below the PEL. The employer shall assure that an employee who is transferred from an area in which the dust level exceeds the PEL due to an inability to wear a respirator suffers no reduction in current wage rate or other benefits as a result of the transfer.

(3) *Respirator program.* The employer shall institute a respirator program in accordance with § 1910.134 of this part.

(4) *Respirator usage.* (i) The employer shall assure that the respirator used by each employee exhibits minimum facepiece leakage and that the respirator is fitted properly.

(ii) The employer shall allow each employee who uses a filter respirator, to change the filter elements whenever an increase in breathing resistance is detected by the employee. The employer shall maintain an adequate supply of filter elements for this purpose.

(iii) The employer shall allow employees who wear respirators to wash their faces and respirator face pieces to prevent skin irritation associated with respirator use.

(g) *Work practices.* Each employer shall, regardless of the level of employee exposure, immediately establish and implement a written program of work practices which shall minimize cotton dust exposure. The following shall be included were applicable:

(1) Compressed air "blow down" cleaning shall be prohibited where alternative means are feasible. Where compressed air is used for cleaning, the employees performing the "blow down" or "blow off" shall wear suitable respirators. Employees whose presence is not required to perform "blow down" or "blow of" shall be required to leave the area affected by the "blow down" or "blow off" during this cleaning operation.

(2) Cleaning of clothing or floors with compressed air shall be prohibited.

(3) Floor sweeping shall be performed with a vacuum or with methods designed to minimize dispersal of dust.

(4) In areas where employees are exposed to concentrations of cotton dust greater than the permissible exposure limit, cotton and cotton waste shall be stacked, sorted, baled, dumped, removed or otherwise handled by mechanical means, except where the employer can show that it is infeasible to do so. Where infeasible, the method used for handling cotton and cotton waste shall be the method which reduces exposure to the lowest level feasible.

(h) *Medical surveillance*—(1) *General.* (i) Each employer covered by the standard shall institute a program of medical surveillance for all employees exposed to cotton dust.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician and are provided without cost to the employee.

(iii) Persons other than licensed physicians, who administer the pulmonary function testing required by this section shall have completed a NIOSH-approved training course in spirometry.

(2) *Initial examinations.* The employer shall provide medical surveillance to each employee who is or may be exposed to cotton dust. For new employees, this examination shall be provided prior to initial assignment. The medical surveillance shall include at least the following:

(i) A medical history;

(ii) The standardized questionnaire contained in Appendix B; and

(iii) A pulmonary function measurement, including a determination of forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1), the FEV_1/FVC ratio, and the percentage that the measured values of FEV_1 and FVC differ from the predicted values, using the standard tables in Appendix C. These determinations shall be made for each employee before the employee enters the workplace on the first day of the work week, preceded by at least 35 hours of no exposure to cotton dust. The tests shall be repeated during the shift, no less than 4 and no more than 10 hours after the beginning of the work shift; and, in any event, no more than one hour after cessation of exposure. Such exposure shall be typical of the employee's usual workplace exposure. The predicted FVE_1 and FVC for blacks shall be multiplied by 0.85 to adjust for ethnic differences.

(iv) Based upon the questionnaire results, each employee shall be graded according to Schilling's byssinosis classification system.

(3) *Periodic examinations.* (i) The employer shall provide at least annual medical surveillance for all employees exposed to cotton dust above the action level in yarn manufacturing, slashing and weaving, cotton washing and waste house operations. The employer shall provide medical surveillance at least every two years for all employees exposed to cotton dust at or below the action level, for all employees exposed to cotton dust from washed cotton (except from washed cotton defined in paragraph (n)(3) of this section), and for all employees exposed to cotton dust in cottonseed processing and waste processing operations. Periodic medical surveillance shall include at least an update of the medical history, standardized questionnaire (App. B–111), Schilling byssinosis grade, and the pulmonary function measurements in paragraph (h)(2)(iii) of this section.

(ii) Medical surveillance as required in paragraph (h)(3)(i) of this section shall be provided every six months for all employees in the following categories:

(A) An FEV_1 of greater than 80 percent of the predicted value, but with an FEV_1 decrement of 5 percent or 200 ml. on a first working day;

(B) An FEV_1 of less than 80 percent of the predicted value; or

(C) Where, in the opinion of the physician, any significant change in questionnaire findings, pulmonary function results, or other diagnostic tests have occurred.

(iii) An employee whose FEV_1 is less than 60 percent of the predicted value shall be referred to a physician for a detailed pulmonary examination.

(iv) A comparison shall be made between the current examination results and those of previous examinations and a determination made by the physician as to whether there has been a significant change.

