

# Testimony to DOL

TESTIMONY OF THE
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
ON THE
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION'S
PROPOSED RULE ON
OCCUPATIONAL EXPOSURE TO CADMIUM

29 CFR Part 1910 Docket No. H-057a

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16. Abstract (Limit: 200 words) This testimony summarizes the porule on cadmium (7440439). NIOSH supports the postassociated with increased incidence of lung cand Because cadmium is a potential occupational carcin should be reduced to the lowest feasible level. engineering controls and work practices instead of respiratory protection, for controlling exposures testimony to specific areas covered in the propose medical surveillance, medical screening requirements of specific control methods is considered for production, and pigment production.	tion of OSHA that exposer, emphysema, and knogen, occupational exposers of the NIOSH strongly records to cadmium. NIOSH drule including respite, and exposure monitor	sure to cadmium is idney dysfunction. posures to cadmium mmends the use of uipment, including responds in this ratory protection, ing frequency. Use					
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I am Richard A. Lemen, Assistant Director of the National Institute for Occupational Safety and Health. With me today are senior staff from NIOSH. NIOSH is pleased to have this opportunity to testify in support of the Occupational Safety and Health Administration (OSHA) proposed rule on cadmium.

#### I. BACKGROUND

The National Institute for Occupational Safety and Health (NIOSH) has reviewed the Occupational Safety and Health Administration's (OSHA's) proposed changes (55 FR 4052) to its existing regulation for occupational exposure to cadmium in the general, construction, agriculture, and maritime industries [29 CFR 1910.1000 (Table Z-2), 29 CFR 1926, 29 CFR 1928, 29 CFR 1910.252(f)(1)(v) and (f)(9)].

For general industry, the current OSHA standard for cadmium is [29 CFR 1910.1000]:

	PEL"	<u>Ceiling</u>
Cadmium fume	$100 \ \mu \text{g/m}^{3**}$	$300  \mu \mathrm{g/m^3}$
Cadmium dust	$200 \mu g/m^3$	$600  \mu \text{g/m}^3$

<sup>\*</sup>Permissible exposure limit

For construction, the current OSHA standard is 100  $\mu g/m^3$  measured as cadmium oxide fume [29 CFR 1926].

OSHA proposes two alternative 8-hour (hr) time-weighted average (TWA) permissible exposure limits (PELs) for cadmium (all forms) (55 FR 4052):

		PEL_	EL***	AL****
Alternative	1	$1 \mu g/m^3$	$5 \mu \text{g/m}^3$	$0.5  \mu \rm g/m^3$
Alternative	2	$5 \mu g/m^3$	$25 \mu g/m^3$	$2.5 \ \mu g/m^3$

<sup>\*\*\*\*</sup>Excursion limit - measured over a 15-minute period \*\*\*\*\*Action level

NIOSH supports OSHA's assessment that exposure to cadmium is associated with the increased incidence of lung cancer, emphysema, and kidney dysfunction. In the 1976 criteria document on cadmium, NIOSH recommended that workers not be exposed to cadmium or its compounds at concentrations greater than 40  $\mu$ g Cd/m³ as an 8-hr TWA and 200  $\mu$ g/m³ during any 15-minute period [NIOSH 1976]. This standard was recommended by NIOSH to prevent the chronic health effects of

<sup>\*\*</sup>Micrograms of cadmium per cubic meter of air

cadmium on the respiratory system and on the kidneys, and to prevent the acute effect of pulmonary edema. The criteria document also mentioned "...some inconclusive evidence of hypertension, cancer, and neonatal anomalies from cadmium exposure." However, the NIOSH recommended standard was not based on these effects.

In a 1984 Current Intelligence Bulletin (CIB), NIOSH concluded that cadmium is a potential occupational carcinogen and that exposures should be reduced to the lowest feasible level [NIOSH 1984a]. This determination of carcinogenicity was based on human epidemiological and animal toxicological data that were published subsequent to the development of the criteria document.

#### II. NIOSH STATEMENT OF POLICY

Because cadmium is a potential occupational carcinogen, occupational exposures to cadmium should be reduced to the lowest feasible level [NIOSH 1984a]. Lowering the TWA PELs from the current standards to either 1  $\mu g/m^3$  or 5  $\mu g/m^3$ (8-hr TWA) will substantially reduce risk. However, even at these levels, which may be the lowest feasible at the present time, the level of excess cancer deaths estimated by OSHA would still be excessive. OSHA estimates the total cancer risk to be 2.1 excess deaths per 1000 if exposures are reduced to an 8-hr TWA of 1  $\mu g/m^3$ . OSHA has estimated that 66,000 workers are potentially exposed to cadmium in the construction industry (not including demolition workers) and NIOSH has estimated that for all industry sectors (excluding agriculture and mining) more than 220,000 different workers are potentially exposed to cadmium-containing compounds (see Appendices 1-4 of the NIOSH comments). If these 220,000 exposed workers were to be exposed at a standard of 1  $\mu$ g/m<sup>3</sup> for a working lifetime, an excess of 440 deaths would be expected for these potentially exposed workers according to OSHA's risk assessment based on the Takenaka [1983] data. As it becomes feasible to control exposures to levels lower than are presently possible, NIOSH would recommend that such levels be required.

NIOSH strongly recommends the use of engineering controls and work practices instead of personal protective equipment (PPE), including respiratory protection, for controlling exposures to cadmium. In its statements to the OSHA docket on methods of compliance (hierarchy of controls), NIOSH concluded that respirators should be worn only when engineering controls are not feasible in controlling exposures [NIOSH 1983a; 1989a].

