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NIOSH

Comments to DOL

COMMENTS TO OSHA DOCKET H-052E:

COTTON DUST

PROPOSED OCCUPATIONAL HEALTH STANDARD

August 1983

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

ACKNOWLEDGEMENTS

This document was developed by Roger A. Nelson, J.D. with the assistance of a NIOSH Working Group consisting of::

Robert M. Castellan, M.D.
Pervis C. Major, Ph.D.
Phillip Morey, Ph.D.
Gregory M. Piacitelli
Stephen A. Olenchock, Ph.D.
Martin R. Petersen

Valuable assistance and comments were provided by:

Paul Baron, Ph.D.
Robert Hughes
Warren Myers
Jerome Smith, Ph.D.

Policy reviews were provided by Robert Glenn, Richard Lemen, Nelson Leidel, Sc.D. and William Wagner.

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. PB90-193749
4. Title and Subtitle NIOSH Testimony on Cotton Dust Standards by R. A. Nelson, August, 1983			5. Report Date 83/08/00
			6.
7. Author(s) NIOSH			8. Performing Organization Rept. No.
9. Performing Organization Name and Address NIOSH			10. Project/Task/Work Unit No.
			11. Contract (C) or Grant(G) No. (C) (G)
12. Sponsoring Organization Name and Address			13. Type of Report & Period Covered
			14.
15. Supplementary Notes			

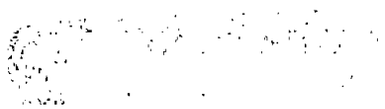
16. Abstract (Limit: 200 words) This testimony concerned the work of NIOSH in the field of controlling worker exposure to cotton dust. Chronic conditions associated with cotton dust inhalation, including byssinosis, contribute to a large extent to the total number of the respiratory system diseases found in the labor force. NIOSH supported OSHA in proposing a standard consistent with the strategy of protecting the respiratory health of workers in the cotton textile industry. NIOSH recommended that the coverage of the proposed revised standard be broadened to protect workers in several of the nontextile industries as well. Recent research mandates that the cotton ginning industry also be covered by a standard. This testimony recommended that the Permissible Exposure Limit of 1.0mg/m3 for total raw cotton dust not be relied upon alone to protect workers in the waste utilization industry from cotton dust exposure. The necessary standard should protect workers from adverse health effects from cotton dust exposure by reducing lint free respirable dust exposures to the lowest level feasible, and monitoring the health of the individual workers. The washing of cotton appeared to be a promising control strategy; NIOSH was engaged in a collaborative effort concerning the washed cotton approach to the problem.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms NIOSH-Publication, NIOSH-Author, NIOSH-Testimony, Nelson-R-A, Dust-control, Respiratory-system-disorders, Airborne-dusts, Plant-dusts, Cotton-dust, Cotton-industry

c. COSATI Field/Group

18. Availability Statement	19. Security Class (This Report)	21. No. of Pages 35
	22. Security Class (This Page)	22. Price



SUMMARY

Occupational lung disease is the number one work-related health problem facing the nation. Acute byssinosis and the chronic conditions associated with exposure to cotton dust are an important component of this problem. Indeed, the United States Public Health Service has adopted in its national objectives for 1990 a specific objective calling for the total prevention after 1985 of new cases of byssinosis in workers newly exposed to cotton dust. NIOSH recognizes that a sound strategy for prevention be based on 1) reducing the exposure of workers to cotton dust, 2) periodically monitoring the health status of cotton workers, and 3) encouraging cotton workers not to smoke.

NIOSH supports OSHA in proposing a standard consistent with this sound strategy to protect the respiratory health of workers in the cotton textile industry. The June 10, 1983 proposal preserves the most protective features of the standard promulgated on June 23, 1978 and subsequently upheld by the U.S. Supreme Court.

Based on recent research, NIOSH recommends the coverage of the proposed revised standard be broadened to protect workers in several of the non-textile industries. Recent research also mandates the coverage of the cotton ginning industry by a standard.

NIOSH recommends that the Permissible Exposure Limit (PEL) of 1.0 mg/m^3 of 29 CFR 1910.1000, Table Z-1 for total raw cotton dust not be relied upon alone to protect workers in the waste utilization industry from cotton dust exposure. A standard designed to protect workers from adverse health effects from cotton dust exposure should provide, at a minimum, the reduction of lint-free respirable dust exposures to the lowest level feasible, the monitoring of the health status of the workers.

Before OSHA considers changing the present definition of cotton dust, definitive information is needed on the active agent(s).