(4) *Information provided to the physician.* The employer shall provide the following information to the examination physician:

(i) A copy of this regulation and its Appendices:

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's exposure level or anticipated exposure level;

(iv) A description of any personal protective equipment used or to be used; and

(v) Information from previous medical examinations of the affected employee which is not readily available to the examining physician.

(5) *Physician's written opinion.* (i) The employer shall obtain and furnish the employee with a copy of a written opinion from the examining physician containing the following:

(A) The results of the medical examination and tests including the FEV_1, FVC, AND FEV_1/FVC ratio;

(B) The physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of the employee's health from exposure to cotton dust;

(C) The physician's recommended limitations upon the employee's

exposure to cotton dust or upon the employee's use of respirators including a determination of whether an employee can wear a negative pressure respirator, and where the employee cannot, a determination of the employee's ability to wear a powered air purifying respirator; and,

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further examination or treatment.

(ii) The written opinion obtained by the employer shall not reveal specific findings or diagnoses unrelated to occupational exposure.

(i) *Employee education and training*—(1) *Training program.* (i) The employer shall provide a training program for all employees exposed to cotton dust and shall assure that each employee is informed of the following:

(A) The acute and long term health hazards associated with exposure to cotton dust;

(B) The names and descriptions of jobs and processes which could result in exposure to cotton dust at or above the PEL.

(C) The measures, including work practices required by paragraph (g) of this section, necessary to protect the employee from exposures in excess of the permissible exposure limit;

(D) The purpose, proper use and limitations of respirators required by paragraph (f) of this section;

(E) The purpose for and a description of the medical surveillance program required by paragraph (h) of this section and other information which will aid exposed employees in understanding the hazards of cotton dust exposure; and

(F) The contents of this standard and its appendices.

(ii) The training program shall be provided prior to initial assignment and shall be repeated annually for each employee exposed to cotton dust, when job assignments or work processes change and when employee performance indicates a need for retraining.

(2) *Access to training materials.* (i) Each employer shall post a copy of this section with its appendices in a public location at the workplace, and shall, upon request, make copies available to employees.

(ii) The employer shall provide all materials relating to the employee training and information program to the Assistant Secretary and the Director upon request.

(j) *Signs.* The employer shall post the following warning sign in each work area where the permissible exposure limit for cotton dust is exceeded:

WARNING

COTTON DUST WORK AREA

MAY CAUSE ACUTE OR DELAYED

LUNG INJURY

(BYSSINOSIS)

RESPIRATORS

REQUIRED IN THIS AREA

(k) *Recordkeeping*—(1) *Exposure measurements.* (i) The employer shall establish and maintain an accurate record of all measurements required by paragraph (d) of this section.

(ii) The record shall include:

(A) A log containing the items listed in paragraph IV (a) of Appendix A, and the dates, number, duration, and results of each of the samples taken, including a description of the procedure used to determine representative employee exposure;

(B) The type of protective devices worn, if any, and length of time worn; and

(C) The names, social security numbers, job classifications, and exposure levels of employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least 20 years.

(2) *Medical surveillance.* (i) The employer shall establish and maintain an accurate medical record for each employee subject to medical surveillance required by paragraph (h) of this section.

(ii) The record shall include:

(A) The name and social security number and description of the duties of the employee;

(B) A copy of the medical examination results including the medical history, questionnaire response, results of all tests, and the physician's recommendation;

(C) A copy of the physician's written opinion;

(D) Any employee medical complaints related to exposure to cotton dust;

(E) A copy of this standard and its appendices, except that the employer may keep one copy of the standard and the appendices for all employees, provided that he references the standard and appendices in the medical surveillance record of each employee; and

(F) A copy of the information provided to the physician as required by paragraph (h)(4) of this section.

(iii) The employer shall maintain this record for at least 20 years.

(3) *Availability.* (i) The employer shall make all records required to be maintained by paragraph (k) of this section available to the Assistant Secretary and the Director for examination and copying.

(ii) Employee exposure measurement records and employee medical records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20(a)–(e) and (g)–(i).

(4) *Transfer of records.* (i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by paragraph (k) of this section.

(ii) Whenever the employer ceases to do business, and there is no successor employer to receive and retain the records for the prescribed period, these records shall be transmitted to the Director.

(iii) At the expiration of the retention period for the records required to be maintained by this section, the employer shall notify the Director at least 3 months prior to the disposal of such records and shall transmit those records to the Director if the Director requests them within that period.

(iv) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.20(h).

(l) *Observation of monitoring.* (1) The employer shall provide affected employees or their designated representatives an opportunity to observe any measuring or monitoring of employee exposure to cotton dust conducted pursuant to paragraph (d) of this section.