#### III. NIOSH RESPONSE TO SPECIFIC SECTIONS OF THE PROPOSED RULE

NIOSH has the following response to specific sections of the proposed rule:

#### 1. Respiratory Protection (55 FR 4122)

Respiratory protection may be required as supplementary protection for workers when engineering controls are not feasible for reducing exposures

to below the OSHA PEL or EL. For example, respirators may be required during emergency situations, some maintenance operations, some demolition work, or while engineering controls are being installed.

NIOSH agrees with the OSHA assessment of the many problems associated with the use of respirators and supports minimizing their use (55 FR 4110). NIOSH has provided to OSHA a detailed explanation of the problems associated with respirator use in our most recent comments to the docket on methods of compliance [NIOSH 1989a].

NIOSH concurs with the OSHA assessment that intermittent users of respirators should not be exempt from medical screening because these "users need to be evaluated for their fitness to wear respirators as well" (55 FR 4112). Use of respiratory protection creates a physiological burden on the user [NIOSH 1989a]. This remains true whether use is intermittent or constant, voluntary or mandatory. For these reasons, NIOSH recommends that OSHA not exempt the proposed (55 FR 4112) medical evaluation of those workers who voluntarily choose to wear respirators to reduce exposures [NIOSH 1989a].

Because cadmium is a potential occupational carcinogen, NIOSH recommends the use of the most protective respirators. These respirators are [NIOSH 1987a]:

- Any self-contained respirator equipped with a full facepiece and operated in a pressure-demand or other positive-pressure mode, or
- (2) Any supplied-air respirator equipped with a full facepiece operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure-demand or other positive-pressure mode.

If respirators other than these are permitted, NIOSH recommends the use of the assigned protection factors (APFs) in the NIOSH Respirator Decision Logic [NIOSH 1987a]. The NIOSH APF is 50 for full facepiece powered airpurifying respirators, rather than the APF of 250 that is proposed.

#### 2. Medical Surveillance (55 FR 4124)

#### Confidentiality

In the proposed rule OSHA would require employers to maintain the medical records generated by the required preplacement, annual, and termination medical examinations. NIOSH recommends that this section explicitly address the various responsibilities of the employer and the physician with regard to confidentiality. NIOSH recommends the maintenance of medical records at the worksite only when the company employs medical professionals on site to maintain the records and ensure that confidentiality is not violated.

The employer should be entitled to receive and maintain (separate from the medical record) a copy of the physician's general opinion regarding the suitability of the worker for continued occupational exposure to cadmium and any work restrictions. In addition, biological monitoring tests (blood and urine cadmium) that assess absorption by measuring the concentration of the substance (or a metabolita) in body fluids should be available to the employer because such information helps assess workers' absorption of cadmium.

#### Medical screening requirements

The medical screening requirements in Section (l)(2)(ii)(B) of the proposed standard require a "complete physical examination" with "emphasis on" various anatomical systems. The following specific comments relate to the medical screening requirements in the proposed standard:

- (1) The blood pressure should be taken; the remainder of the cardiovascular examination as proposed may not be relevant in screening for cadmium toxicity.
- (2) Cadmium-related musculoskeletal effects are rare and require long or very high exposures, often in combination with dietary deficiencies or renal disease [Thun et al. 1989; Kjellstrom 1986]. Because other effects occur much earlier and are detectable by more sensitive tests, it is not necessary to screen for musculoskeletal disorders.
- (3) If the complete blood count is normal, physical examination of the hematological system may not be relevant for screening purposes.
- (4) Because prostate cancer has been associated with exposure to cadmium, the requirement for a rectal examination is appropriate to screen male workers over age 40 for prostate cancer. NIOSH is not aware of other genitourinary health effects known to be associated with cadmium that are likely to be detected by physical examination of workers.

In addition, some of the medical tests required under the proposed standard, particularly liver enzymes and microscopic examination of urinary sediment, may not be useful in screening for cadmium-induced damage. Other tests, particularly blood urea nitrogen and serum creatinine, should be obtained for baseline examination (and in the termination examination), but need not be repeated during periodic screening examinations of healthy workers.

The proposed standard would require in Section (l)(4)(i)(E) that certain actions be triggered by repeated diagnoses of upper or lower respiratory infections (presumably acute); such diagnoses are seldom related to cadmium exposure and therefore would not be useful as triggers for intervention.

#### The questionnaire (Appendix D)

NIOSH recommends that only a respiratory questionnaire be used in medical screening related to cadmium exposure; questions 3-9 and 26 of the proposed questionnaire relate to the respiratory system.

#### Screening for respiratory health effects

#### Non-malignant respiratory health effects

NIOSH agrees that screening for obstructive diseases of the airways (e.g., emphysema) is best accomplished with pulmonary function tests. Section  $(\ensuremath{\mathcal{l}})(2)(ii)(D)$  requires determination of forced vital capacity (FVC) and forced expiratory volume at 1 second (FEV $_1$ ). NIOSH recommends that the largest FVC, largest FEV $_1$ , and the ratio of the largest FEV $_1$  to the largest FVC (FEV $_1$ /FVC%) from each worker's pulmonary function examination should each be compared to the lower limit of normal (LLN or 95th percentiles) cutoff for the respective parameter using Knudson's [1983] reference values and 95th percentiles (See Attachment--Tables 1, 2, and 3 for males, and Tables 4, 5, and 6 for females).

When previous test results for a worker are available, in addition to comparing the current results with predicted values, a physician should determine if any significant change in pulmonary function results has occurred. The Attachment describes one method of interpreting longitudinal changes in  $FEV_1$  for workers whose current pulmonary function tests are still within the normal range. While this method is offered for consideration, NIOSH is continuing to refine the method used to determine excessive decrements in pulmonary function over time.