The washing of cotton shows promise as a control strategy. NIOSH is currently participating in a government/industry/labor collaborative research effort concerning the washed cotton approach. NIOSH comments will be part of the Industry/Government/Union Task Force, Washed Cotton Evaluation/Cotton Dust Research Task Force comments to OSHA.

INTRODUCTION

Exposure to cotton dust has long been recognized as causing the occupational respiratory disease, byssinosis. Symptoms from this disease have been described in the medical literature since early in the eighteenth century. Acute byssinosis is typified as a sensation of chest tightness, coughing and/or breathlessness starting two to three hours after returning to the workplace, on the first day back to work after an absence over a weekend or longer. In higher grades of byssinosis this "Monday phenomenon" persists into other days of the week. These symptoms are often accompanied by a loss of ventilatory capacity over a workshift, typically measured by a change in Forced Expiratory Volume in one second (FEV_1).

Schilling in 1955 (SCHILLING,1955) validated a grading system to categorize byssinosis on the basis of symptoms. Four grades have been identified, from 1/2 to Grade 3. Grade 3 is the irreversible stage of byssinosis. The symptoms of the chronic irreversible stage of byssinosis are chest tightness and/or breathlessness throughout the week. They are accompanied by evidence of permanently reduced ventilatory capacity.

In its' preamble to the 1978 standard (43 FR 27352), OSHA stated that:

> "It was the overwhelming opinion of the medical experts testifying at the hearings that byssinosis can develop into chronic obstructive pulmonary disease which is, in most cases, irreversible and disabling."

OSHA, in the present proposed standard, reiterates this conclusion by citing reports by Beck et al. (BECK,1981) in which significantly higher prevalences of respiratory symptoms and pulmonary impairment were found in active and retired cotton textile workers as compared to controls. Beck (BECK,1982) later reported on a follow-up of cotton textile workers and controls. These findings included a significantly higher prevalence and attack rate of respiratory symptoms as well as accelerated pulmonary function declines in cotton workers as compared to controls.

A strong linear relationship between total dust concentrations and byssinosis was reported in 1962 by Roach and Schilling (ROACH,1960) and in 1962 by El-Batawi (EL BATAWI,1962). Based on these studies, the American Conference of Governmental Industrial Hygienists in 1966, adopted a total cotton dust "Threshold Limit Value" (TLV) of 1 mg/m^3 ($1000\mu g/m^3$) (ACGIH,1966). This value was adopted by the Department of Labor under the Walsh-Healey Act and later by OSHA in its first promulgation of standards in 1971.

Subsequent studies in the 1970's showed that a stronger dose-response relationship existed between byssinosis and the respirable portion of the inhaled cotton dust. In 1973, Merchant et al. (MERCHANT,1973), demonstrated a clear dose-response relationship to the respirable fraction as determined from samples collected using a device known as a vertical elutriator. This device, designed to sample the lint-free portion of cotton dust, has since become the standard device for sampling cotton dust.

The Merchant et al. (MERCHANT,1973) studies of cotton textile workers presented a thorough and objective analysis of byssinosis prevalence in the

cotton textile industry. These studies covered approximately 3,000 workers employed in eight textile mills in which was found a strong association between the prevalence of byssinosis and the concentration of lint-free dust as sampled by the vertical elutriator. Prevalences of byssinosis (all grades) of 7 percent (at 100 $\mu g/m^3$), 13 percent (at 200 $\mu g/m^3$), and 26 percent (at 500 $\mu g/m^3$) were estimated in workers from the cotton preparation and yarn production areas. Lower prevalences were described in other work areas. Cigarette smokers had a steeper dose-response curve than non-smokers. This strong relationship between dust concentrations and byssinosis was the cornerstone of the 1978 OSHA cotton dust standard which was upheld by the U.S. Supreme Court in 1981 (ATMI v. Donovan, 452 U.S.490).

TEXTILE INDUSTRY

NIOSH reiterates its previous recommendation that exposure to cotton dust be reduced to the lowest concentration feasible by the use of engineering controls in order to reduce the prevalence and severity of byssinosis. NIOSH in its 1974 Cotton Dust Criteria Document, considered the lowest concentration feasible to be less than 200 $\mu g/m^3$ for yarn production areas of the textile industry.

NIOSH supports the conclusion of OSHA that the evidence of significant risk of material health impairment to workers in the textile industries is clear. The studies cited by OSHA in the preamble to the 1978 standard provide ample evidence of adverse respiratory disease impact.

NIOSH has reviewed the survey by Dr. Harold Imbus "Medical Surveillance Data in the Cotton Textile Industry" (OSHA Exhibit 175-60) and submitted its critique as supplemental comments to the OSHA Docket on September 9, 1982 (OSHA Exhibit 175-56A). NIOSH stated that results of this survey cannot be considered representative of lung disease prevalence in the cotton textile industry as a whole.