(2) Whenever observation of the measuring or monitoring of employee exposure to cotton dust requires entry into an area where the use of personal protective equipment is required, the employer shall provide the observer with and assure the use of such equipment and shall require the observer to comply with all other applicable safety and health procedures.

(3) Without interfering with the measurement, observers shall be entitled to:

(i) An explanation of the measurement procedures:

(ii) An opportunity to observe all steps related to the measurement of airborne concentrations of cotton dust performed at the place of exposure; and

(iii) An opportunity to record the results obtained.

(m) *Effective date.*—(1) *General.* This section is effective March 27, 1980, except as otherwise provided below.

(2) *Startup dates.*—(i) *Initial monitoring.* The initial monitoring required by paragraph (d)(2) of this

section shall be completed as soon as possible but no later than March 27, 1980.

(ii) *Methods of compliance: engineering and work practice controls.* (A) The engineering and work practice controls required by paragraph (e) of this section shall be implemented no later than March 27, 1984 except as set forth in paragraph (m)(2)(ii)(B) of this section.

(B) The engineering and work practice controls required by paragraph (e) of this section shall be implemented no later than March 27, 1986, for ring spinning operations (including only ring spinning and winding, twisting, spooling, beaming and warping following ring spinning) where the operations meet the following criteria:

(*1*) The weight of the yarn being run is 100 percent cotton and the average yarn count by weight is 18 or below;

(*2*) The average weight of the yarn run is 80 percent or more cotton and the average yarn count by weight is 16 or below; or

(*3*) The average weight of the yarn being run is 50 percent or more cotton and the average yarn count by weight is 14 or below:

(C) When the provisions of paragraph (m)(2)(ii)(B) of this section are being relied upon, the following definitions shall apply:

(*1*) The average cotton content shall be determined by dividing the total weight of cotton in the yarns being run by the total weight of all the yarns being run in the relevant work area.

(*2*) The average yarn count shall be determined by multiplying the yarn count times the pounds of each particular yarn being run to get the "total hank" for each of the yarns being run in the relevant area. The "total hank" values for all of the yarns being run should then be summed and divided by the total pounds of yarn being run, to produce the average yarn count number for all the yarns being run in the relevant work area.

(D) Where the provisions of paragraph (m)(2)(ii)(B) of this section are being relied upon, the employer shall update the employer's compliance plan no later than February 13, 1986 to indicate the steps being taken to reduce cotton dust levels to 200 $\mu g/m^3$ through the use of engineering and work practice controls by March 27, 1986.

(E) Where the provisions of paragraph (m)(2)(ii)(B) of the section are being relied upon, the employer shall maintain airborne concentrations of cotton dust below 1000 μg/MG53 mean concentration averaged over an eight-hour period measured by a vertical elutriator or a method of equivalent accuracy and precision with engineering and work practice controls and shall maintain the permissible exposure limit specified by paragraph (c)(1)(i) of this section with any combination of engineering controls, work practice controls and respirators.

(iii) *Compliance program.* The compliance program required by paragraph (e)(3) of this section shall be established no later than March 27, 1981.

(iv) *Respirators.* The respirators required by paragraph (f) of this section shall be provided no later than April 27, 1980.

(v) *Work practices.* The work practices required by paragraph (g) of this section shall be implemented no later then June 27, 1980.

(vi) *Medical surveillance.* The medical surveillance required by paragraph (h) of this section shall be completed no later than March 27, 1981 for the textile industry and no later than June 13, 1986 for the cotton seed processing and waste processing industry.

(vii) *Employee education and training.* The initial education and training required by paragraph (i) of this section shall be completed as soon as possible but no later then June 27, 1980.

(3) *Amendments.* The amendments to this section published on December 13, 1985 become effective on February 11, 1986. If the amendments are not in effect because of stays of enforcement or judicial decisions, the provisions published in 29 CFR Parts 1900 to 1910, received as of July 1, 1985 are effective.

(n) *Washed Cotton*—(1) *Exemptions.* Cotton, after it has been washed by the processes described in this paragraph, is exempt from all or parts of this section as specified if the requirements of this paragraph are met.

(2) *Initial requirements.* (i) In order for an employer to qualify as exempt or partially exempt from this standard for operations using washed cotton, the employer must demonstrate that the cotton was washed in a facility which is open to inspection by the Assistant Secretary and the employer must provide sufficient accurate documentary evidence to demonstrate that the washing methods utilized meet the requirements of this paragraph.