#### Lung Cancer

NIOSH does not currently recommend screening for lung cancer because it has not been established that such screening is beneficial to those screened. While chest radiograph and sputum cytological examination are capable of detecting lung cancer in an early stage, the low yield of cancers found among asymptomatic individuals and the lack of convincing evidence that early screening decreases lung cancer mortality, has led to a consensus that current evidence does not support routine screening for lung cancer among asymptomatic persons. This also is the official policy of the American Cancer Society, the National Cancer Institute, the Food and Drug Administration, the American College of Radiology, the Royal College of Radiologists, and the World Health Organization [USPSTF 1989].

#### 3. Exposure Monitoring Frequency (55 FR 4121)

NIOSH recommends that initial and periodic (at least quarterly) exposure monitoring be conducted in all workplaces where workers may be exposed to

cadmium [NIOSH 1987b]. Because there is no safe level of exposure to a potential occupational carcinogen, NIOSH recommends omitting the proposed provision that periodic monitoring can be discontinued when the "...periodic monitoring indicates that employee exposures are below the action level and that result is confirmed by the results of another monitoring taken at least seven days later..." (55 FR 4121). Moreover, exposure levels will vary because of day-to-day fluctuations in the manufacturing processes. Also, the measurement of exposure levels may not be consistently accurate because some exposures are of short duration (e.g., welding) and because there are inherent sampling variability and measurement inaccuracies.

#### 4. Sampling and Analytical Methods (55 FR 4138)

NIOSH has previously submitted its comments to OSHA on the proposed analytical methods for cadmium (ID-189, ID-189GF) [NIOSH 1989b]. In these comments, NIOSH indicated that the OSHA methods are appropriate for use with the proposed alternative OSHA standards (i.e., both the 8-hr TWAs of 5  $\mu \text{g/m}^3$  and 1  $\mu \text{g/m}^3$  and their associated ELs and ALs).

As a result of additional consideration regarding limits of detection, NIOSH recommends that OSHA make the following changes to improve the methods (55 FR 4138):

- 1) ID-189 (Section 6.5.2) Change "0.02" to "0.005"
- 2) ID-189GF (Section 6.5.2) Change "1.0" to "0.02"

These changes ensure that standard solutions will be prepared at the "qualitative detection limit" of each method (as stated in Section 2.1 of each method). Otherwise, it will not be possible to calibrate the analytical instruments for concentrations near the action level.

#### IV. CONTROL OF CADMIUM EXPOSURES

#### Introduction

Occupational exposures are controlled by a number of well-known techniques as summarized in Table I. As this table indicates, these controls may be applied at the hazard source, to the general work environment, and at or near the point of worker exposure. A system of control measures is usually necessary, with controls applied at all three points to provide adequate flexibility and reliability.

In general, more toxic materials require more stringent and more reliable controls. The selection of a strategy for controlling exposures in a process or operation of interest is a critically important first step. The control of highly toxic materials, such as cadmium, requires the careful application of a

Table I. Principles of Control

Point of Application of the Control Measure	Examples of Control Measures
At or near the hazard source	Substitution of non-hazardous or less hazardous materials
	Process modification or substitution
	Equipment selection and modification for containment
	Wet processing to reduce dust formation
	Isolation of the source and automation of operations
	Local exhaust ventilation
	Work practices to maintain containment and control effectiveness
To the general workplace environment	Dilution ventilation
	Local room air cleaning devices
	Work practices such as housekeeping
At or near the worker	Careful work practices and personal hygiene
	Isolation of workers in booths, cabs, etc.
	Personal protective equipment
Other measures for hazard control	Management commitment to controlling exposures
	Workplace and process monitoring systems with feedback
	Training of workers and supervisors
	Preventive maintenance of equipment and controls
	Ergonomically sound designs

system of controls, beginning with material and process substitution, and relying on containment as the principle control measure. Local ventilation is an essential adjunct to this containment.

NIOSH has studied the controls that were successfully implemented for reducing exposures to vinyl chloride to low levels [NIOSH 1978]. There are several lessons from this experience that are applicable to cadmium exposure:

- 1. The technology-forcing aspects of the OSHA standard (29 CFR 1910.1017) of 1 ppm (8-hour TWA) for vinyl chloride resulted in an appreciable degree of innovation, which allowed for easier and more effective control than might have seemed possible based on the previous state of control in this industry.
- 2. The selection of an appropriate control strategy by individual plants was a critical factor in the success of the controls. The use of local ventilation was described as follows [NIOSH 1978]:

"For vinyl chloride, the principle control strategy was the use of sealed processing equipment to contain the vinyl chloride monomer. Leak detection systems were used to help assure the reliability of the containment. Local ventilation was used as an adjunct, typically on an as-needed basis. Ventilation was not used as a principle control strategy to achieve the very low exposure levels required for vinyl chloride."

3. The selection of a control strategy that involved process modifications and containment within sealed equipment had the additional advantages of reducing environmental emissions and of preventing possible exposures to downstream users of the product. For example, the exposures of downstream users of bulk PVC resin were controlled by stripping the unreacted monomer at the relatively few points of manufacture, rather than relying on containment or local ventilation at the much larger number of points of

These same principles also apply to the control of cadmium. Technological innovation based on strategy of containment within sealed equipment should allow control of both occupational exposures and environmental emissions of cadmium to very low levels, as was done with vinyl chloride monomer.

#### Control of Cadmium Exposures

The following is a discussion of control technologies for different cadmiumusing processes that have been evaluated by NIOSH.

Cadmium Plating--Electrolytic plating of cadmium has inherently low exposures because it is a wet process. A NIOSH study of cadmium operations (plating report) included evaluations of controls and exposures for four cadmium cyanide baths at two different plating shops [NIOSH 1984b]. Sampling results were generally below the detection limit of 2  $\mu$ g/m³, even for "worst case"

samples taken directly over the plating bath. Additional controls, such as floating plastic balls or other mist suppressants, were not used in these tanks, but had they been used, they might have further reduced exposures.