NON-TEXTILE COTTON INDUSTRIES

NIOSH reiterates its previous recommendation that exposures to cotton dust be reduced to the lowest concentration feasible and that medical surveillance procedures be implemented to ensure that workers are not developing respiratory disease and to identify workers who are developing byssinosis so that they can be removed from exposure to cotton dust before they develop irreversible impairment of lung function.

While it was demonstrated by Merchant that a strong association between cotton dust concentrations and byssinosis in the textile industry existed, there are questions remaining as to the prevalence of byssinosis in the non-textile industries.

Partly as a result of the "Benzene Decision" in 1980 (IUD v. API, 448 US 607), OSHA administratively stayed the 1978 cotton dust standard as it applied to non-textile industries in order to ascertain whether there was a significant health risk to workers exposed to cotton dust in these industries. The

non-textile industries at issue in this rulemaking are the waste utilization, the cottonseed oil mills, the cotton compress/warehousing, and the cotton classing offices. NIOSH is also considering the ginning industry in its comments.

As was noted by Merchant (MERCHANT,1973), the cotton dust dose-response relationship can be different for different textile mill operations. This is probably due to differing composition of the dust sampled in the various operations . The specific agent(s) within the dust which produces the disease is not known at present. Varying proportions of bract, fiber, trash and other extraneous materials can account for these differing dose-response relationships.

At the time of the 1977 OSHA cotton dust rulemaking studies, of dose-response relationships in the non-textile industries were limited in number. For this reason, NIOSH undertook to study the health effects found in several non-textile industries. These are of particular interest to OSHA in the context of the present cotton dust rulemaking. NIOSH conducted cross-sectional respiratory morbidity and environmental surveys of cotton gins, cotton compress warehouses, cottonseed oil mills, cotton classing offices, and the cotton waste utilization industry. NIOSH furnished final draft reports to OSHA in March 1982 and submitted final reports to the OSHA Cotton Dust Docket in September 1982.

The common respiratory health link between these non-textile industries and the textile industry is that exposure to cotton dust has the potential to produce disease. The World Health Organization Technical Report "Recommended Health-based Occupational Exposure Limits for Selected Vegetable Dusts"

(WHO,1983) noted that, for dust concentrations less than 600 $\mu g/m^3$, (vertical elutriated) the dose-response curve of byssinosis prevalence and respirable dust concentrations from Merchant's 1973 data bisected the dose response curves developed from data points from five byssinosis studies of other investigators (Lammers, Mekky, Bouhuys, Wood and Roach, and Zuskin). In view of the many potential sources of variation, the WHO Report considered it remarkable that there was such agreement between the different studies (Figure 1, page 44 of WHO,1983). The WHO, while recognizing that demonstrated exposure-response relationships did not provide any clear evidence of a threshold dust concentration below which no symptoms or functional changes would occur, recommended permissible exposure limits for several cotton processing operations. These permissible limits are based on concentrations measured by vertical elutriator and are based on the assumption that medical surveillance and reduced exposures can effectively prevent significant health effects. The WHO recommended permissible exposure limits are:

Industry	PEL
Cotton ginning	500 $\mu g/m^3$ (TWA)
Cotton waste utilization	500 $\mu g/m^3$ (TWA) (tentative)
Cottonseed oil mills	1,000 $\mu g/m^3$ (TWA) (tentative)

Studies cited by OSHA in the June 10, 1983 Proposed Standard (48 FR 26962) as well as in the 1978 Standard also provide evidence of dose-response relationships in three of the non-textile industries. While the findings from the studies cited by OSHA may not be as definitive as those of Merchant, the

implications for each non-textile industry where there are exposures to cotton dust of varying compositions must be considered. With this in mind, NIOSH has reviewed the available information on five non-textile industries in order to identify the existence of health effects and their prevalence at various exposure concentrations.

WASTE UTILIZATION INDUSTRY

NIOSH disagrees with the OSHA conclusion that workers in the waste processing industry appear to have no significant risk of impaired health. The recommendations of the 1974 NIOSH Cotton Dust Criteria Document should be used as the basis for a standard to protect workers in this industry from the demonstrated adverse respiratory health effects resulting from exposure to cotton dust. Exposure concentrations should be reduced by engineering controls to the lowest level feasible; a medical surveillance program and an employee information program should be implemented.