(ii) An employer who handles or processes cotton which has been washed in a facility not under the employer's control and claims an exemption or partial exemption under this paragraph, must obtain from the cotton washer and make available at the worksite, to the Assistant Secretary, to any affected employee, or to their designated representative the following:

(A) A certification by the washer of the cotton of the grade of cotton, the type of washing process, and that the batch meets the requirements of this paragraph;

(B) Sufficient accurate documentation by the washer of the cotton grades and washing process; and

(C) An authorization by the washer that the Assistant Secretary or the Director may inspect the washer's washing facilities and documentation of the process.

(3) *Medical and dyed cotton.* Medical grade (USP) cotton, cotton that has been scoured, bleached and dyed, and mercerized yarn shall be exempt from all provisions of this standard.

(4) *Higher grade washed cotton.* The handling or processing of cotton classes as "low middling light spotted or better" which has been washed:

(i) On a continuous batt system or a rayon rinse system.

(ii) With water,

(iii) At a temperature of no less than 60° C,

(iv) With a water-to-fiber ratio of no less than 40:1, and

(v) With bacterial levels in the wash water controlled to limit bacterial contamination of the cotton.

shall be exempt from all provisions of the standard except the requirements of paragraphs (h) Medical Surveillance, (k)(2)–(4) Recordkeeping-Medical Records, and Appendices B, C, and D of this section.

(5) *Lower grade washed cotton.* The handling and processing of cotton of grades lower than "low middling light spotted," that has been washed as specified in paragraph (n)(4) of this section and has also been bleached, shall be exempt from all provisions of the standard except the requirements of paragraphs (c)(1)(ii) Permissible Exposure Limit, (d) Exposure Monitoring, (h) Medical Surveillance, (k) Recordkeeping, and Appendices B, C and D of this section.

(6) *Mixed grades of washed cotton.* If more than one grade of washed cotton is being handled or processed together, the requirements of the grade with the most stringent exposure limit, medical and monitoring requirements shall be followed.

(o) *Appendices.* (1) Appendices B, C, and D of this section are incorporated as part of this section and the contents of these appendices are mandatory.

(2) Appendix A of this section contains information which is not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations.

(3) Appendix E of this section is a protocol which may be followed in the validation of alternative measuring devices as equivalent to the vertical elutriator cotton dust sampler. Other protocols may be used if it is demonstrated that they are statistically valid, meet the requirements in paragraph (d)(1)(iii) of this section, and are appropriate for demonstrating equivalency.

* * * * *

(Appendices A through D are unchanged and not reprinted.)

Appendix E—Vertical Elutriator Equivalency Protocol

a. *Samples to be taken*—In order to ascertain equivalency, it is necessary to collect a total of 100 samples from at least 10 sites in a mill. That is, there should be 10 replicate readings at each of 10 sites. The sites should represent dust levels which vary over the allowable range of 0.5 to 2 times the permissible exposure limit. Each sample requires the use of two vertical elutriators (VE's) and at least one but not more than two alternative devices (AD's). Thus, the end result is 200 VE readings and either 100 or 200 AD readings. The 2 VE readings and the 1 or 2 AD readings at each time and site must be made simultaneously. That is, the two VE's and one or two AD's must be arranged together in such a way that they are measuring essentially the same dust levels.

b. *Data averaging*—The two VE readings taken at each site are then averaged. These averages are to be used as the 100 VE readings. If two alternate devices were used, their test results are also averaged. Thus, after this step is accomplished, there will be 100 VE readings and 100 AD readings.

c. *Differences*—For each of the 100 sets of measurements (VE and AD) the difference is obtained as the average VE reading minus the AD reading. Call these differences D_i. Thus, we have.

$$D_i = VE_i - AD_i,\ i = 1.2, \ldots ,100 \qquad (1)$$

Next we compute the arithmetic mean and standard deviations of the differences, using equations (2) and (3), respectively.

$$\overline{X_D} = \frac{1}{N}\sum_{i=1}^{N} D_i \qquad (2)$$

$$S_D = \sqrt{\frac{\sum D_i^2 - \frac{(\sum D_i)^2}{N}}{N-1}} \qquad (3)$$

where N equals the number of differences (100 in this case), $\overline{X}_D$ is the arithmetic mean and S_D is the standard deviation.

We next calculate the critical value as $T = KS_D + |\overline{X}_D|$ where $K = 1.87$, based on 100 samples.

d. *Equivalency test.* The next step is to obtain the average of the 100 VE readings. This is obtained by equation (4)

$$X_{VE} = \frac{1}{N}\left(\sum_{i=1}^{N} VE_i\right) \qquad (4)$$

We next multiply 0.25 by $\overline{X}_{VE}$. If $T < 0.25\ \overline{X}_{VE}$, we can say that the alternate device has passed the equivalency test.

(The information collection requirements contained in the section are under consideration by the Office of Management and Budget. They will not take effect until approved.)

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