One additional source of exposure in cadmium plating operations may be the weighout of dry cadmium or cadmium salts for the plating bath. A cost-effective solution for this exposure source would be the receipt of the cadmium in slurry or solution form to prevent dusting. Weighout or volumetric measurement could be done in a laboratory hood (or similar ventilated enclosure).

Mechanical plating of cadmium is inherently more difficult to control than electrolytic plating because it involves handling cadmium powder. Because of this, one control option is to substitute electroplating for mechanical plating of cadmium parts as much as possible. Heavier electroplating, combined with a slightly greater clearance between threaded fittings (to compensate for possible nonuniform deposition of cadmium electroplate on threads), may permit the substitution of electroplating for mechanical plating in many cases. This process substitution has the additional advantage of reducing exposures from cadmium dust that could be emitted from mechanically plated fasteners during their end use.

When mechanical plating is necessary, there are still cost-effective control options. For example, the following processing step is described in the literature [PACE 1990]:

"The cadmium powder is received in 100-pound metal cans. The cans are opened in a ventilated sandblast booth, which is a simplified type of glove box; the required amount of cadmium is weighed in paper bags. The paper bags are placed in the barrel intact. The acid disintegrates the paper."

Rather than using a ventilated drum dump station, one alternative control would be to purchase prebagged cadmium from the supplier (e.g., in 10-pound bags), and to add the bags directly, without opening, to the mixer. Should there be some weighout required to obtain the exact amount of cadmium for the batch (i.e., if the required batch size is not in an even 10-pound increment), a relatively small laboratory hood should suffice. There is precedent for the use of such technology from other industries [NIOSH 1980]. It should be technologically easier for the relatively few suppliers of cadmium powder to install bagging machines for packaging their product than for each plating plant to install weighout and drum-dumping stations. Also, the problem of contaminated drums would be avoided.

In the event that a new mechanical plating plant were being built, additional opportunities would be presented to employ isolation, automation, and containment of hazardous operations. The use of double mechanical seals on rotating equipment (such as the plating barrel) provides a highly reliable degree of containment. Provisions could be made for automatically emptying the barrel, for rinsing the residual cadmium from the coated parts, and for

recovering the cadmium, all in an isolated area. A "clean plant" design to permit periodic washdown to a sump for treatment would prevent accumulation of dust.

Stabilizer Production -- OSHA has estimated that 80% of stabilizer is produced in a wet process [JACA 1988], which is inherently easier to control than is a dry process (used for the other 20%). Stabilizers produced by the wet processor using less toxic metals should, when possible, be substituted for those produced by the dry process. The major source of exposure in the wet process has been identified [PACE 1990] as the initial feeding of dry material into the reactor. NIOSH has described technology whereby bags made of product-compatible packaging (e.g, polyvinyl alcohol) can be dumped directly, without opening, into the reactor [NIOSH 1980]. Although the use of this technology may not have been demonstrated for stabilizer production, it could potentially provide a safe and economical alternative to drum handling and dumping. Another alternative is the use of the automated bag dumping machine, in which bags are fed onto a conveyor and are automatically slit, emptied, and disposed of inside a ventilated enclosure. NIOSH researchers evaluated one asbestos bag-opening and emptying operation that showed dust levels in the range of 1 to 4  $\mu$ g/m³ [NIOSH 1984c].

In the production of solid stabilizers, a spray drying or prilling process instead of a flaking/crushing/grinding process may provide for more effective containment of cadmium dust. If materials could be packaged in product-compatible bags for use by the end users, then downstream exposures would also be reduced.

Pigment Production--As with stabilizer manufacture, processing steps that are amenable to isolation, automation, and enclosure should substantially reduce exposures compared to the present processing scheme. Examples include substitution of centrifuges for filter presses; use of spray drying instead of tray or pan drying; the production of liquid formulation rather than of powders. Rather than using elaborate "piston flow" ventilation systems for a new plant [PACE 1990], the preferred approach would be to contain the cadmium pigment in sealed equipment.

#### V. NIOSH EVALUATION OF OSHA RISK ASSESSMENT

Regarding its risk assessment, OSHA requested comments on the quality of the Takenaka et al. [1983] and Thun et al. [1985] studies, the appropriate risk assessment model to use for each data set, the effect of particle size distribution on risk assessment, the assumptions involved in absolute and relative risk models, logistic regression analysis for kidney dysfunction, and control of confounding factors in the analysis of kidney dysfunction (55 FR 4080).

#### Thun versus Takenaka Studies

It is generally preferable, when possible, to base risk assessments on both animal and human data, as OSHA has done. Both studies are scientifically

sound and appropriate as sources of information for quantitative risk assessment. There are tradeoffs in relying on either data source as the basis for the risk assessment. Using the Takenaka study requires interspecies extrapolation, which always involves a high degree of uncertainty. On the other hand, relying on the Thun study introduces uncertainties related to the estimation of cadmium exposures and the influence of potentially confounding variables (e.g., smoking and arsenic). Reliance on the Thun study may result in an underestimation of risk because this study relied on comparisons with the U.S. population. The NIOSH cadmium cohort had a large proportion of Hispanics relative to the proportion of Hispanics in the U.S. population. Hispanics are known to experience lower lung cancer rates than the U.S. population [Savitz 1986].

The risk estimates derived from these two studies are similar. For the cadmium proposed rule, there is no scientific reason to choose to base the risk assessment on one data set in preference to the other. However, NIOSH agrees with OSHA's decision to base health policy on the Takenaka data because that is more protective of workers.

#### Multistage Model

NIOSH agrees with the OSHA reliance on the multistage model as providing the "best" estimate of risk based upon the animal bioassay data. This approach is consistent with current risk assessment philosophy and practices at NIOSH and elsewhere in the federal government. As OSHA points out, other models provide an equally good fit to the data and it is not possible from a statistical viewpoint to determine which is the preferred model.