The cotton waste utilization industry (sometimes referred to as waste recycling) utilizes waste materials generated from other processes and clean this material for use in other industries such as mattress and other upholstery manufacturing. Of the 19 U.S. plants identified by NIOSH as processors of waste, six processed waste from synthetic textile mills exclusively and were excluded from the study. The remaining 13 plants processed both cotton waste and synthetic waste in varying degrees. While NIOSH is not required to consider feasibility in its recommendations, the results of the NIOSH Study submitted to OSHA showing that the geometric mean dust concentrations encountered in 8 of the 13 plants to be below 500 $\mu g/m^3$

can add to the understanding of this issue. The highest mean exposure level found in the plants was 1668 $\mu g/m^3$.

The cotton workers were found to have a higher prevalence of bronchitis (27.5 percent vs. 13.3 percent), 5 percent or greater shift decrements FEV_1 (28.5 percent vs. 15.6 percent), and 10 percent or greater shift decrements in FEV_1 (11.0 percent vs. 3.2 percent) than controls after matching on age and smoking status. As OSHA points out in its 10 June 1983 proposal, earlier studies of the waste utilization industry identified disease prevalence including byssinosis. All of these studies indicate that cotton dust exposure causes respiratory effects in the waste utilization industry. The WHO has tentatively recommended a permissible exposure limit of 500 $\mu g/m^3$ (vertical elutriated) dust. NIOSH reiterates the recommendations from the NIOSH Criteria Document (NIOSH,1974).

OSHA has proposed to cover the waste processing (utilization) industry under the 1910.1000 permissible exposure limit (PEL). This PEL is an 8 hour time weighted average of 1 mg/m^3 (1000 $\mu g/m^3$) based on total dust and is based on the 1968 ACGIH TLV.

As stated earlier, the health hazards presented by cotton dust exposure in the waste processing industry justify coverage under the proposed cotton dust standard of 29 CFR 1910.1043. The principal problem with relying on 1910.1000 as OSHA has proposed is that there are no medical surveillance provisions in that standard. Also, the measurement of the dust is inappropriate to the environmental hazard, namely lint-free respirable cotton dust.

Consistent with the 1974 NIOSH Criteria for a Recommended Standard for Occupational Exposure to Cotton Dust, the 1977 testimony to OSHA, and in the 1982 comments to OSHA's Advanced Notice of Proposed Rulemaking (ANPR), NIOSH continues to recommend a strong medical surveillance requirement to identify affected workers. These individuals may then be removed from the cotton dust exposure situation. Since the detection of the disease is a major means of identification and prevention of byssinosis in workers, it is important that any standard provide for this.

COTTONSEED OIL MILLS

The recommendations of the NIOSH Cotton Dust Criteria Document should be used as the basis for a standard to protect workers in this industry from the demonstrated adverse respiratory health effects resulting from exposure to cotton dust. Exposure concentrations should be reduced by engineering controls to the lowest level feasible and a medical surveillance program and employee information program should be implemented.

NIOSH disagrees with OSHA's conclusion that workers in the cottonseed processing industry appear to have no significant risk of impaired health as a result of their exposure to cotton dust. The NIOSH studies conducted between 1978 and 1980 of 723 cottonseed oil mill workers showed acute and chronic effects to exposed workers. Specifically NIOSH found that compared to matched controls cottonseed oil mill workers who smoked had excess prevalences of chronic cough and decrements of FEV_1. In addition, among smokers,

cottonseed oil mill workers had a higher prevalence of 10 percent or greater shift decrements in FEV_1 (8 percent vs. 3 percent) and a larger mean acute FEV_1 decrement than controls. The geometric mean dust concentration by plant ranged from 220 $\mu g/m^3$ to 1460 $\mu g/m^3$ (vertical elutriated). While NIOSH is not required to consider feasibility in its recommendations, the results of the NIOSH Study showing that the geometric mean dust concentrations in only 2 of the 18 cottonseed oil mills studied exceeded 1000 $\mu g/m^3$ (1 mg/m^3) can add to the understanding of this issue.

Among other studies cited by OSHA in the 10 June 1983 notice, the study by Jones (JONES,1981) reported a low prevalence of byssinosis (2.3 percent) and chronic bronchitis (4.0 percent) among workers exposed to cotton dust concentrations in excess of the then 500 $\mu g/m^3$ (vertical elutriated) OSHA standard for non-textile industries. The mean dust concentrations ranged from 300 $\mu g/m^3$ to 2,700 $\mu g/m^3$ (vertical elutriated) for 14 operations with one very high concentration of 7,600 $\mu g/m^3$ found in the one baling operation measured. Significant acute bronchoconstrictor responses on Monday that were not present on Friday of the same week were taken by the investigators as evidence of the bioactivity of the dust. The authors believed this effect warranted a reduction of dust concentrations and that their data suggested a dose-response relationship different than that described in the textile industry.