#### Particle Size

Comments were requested on whether different lung disease risks would be posed by different size particles and whether regulation should address particle size distribution. There is sufficient information available indicating that deposition of particulates in the respiratory tract is a function of particle size distribution (e.g., Rudolf et al. [1988], Ann Occup Hyg 32:919-938). Thus, one would expect that the risk of lung cancer and nonmalignant respiratory disease among workers exposed to cadmium exposure would vary depending on the particle size distribution. However, the information currently available is inadequate to form the basis for a regulation of exposures that accounts for particle size distribution.

#### Assumptions Involved in Absolute and Relative Risk Models

Comments were requested concerning use of the NIOSH cadmium study in risk modeling in the proposed standard (55 FR 4078). Use of the study assumes that the relative effects of cadmium exposure were constant across the age groups. An additional assumption inherent to the OSHA assessment is that the effect of

cadmium exposure is not dependent on dose rate. Thus, an individual exposed to  $0.1~\text{mg/m}^3$  for 10 years is assumed to have the same risk as an individual exposed to  $1~\text{mg/m}^3$  for a year.

Neither of these assumptions can be tested given the results as reported by Thun et al. [1985]. Had a Poisson regression or Cox proportional hazards model been used, the assumption of the risk being constant with age (proportional hazards assumption) could be tested. However, it would not be possible to examine the assumption of a dose-rate effect given the limited number of lung cancer deaths and exposure information from the Thun study.

#### Logistic Regression Analysis for Kidney Dysfunction

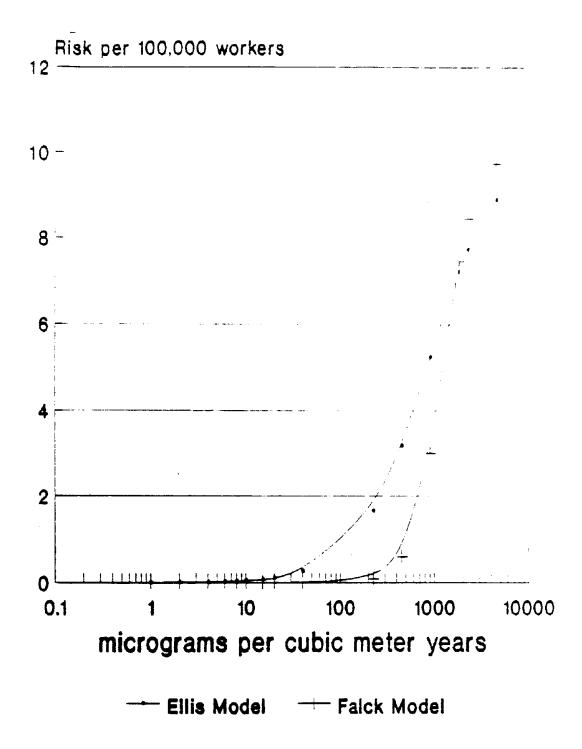
Comments were requested on the use of logistic regression as a model for estimating risk of kidney dysfunction. The primary concern expressed by a commenter to OSHA regarding the use of this model is that it may be inappropriate if a threshold exists for the effects of cadmium exposure on kidney function. This model would predict some finite risk at any exposure level above zero (55 FR 4083).

The logistic regression model may be an appropriate method for modeling effects that are believed to have a threshold. Figure 1 is a graph of the dose-response curves derived from the logistic regression models presented by OSHA in its risk assessment for kidney dysfunction. As can be seen from these graphs, the risk estimates from these logistic dose-response functions rapidly approach zero at low exposures. Thus, the results from a logistic regression analysis may be viewed as being consistent with a distribution of thresholds for the toxic renal effect in the population, and this model has thus been described as belonging to a family of "tolerance" distribution models.

#### Typographical and Other Minor Issues

- 1) On page 4077, OSHA states that for the NIOSH study (Thun), "Once cumulative dose was estimated for each worker, each worker was assigned to the high, medium, or low exposure group." In the NIOSH life-table program, which was used in this study, person-years at risk of death (not persons) and deaths are allocated to each exposure group.
- 2) On page 4078, OSHA states that "The maximum likelihood estimate of the unknown parameter  $\beta$  is obtained by maximizing the first derivative of the log likelihood with respect to  $\beta$ ." This statement would be technically correct if "the first derivative of" is eliminated.
- 3) On page 4078, the likelihood expressions contain some errors. The expression at the top of the page contains EG5<sub>j</sub> which should be E<sub>j</sub>. The other likelihood expression has  $E_j\beta_j$ , which should be  $E_j\beta X_j$ .
- 4) On page 4079, the last sentence of the next to last paragraph contains a mathematical formula used to compute 95% confidence intervals for the risk estimates. This should be changed to  $\beta \pm 1.96$  SE( $\beta$ ).

# Comparison of Risk Estimates From the Ellis and Falck Models



Based on Logistic Regression Models

Figure 1. Cadmium and nephrotoxicity results from OSHA risk assessment

#### VI. NIOSH RESPONSE TO OSHA QUESTIONS (55 FR 4053)

NIOSH has the following responses to OSHA's questions:

1. Do OSHA's proposed TWA PELs of 1  $\mu g/m^3$  and 5  $\mu g/m^3$  substantially reduce risk?

Lowering the exposure limits from the current standards to either 1  $\mu g/m^3$  or 5  $\mu g/m^3$  will substantially reduce risk.

In its risk assessment, OSHA used two major studies [Takenaka et al. 1983; Thun 1985 et al.]:

#### LIFETIME ESTIMATE OF EXCESS LUNG CANCER MORTALITY

•	1 μg/m <sup>3*</sup>	5 μg/m <sup>3*</sup>	100 μg/m <sup>3**</sup>
Thun	0.3 per 1000	1.6 per 1000	30.7 per 1000
Takenaka	2 per 1000	10.6 per 1000	221.3 per 1000

<sup>\*</sup>Proposed alternative TWA PELs.