In both an Australian study by Barnes and Simpson (BARNES,1968) and an Egyptian study by Noweir (NOWEIR,1981) byssinosis was found in cottonseed processing operations where the total cotton dust concentrations were as high as 20mg/m^3 (Barnes) and 90 to 590 mg/m^3 (Noweir).

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.

The World Health Organization Study Group (WHO,1983) concluded that there is evidence of adverse health effects in the cottonseed oil mill industry from exposure to cotton dust. However, they believed the data to be too few to establish a recommended exposure limit. They did recommend that dust in this industry be considered to be more hazardous than nuisance dust and tentatively recommended a permissible level of 1000 $\mu g/m^3$ (vertically elutriated) dust.

GINNING

NIOSH has concluded that worker exposure to cotton dust in the ginning industry produces adverse health effects. This conclusion is based on the consistency of findings showing significant pulmonary morbidity among gin workers. The recommendations of the NIOSH Cotton Dust Criteria Document should be used as the basis for a standard to protect workers in the ginning

industry from the demonstrated adverse respiratory health effects resulting from exposure to cotton dust. Exposure concentrations should be reduced by engineering controls to the lowest level feasible and a medical surveillance program and an employee information program should be implemented. While NIOSH is not required to consider feasibility in its recommendations, the results of the NIOSH Study showing that the geometric mean dust concentrations for 32 of the 37 gins surveyed were below 500 $\mu g/m^3$ can add to the understanding of this issue.

As the June 23, 1978 preamble to the OSHA cotton dust in gins standard (43 FR 27420-2) indicates, the several foreign and U.S. studies of cotton ginning show clearly the prevalence of acute pulmonary effects. A major study of gins in the U.S. by Palmer et al. (PALMER,1978), while demonstrating clear evidence of acute ventilatory effects, did not provide an indication of byssinosis prevalence nor did it quantify dose and response.

In 1981, Larson et al. (LARSON,1981) reported no excess of chronic obstructive airway disease in gin operators when compared with a control group of agricultural workers not exposed to cotton dust. Symptoms of byssinosis such as cough, chest tightness and breathing difficulty were found in 13 percent of the gin workers studied, but also in 9.6 percent of the control group. There was a lack of correlation between these subjective symptoms and an objective decrease in FEV_1 during the workshift. The authors suggested that this lack of significance of change over the workshift could be due to several factors: the continuing nature of gin work without any days off during the season would

not permit the analysis of symptoms on the first day after the break ("Monday symptoms"), an important indicator of the disease; and secondly, the differences in the prevalence of byssinosis could be the result of different compositions of an active disease producing "agent" in the different operations and industries.

NIOSH in 1977 began a cross-sectional medical and industrial hygiene study of the ginning industry. Five hundred fifty-one cotton gin workers in 37 gins throughout the U.S. cotton belt and 1218 worker in non-dusty comparison plants were studied. No excess prevalence of acute byssinosis was found in gin workers compared to controls. Gin workers who had never smoked had greater prevalences of bronchitis than controls (16 percent vs. 3 percent). Gin workers who smoked also were found to have significantly lower mean before shift FEV_1 (by 0.540 liters for ex-smokers and by 0.200 liters for current smokers) than matched controls, and were also found to have a higher prevalence of FEV_1 less than 80 percent of predicted (18 percent vs. 5 percent for current smokers and 24 percent vs. 0 percent for ex-smokers). A trend of increasing prevalence of bronchitis in nonsmokers was associated with increasing dust concentrations.

These results are in many ways consistent with the previous studies of cotton gins. Although acute byssinosis like that described in cotton textile workers may not appear in gin workers, there is considerable evidence that cotton dust exposure is having an adverse effect on normal respiratory values for U.S. cotton gin workers. Respiratory symptoms, especially bronchitis among

nonsmokers, were clearly increased. The data suggests a dust and duration influence on the increase of bronchitis and respiratory disorders. Similarly, evidence of a decrease in lung function over the work shift with increasing respirable dust concentrations was observed. This is consistent with Palmer's (PALMER,1978) previous findings. Finally, base line lung function was decreased among gin workers, and significantly so among smokers. These findings are consistent with those found among cotton textile workers by Merchant (1973) and Beck (1981).

The NIOSH study results corroborate OSHA's statement in the 1978 cotton ginning standard that evidence of pulmonary effects in other U.S. cotton industry operations alone strongly suggest that cotton dust exposure may cause respiratory disease in the U.S. ginning industry. This relationship is based on the view that the etiologic agent(s) present in the dust found in all other stages of cotton processing are also found in the ginning stage. For this reason, NIOSH recommends that ginning be included under a standard designed to prevent respiratory health impairment in gin workers.

COTTON CLASSING OFFICES

NIOSH studied 609 workers in 13 of the 24 cotton classing offices operated by the U.S. Department of Agriculture and found no association of adverse respiratory health effects with exposure to cotton dust in this industry. The geometric mean dust concentrations found ranged from 70 $\mu g/m^3$ to 340 $\mu g/m^3$ (vertical elutriated) with 10 of the 13 offices having geometric means below

200 $\mu g/m^3$. The very low exposure concentrations found and the seasonal nature of the operations in the 13 Department of Agriculture classing offices studied may account for the lack of statistically significant effects, consistent trends, or any dose-response relationship for adverse health effects. NIOSH does recommend the continuation of the dust control programs which have produced the minimization of dust concentrations in the Department of Agriculture classing offices studied by NIOSH and previously reported to OSHA. This is consistent with the previous NIOSH recommendations to reduce cotton dust concentrations by engineering controls to the lowest level feasible.

COTTON COMPRESS WAREHOUSES

The lack of data demonstrating adverse respiratory health effects precludes any recommendation more specific than that of the 1974 NIOSH Cotton Dust Criteria Document.

DEFINITIONS

Cotton Dust

NIOSH believes that the OSHA definition of cotton dust is the best practical definition and should be retained for compliance purposes.

> Cotton dust is "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. . ." (29 CFR 1910.1043 (b)).

NIOSH recognizes that cotton dust is a heterogeneous particulate consisting primarily of vegetable, microbial and soil materials. As more information on the nature of active agent(s) in cotton dust becomes available from research and as the relationship of active agent(s) to adverse health effects becomes known, OSHA may wish to narrow the compliance definition of cotton dust. However, one important consequence of a narrow definition of cotton dust based on a specific active agent(s) or indicator substance must be the development of practical environmental sampling methods other than or in addition to, the collection of vertically elutriated particulate. Therefore at this time, NIOSH does not recommend any change in the compliance definition of cotton dust.

The National Cotton Council's (NCC) suggestion that the definition exclude "non-cotton dust" materials such as oil mist, mineral dust and synthetic fiber dust is impractical and unattainable. The identification and differentiation of such materials in the air is not easily or readily accomplished and would place an unreasonable burden on the employer required to monitor the work environment. Furthermore, the epidemiologic studies from which the assessment of significant risk has been determined and upon which the current OSHA Standard is based, have included many "extraneous" materials in the airborne samples from which dust concentrations are calculated and to which workers are exposed.

Washed Cotton

NIOSH in its 1977 testimony to OSHA on the then proposed cotton dust standard, indicated that the washing of cotton would reduce its "biological activity." As OSHA has indicated in its 10 June 1983 proposal, the Merchant "washed cotton" study published in 1973, presented evidence that cotton could be washed free of measurable biological activity. NIOSH is currently participating in a tripartite investigation of the washed cotton approach to

byssinosis prevention. Comments concerning these investigations and their implications for an occupational health standard are expected to be submitted to OSHA in August, 1983.

ENVIRONMENTAL MONITORING - "AREA" DEFINED

The OSHA "Cotton Dust Manual" (OSHA Instruction CPL 2-2.31 prepared by the Office of Compliance Programming) provides adequate guidance for conducting area monitoring. Specifically, Chapters VI and VII of this manual contain standardized sampling strategies and procedures for using the vertical elutriator in discrete areas of the work environments that contain airborne cotton dust. Instructions for accurately representing employee exposures are also outlined. Although originally designed for use by OSHA enforcement personnel, this manual can be appropriately modified to provide specific instructions and requirements for monitoring the workplace by the employers.

ACTION LEVELS

OSHA in its 10 June 1983 proposed standard, proposes to incorporate an Action Level into the cotton dust standard. NIOSH in its comments of 26 March 1982 to the OSHA cotton dust ANPR of 9 February 1982, recommended that no action level be set for cotton dust.

EXPOSURE MONITORING AND MEASUREMENT

Methods of Exposure Measurement

OSHA has raised the question of what is an acceptable demonstration of equivalency of an alternate sampling method to the standard vertical elutriator method. The final report of the OSHA-contracted protocol for equivalency of sampling devices to the vertical elutriator, by Wadsworth and Rockette submitted to the Docket has been reviewed by NIOSH. NIOSH has no potential problem with the statistical assumptions presented. OSHA is to be commended in seeking the advice of experts in this complex area. NIOSH in the past has assisted OSHA in the review of variance requests where the issue has been equivalency of the instrument or method to the vertical elutriator.