NIOSH is concerned that the number of estimated cancer deaths for either proposed PEL is still excessive. As with all potential occupational carcinogens, NIOSH recommends that occupational exposure to cadmium should be reduced to the lowest feasible level [NIOSH 1984a]. As it becomes feasible to control exposures to levels lower than are presently possible, NIOSH would recommend that such levels be required.

### 2. Are the proposed TWA PELs of 1 $\mu g/m^3$ and 5 $\mu g/m^3$ technologically feasible?

This issue is addressed in more detail in the NIOSH testimony under Section IV - Control of Cadmium Exposures, and is summarized below:

For cadmium electroplating, exposures are judged by NIOSH to be controllable to 1  $\mu g/m^3$  using available engineering controls [NIOSH 1984b]. The process itself has inherently low exposures because it is conducted in solution.

<sup>\*\*</sup>Existing TWA PEL for cadmium fume.

For mechanical cadmium plating, which is a relatively small part of the total cadmium plating market, exposures may be controllable to 5  $\mu g/m^3$  using improved engineering controls for containment, materials handling, isolation, and automation. Exposures can be reduced even further by the use of good work practices and appropriate respiratory protection. When possible, cadmium plating should be done electrolytically rather than mechanically because of the inherently lower potential for exposure from the wet process.

Stabilizer manufacture is a typical batch chemical process. Liquid formulations may be controllable to less than 5  $\mu g/m^3$  using commercially available engineering controls. When possible, liquid formulations should be used in place of solid formulations. Solid formulations may be controllable to low levels (5  $\mu g/m^3$ ) through engineering containment and ventilation.

Pigment manufacture is a somewhat more complex process to control because of the variety of products produced, the complexity of the processing steps, and the solid materials handling problems. These processes should be controllable to low levels using engineering controls.

NIOSH has no information on the feasibility of controlling cadmium exposures in nickel-cadmium battery manufacture or in smelting operations.

### How many workers are exposed to cadmium? and

#### 9. In what industries and jobs are these workers exposed?

Appendices 1 through 4 (submitted with the NIOSH comments) are the NIOSH National Occupational Exposure Survey (NOES) estimates for the number of United States workers who are potentially exposed to cadmium-containing compounds. Not covered in these estimates are the major industry sectors of agriculture and mining. Appendix 1 lists by Standard Industrial Classification (SIC) code the number of workers who are exposed to cadmium metal (total workers = 68,500). Appendix 2 lists by SIC code the number of workers who are exposed to cadmium dust (total workers = 3,900). Appendix 3 lists by SIC code the number of workers who are exposed to cadmium oxide (total workers = 15,500). Appendix 4 lists by SIC code the number of different workers who are exposed to all cadmium compounds (total workers = 221,000).

With these estimates, NIOSH also has provided, by SIC code, the type and percentage use of the predominant methods for controlling exposure to cadmium. This information indicates generally to what extent the industry (or occupational group) has utilized the control methods listed.

#### 10. Should this standard cover the construction industry?

NIOSH recommends that the cadmium standard apply to all sectors of industry, including construction. Construction workers are potentially exposed to cadmium from cadmium-containing paint and metals during demolition, renovation, repair, and clean-up. Moreover, in construction there is the unique problem that material safety data sheets (MSDS) are often unavailable. In addition, the need for MSDSs may not be recognized during some operations, for example, during demolition work where old cadmium paint or materials containing cadmium may be encountered. Furthermore, relatively unique circumstances exist, such as multiemployer work sites and workers readily moving from site to site, that complicate typical approaches to medical and exposure monitoring. Programs should be tailored to these circumstances.

## 11. What is the lowest level of cadmium exposure achievable by engineering and work practice controls?

NIOSH research suggests that the use of innovative engineering and work practice controls in new facilities or operations can effectively contain cadmium to a level of 1  $\mu g/m^3$  [NIOSH 1984b]. Also, most existing facilities or operations can be retrofitted to contain cadmium to a level of 5  $\mu g/m^3$  through engineering and work practice controls.

### 14. Are there conditions under which respirator use should be permitted in addition to those proposed?

NIOSH recommends that respirator use should not be expanded. Respirator use places a burden on the individual wearer [NIOSH 1987a]. Both training and motivation are required for a respirator to be used properly [NIOSH 1987c]. NIOSH continues to recommend only the most protective respirators be worn when workers are exposed to potential carcinogens [NIOSH 1987a]. Furthermore, NIOSH continues to support the hierarchy of controls that were outlined in our comments to OSHA docket H-160 on methods of compliance [NIOSH 1983a; 1989a].

17. What measurement and analytical methods, in addition to the methods in Appendix E, are available for use in determining compliance with a cadmium exposure limit or action level of less than 0.5  $\mu$ g/m³?

NIOSH is not aware of any other validated analytical methods for use in determining compliance with a cadmium exposure limit or action level of less than 0.5  $\mu g/m^3$ .

18. Is it appropriate that OSHA allow the use of "objective data" instead of air monitoring to estimate exposure to cadmium?