An issue OSHA will have to eventually address is the calibration of the device to a particular work area. There is evidence that the composition and size distribution of cotton dust can vary widely between plants and between work areas within the same plant.

The response of the scattered light aerosol measurement devices being used at this time is a function of the size distribution of the aerosol being measured. Some devices attempt to compensate for size distribution changes. Other devices proposed as vertical elutriator equivalents may have a more severe particle size dependence for their response. Their calibration can drastically change for the different work areas measured. Any protocol for

the evaluation of equivalence must give clear guidance for the determination and application of calibration factors for different work areas. Some guidance must also be given for the periodic redetermination of these calibration factors to account for any temporal changes in calibration or in the environment itself.

A factor in determining the equivalency of a sample collection system to the vertical elutriator is the collection of the same particle size. NIOSH has recently made measurements of the penetration curve of the vertical elutriator up to 20 um and these measurements agree with those semi-empirically predicted by Robert (ROBERT,1980) and those made by Rubow and Marple (RUBOW,1983). NIOSH is attempting to develop a personal size selective sampler with penetration characteristics similar to the vertical elutriator. However, due to the limitations of flow rate imposed by personal sampling pumps (generally 2.0 or less liters per minute), these personal monitors will probably not be able to measure concentrations much below 200 $\mu g/m^3$.

Frequency of Exposure Monitoring

The purpose of a worker exposure monitoring program is to measure the exposure of each worker so that the exposure to the substance is known quantitatively, with a suitable degree of confidence under all work conditions. Ideally, this is accomplished by daily full-shift exposure measurements of each worker with the use of personal dosimeters that integrate over short periods through the exposure period defined by the standard, so that the concentration of the substance actually breathed by the worker is what is measured.

This approach, however, imposes a substantial burden on the employer and the employee without increasing the protection to the employee (LYNCH et al.,1978). In order to ideally determine the concentration of dust which is likely to enter the worker's respiratory system, the dust sample should be taken near the breathing zone. In order for this measurement to produce a meaningful result, the sample actually collected must correspond closely to what the standard itself is based on. For cotton dust samples, this means vertically elutriated dust sampled with a vertical elutriator. The vertical elutriator is too large to be used in a personal sampling scheme; therefore, one must rely on stationary area samples to produce an approximation of what is breathed by the worker (NIOSH,1974).

The frequency of sampling likewise represents a compromise with the ideal sampling strategy. Ideally, one would want samples taken everyday in order to account for the variability of the substance encountered in the environment. This variability could result from seasonal changes (the windows in the plant being closed in the winter, slight changes in the day-to-day operations, decreases in efficiency of engineering control measures over time, or from processes changes). For this reason, NIOSH in the Standards Completion Program recommended a sampling frequency of once every 3 months. This frequency would provide an employer with some level of statistical confidence that employee exposure is not exceeding the permissible exposure (LYNCH,1978), (LEIDEL,1975). It is important to closely monitor the environmental dust concentrations to identify any trends of increasing dust exposure.

NIOSH has also recommended that full-shift sampling be required when measuring worker exposure levels. Full-shift samples allow an accurate indication of a worker's true exposure during the work shift; less than full-shift samples are more subject to the variability of dust emissions (LEIDEL,1977).

Also there is evidence that dust concentrations vary between shifts in multi-shift industrial operations including the cotton processing industry and that workplace monitoring is necessary to measure these different concentrations. The requirements for multi-shift, multi-area and full-shift sampling are intended to insure that the exposure monitoring is truly representative of every employee's exposure over the entire work period. Their specific inclusion in the regulations are critically important for effectively measuring and controlling worker exposures to cotton dust.

The American Textile Manufacturers Institute (ATMI) submitted a report (OSHA exhibit 175-41) as its supplemental comments to the OSHA ANPR on cotton dust. This report included a statistical analysis by Dr. Suh of Burlington Industries of workplace exposure data gathered by ATMI. The purpose of the analysis was to demonstrate a method where a known single shift average could be used to predict a "true-day" average of all three shifts. However, this method does not consider that it is the specific measured concentrations which are required to be lower than the PEL. The evidence presented by ATMI to justify this method is not persuasive. NIOSH agrees with OSHA that this report must be regarded as inconclusive until further information is available.

Although NIOSH does not recommend an action level, the following would be the implications of an action level as it relates to exposure measurements. It has been suggested that in using the action level scheme, exposure measurements should be curtailed if two successive measurements are below the action level. It should be pointed out though, that as environmental exposure variability increases, the use of the decision process of the action level can result in premature discontinuation of periodic sampling. The decision to discontinue exposure sampling after two consecutive measurements in a high variability environment can result in a high probability of having workers receive excessive exposures without the ability to detect them by sampling. A better approach suggested by Tuggle (TUGGLE,1981) would allow all of the measurements collected to be used in the decision rather than relying only on the last two measurements. This assumes that no process changes have occurred, a necessary assumption in applying this scheme.