NIOSH regards air monitoring to be the most appropriate means of estimating airborne exposure to cadmium. NIOSH further suggests that the use of "objective data" (e.g., use of mathematical estimates of exposure based upon historical exposure data and production information) may not be appropriate for many of the exposures to cadmium because of the variability of the conditions surrounding the exposure. For example, in certain industries, exposure could occur at outside environments during crucible welding to fuse re-enforcement bars or during the cutting of cadmium-coated steel on bridge structures. Exposure could also occur at inside environments during the demolition or repair of cadmium-coated materials. Exposure to cadmium may occur in enclosed or confined spaces such as inside storage tanks or submarines. In the agricultural industry, exposure may occur outside during the application of fungicides containing cadmium or during the cutting of cadmium-coated metal. In all of these circumstances, exposure variables (e.g., wind, humidity, temperature) are not only unpredictable from one exposure period to the next, but the variables may change during an exposure period. These fluctuations would not be accurately estimated by "objective data" because these estimates do not account for random disturbances in these variables. Therefore, NIOSH urges that "objective data" not be used to estimate exposures to cadmium, particularly when exposure variables are unpredictable.

19. What is the appropriate monitoring interval that is required to demonstrate the lowered exposure levels necessary to reduce the frequency of monitoring?

NIOSH recommends that periodic air monitoring (at least quarterly) be required for all workers who are potentially exposed to cadmium. NIOSH further recommends there be no provision for reducing this frequency. [See Section III. 3. (Monitoring Frequency) of these comments for detailed response to this question.]

21. Are the proposed medical surveillance provisions adequate?

NIOSH recommends that workers exposed to cadmium be screened for emphysema and toxic nephropathy (glomerular and tubular types). Screening for emphysema should include a respiratory questionnaire and spirometry. Screening for glomerular nephropathy should include quantitative measurement of urinary albumin; screening for tubular nephropathy should include an assay of urinary low-molecular-weight proteins.

## 23. Is it reasonable and feasible to use low-molecular-weight proteins to screen for early cadmium-related kidney dysfunction?

Measurement of urinary low-molecular-weight protein is a reasonable and feasible workplace screening method for early detection of cadmium-related renal damage. The screening tests available are (1) beta 2-microglobulin (B2M) and (2) retinol binding protein (RBP).

Because the B2M test is more widely available and more thoroughly studied, it is currently recommended for screening purposes. However, RBP potentially is a better test than B2M, because B2M is degraded in acid urine. This degradation of B2M is not entirely prevented by buffering of specimens in the laboratory (or even immediately following collection) because breakdown of the B2M proceeds while urine is still in the urinary bladder [Bernard et al. 1987; Lauwreys et al. 1984]. Thus, measurements of B2M in acid urine specimens will be falsely low. The urine pH should be measured when testing for B2M; if the urine Ph is less than 6, RBP is preferable to B2M. As RBP becomes more widely available, OSHA should allow substitution of RBP for B2M.

There are no meaningful "normal" values established for urinary low-molecular-weight proteins; a result more than two standard deviations above the laboratory's mean should be considered "elevated" for medical screening purposes. A standardized test kit for analysis of B2M has been available since 1972 (Phadebas Kit, Pharmacia Diagnostics AB, Uppsala, Sweden). The upper limit of normal with this method varies between approximately 0.2 and 0.3 mg/gm creatinine, depending on the laboratory [Roels et al. 1982; Elinder et al. 1985; Ellis et al. 1984]. The third National Health and Nutrition Examination Survey, being conducted through 1992 by the National Center for Health Statistics, includes measurement of urine RBP, so population-based "normal" values should eventually be available.

#### 24-26. Questions regarding biological monitoring and medical removal.

Both blood and urine cadmium are potentially useful for detecting excessive exposure prior to the development of renal tubular damage, although neither is completely reliable for this purpose. NIOSH [1976] and other organizations [WHO 1980; ACGIH 1989] have recommended that the urinary cadmium levels of workers not exceed 10  $\mu$ g/liter (or  $\mu$ g/g creatine, which is approximately equivalent to  $\mu$ g/liter according to Rosenberg et al. [1989]). It is prudent to maintain urinary cadmium levels well below this level, because recent evidence suggests that a significant number of workers will progress to proteinuria if urinary cadmium levels reach 10  $\mu$ g/g creatinine [Bernard et al. 1990; Roels et al. 1981] or 10 to 15  $\mu$ g/g creatinine [Jakubowski et al. 1987].

The actions required in paragraph (l)(4)(i)(A) when a worker's urinary cadmium exceeds 5  $\mu$ g/gm creatinine should help to protect workers against renal damage. OSHA should specify the level of cadmium in urine that

will trigger removal from further exposure. Although NIOSH has not specified such a trigger level, we recommend that urinary cadmium levels be kept to the lowest possible level--certainly below 10  $\mu$ g/g creatinine. NIOSH is aware that background levels of cadmium in urine for the general population without occupational exposure to cadmium are usually below 2  $\mu$ g/g creatinine [Thun et al. 1989; Kowal et al. 1979]. NIOSH has no recommendations for concentrations of cadmium in blood.

#### 27. Questions regarding proteinuria and medical removal.

Cadmium-induced renal disease appears to be progressive and irreversible [Thun et al. 1989; Roels et al. 1989]. For this reason, medical removal is appropriate for employees with proteinuria and in most cases the worker should not return to a job involving cadmium exposure.

The following action plan is being considered for dealing with elevated urinary levels of <a href="low-molecular-weight protein">low-molecular-weight protein</a> [NIOSH 1989c]:

- (a) All abnormal results should be repeated to confirm the results.
- (b) If re-testing confirms an abnormal result, the worker should be informed of the test result and referred to a physician experienced in the evaluation of renal disorders. The evaluation should include assessment of renal function and testing for potential nonoccupational etiologies of low-molecular-weight proteinuria. The worker should be informed of the findings of the examinations and any potential association with occupational or nonoccupational etiologies.
- (c) If clinical evaluation determines renal function to be normal (other than low-molecular-weight proteinuria) and no nonoccupational etiologies of low-molecular-weight proteinuria are discovered, the worker should be retested at 3-month intervals. An industrial hygiene survey should be undertaken to assess and control potential exposures.
- (d) A reasonable approach to medical removal from continued exposure to cadmium would be to remove any worker from exposure who was found to have any of the following:
  - -- two separate screening results (i.e., not including confirmatory retesting described above) that exceed the upper limit of normal, or
  - -- progressive increases in low-molecular-weight proteinuria over time which (although still in the normal range) represent an adverse effect on the worker's health in the opinion of the examining physician, or
  - -- renal disease on further clinical evaluation.