USE OF RESPIRATORS

NIOSH has consistently recommended that the most protective approach to prevent worker exposure to hazardous agents is to provide an uncontaminated work environment. The hazardous substance should be prevented from entering the work environment in the first place. This is often the most straightforward approach. The second line of prevention is the removal of the contaminant from the workplace. Respirators should be used primarily as an

adjunct to and not as a substitute for maintaining an uncontaminated work environment. NIOSH supports the 1978 cotton dust standard in requiring this approach.

In those circumstances where respirators are permitted, they must be used in a well-designed respirator program. NIOSH has made recommendations for respirator usage conditions in the NIOSH Cotton Dust Criteria Document. Many of these recommendations were incorporated in the 1978 OSHA cotton dust standard. NIOSH continues to support the overall provisions of the 1978 standard, although as shall be pointed out later in these comments the assumptions behind these provision need to be reexamined in light of new information. At the present time, NIOSH views the changes that OSHA has proposed in the respirator provisions of the proposed standard as useful. Users should find the requirements to be clearer.

The foundation for the respirator provisions of the cotton dust standard and for other toxic substance standards as well is the table of appropriate respirators. This respirator table specifies the maximum concentrations for which the several classes of respirators can be used and still provide

protection to the workers wearing them. These maximum concentrations are calculated from the PEL multiplied by a numerical "Protection Factor."

The protection factor is assigned to a particular class of respirators based on certain derived measures of the ability of the device to prevent the workplace contaminant from reaching the worker's breathing zone inside the device. These protection factors were derived primarily from tests performed by Hyatt (HYATT,1976) and were the basis of many NIOSH recommendations to OSHA for the proper respirator selection.

It has been difficult to quantify the difference between the protection factor assigned to a particular respirator in a class and the actual protection achieved by a wearer wearing the device. OSHA should consider this discrepancy in specifying respirator selection requirements.

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PREVIOUS NIOSH SUBMISSIONS
TO OSHA ON COTTON DUST

as of July 1983

26 SEP 74 Criteria for a Recommended Standard - Occupational Exposure to Cotton Dust

APR 77 NIOSH Testimony at OSHA public hearing on the then proposed cotton dust standard

FEB 82 NIOSH Cottonseed Oil Mill Study Draft Report (20 Nov 81) (OSHA Exhibit 175-56)

MAR 82 NIOSH Comments on the OSHA cotton dust Advance Notice of Proposed Rulemaking (ANPR) Docket (H-052C). These comments consisted of five attachments:

Attachment A Comments addressing specific questions raised by OSHA ANPR of 9 Feb. 1982

Attachment B Characterization of Byssinosis and Other Pulmonary Abnormalities in the Cotton Waste Utilization Industry, Draft Report; NIOSH, DRDS, (Nov. 1981)

Attachment C Respiratory Disorders and Dust Exposure in Sectors of the Cotton Industry of the United States - Part 1: Cotton Gins; NIOSH, DRDS, (Nov. 1981)

Attachment D Appendix to Characterization of Byssinosis and Other Pulmonary Abnormalities in the Cotton Waste Utilization Industry and Respiratory Disorders and Dust Exposure in Sectors of the Cotton Industry of the United States - Part 1: Cotton Gins; NIOSH, DRDS, (Nov. 1981)

Attachment E Classification of Clinical Manifestations and Lung Function Changes in Respiratory Disorders from Exposure to Vegetable Dusts Causing Byssinosis or Respiratory Tract Irritations; assembled by NIOSH 26 March 1982

9 SEP 82 Supplemental Comments to OSHA Docket H-052C reviewing "Medical Surveillance Data in the Cotton Textile Industry" by Harold Imbus. (OSHA Exhibit 175-56A)

1 OCT 82 Comments on OSHA Proposed Stay for Knitting Operations (H-052D). This was a NIOSH review of "Analysis of Pulmonary Function Data of Knitting Industry Workers" report by Boehlecke and Batigelli.

3 JAN 83 Transmittal to OSHA Docket H-052C of 4 NIOSH Reports of studies of 4 non-textile industries:

Part 2: Cotton Compress Warehouses (Sep. 1982)

Part 3: Cottonseed Oil Mills (Sep. 1982)

Part 4: Cotton Classing Offices (Sep. 1982)

Cotton Waste Utilization Industry with Addendum (Oct. 1982)