(e) Any worker removed from exposure to cadmium as a result of low-molecular-weight proteinuria (see d above), who is not found to have another (nonoccupational) etiology should be reported as a case of toxin-induced nephropathy on the OSHA 200 Log.

The action plan proposed above for protecting workers with low-molecular-weight proteinuria requires the exercise of medical judgement. If the decision logic adopted by OSHA also depends substantially on the medical judgement of the examining physician, NIOSH supports the concept of multiple physician review to resolve any disagreements regarding individual medical decisions relating to an individual worker [NIOSH 1990].

#### 28. Questions regarding medical removal and return to work.

Cadmium-induced nephropathy occurs as a result of cadmium accumulation in the kidney. Tubular damage, as manifested by low-molecular-weight proteinuria, is either irreversible or the recovery is so slow that researchers have been unable to discern it [Thun et al. 1989]. Thus, while medical reevaluation after 3 months is reasonable (see Question 27, above), proteinuria -- and the need to avoid exposure -- may persist indefinitely.

The current draft standard proposes medical removal based on abnormal levels of low-molecular-weight protein in the urine; as discussed in our response to questions 24 to 26, the standard should also specify what level of urine cadmium would lead to medical removal. Workers with elevated levels of cadmium in the urine should be removed before low-molecular-weight proteinuria develops.

#### 29. Questions regarding medical removal and respirator usage.

The ability to wear a respirator depends not only on the health status of the worker but on the type of respirator and the inherent physical demands of the job. Generally, a negative pressure respirator adds to the work of breathing since air must be drawn through a filter (there is no appreciable resistance to exhalation).

A positive-pressure respirator does not add a substantial burden to breathing. A self-contained breathing apparatus (SCBA) often weighs as much as 35 pounds, however, and can add to the cardiopulmonary stress (as can any additional protective clothing).

The ability of a particular worker to function in a designated job with a specific respirator requires an individualized medical judgement. Although this determination is not easily reduced to a formula based on level of "lung function loss," NIOSH has developed general medical evaluation criteria for screening respirator wearers [NIOSH 1987a; 1987b].

#### 30. Questions regarding baseline and periodic medical examinations.

Workers with cadmium exposure preceding adoption of the proposed standard should receive the same medical screening evaluations as new workers -- all workers with occupational exposure to cadmium (in the past, present, or future) should receive baseline medical examinations.

#### 31. Questions regarding reproductive effects.

NIOSH is not aware of data to suggest that cadmium exposure in humans at the proposed PELs would have adverse reproductive effects. Cadmium has been associated has been associated with reproductive toxicity in animals exposed to very high doses [Holmberg et al. 1969; Bomhard et al. 1987].

#### 32. Questions regarding medical examinations for termination of employment.

NIOSH supports the use of termination medical examinations. The information obtained in termination medical examinations may be used to:

- a. advise the worker regarding future employment in jobs with cadmium exposure;
- b. evaluate the need for future medical screening or medical treatment.
- c. provide additional data for purposes of occupational health surveillance.

At termination, NIOSH recommends that the worker should be provided with a copy of the medical record and the exposure record (including air and biological monitoring data, and use of respirators and other PPE). NIOSH recommends that all medical and exposure records be held by the employer for 40 years after termination of employment.

#### REFERENCES

ACGIH [1989]. TLVs®: threshold limit values and biological exposure indices for 1989-1990. Cincinnati, OH: American Conference of Governmental Industrial Hygienists. Submitted with NIOSH comments.

Bernard A, Lauwerys R [1990]. Early markers of cadmium nephrotoxicity: Biological significance and predictive value. Toxicol Environ Chem  $\underline{27}$ :65-72. Submitted with NIOSH testimony.

Bernard AM, Vyskocil AA, et al. [1987]. Assessment of urinary retinol-binding protein index as an of proximal tubular injury. Clin Chem  $\underline{33}(6):775-779$ . Submitted with NIOSH comments.

Bomhard E, Vogel O, et al. [1987]. Chronic effects on single and multiple oral and subcutaneous cadmium administrations on the testes of Wistar rats. Cancer Letters  $\underline{36}$ : 307-315. Submitted with NIOSH testimony.

Elinder CG, Edling C, et al. [1985]. Assessment of renal function in workers previously exposed to cadmium. Br J Ind Med  $\underline{42}$ :754-760. Submitted with NIOSH comments.

Ellis KJ, Yuen K, et al. [1984]. Dose-response analysis of cadmium in man: body burden vs kidney dysfunction. Environ Res  $\underline{33}$ :216-226. Submitted with NIOSH comments.

Hankinson JL [1986]. Pulmonary function testing in the screening of workers: guidelines for instrumentation, performance, and interpretation. JOM 28(10):1081-1092. Submitted with NIOSH comments.

Holmberg RE Jr, Ferm VH [1969]. Interrelationships of selenium, cadmium, and arsenic. Arch Environ Health 18:873-877. Submitted with NIOSH testimony.

JACA [1988]. Economic impact analysis of the proposed revision to the cadmium standard. Final report. In partial fulfillment of contract J-9-F-5-0058 to the Occupational Safety and Health Administration. Fort Washington, PA: JACA Corporation. OSHA docket.

Jakubowski M, Trojanowska B, et al. [1987]. Occupational exposure to cadmium and kidney dysfunction. Int Arch Occup Environ Health <u>59</u>:567-577. Submitted with NIOSH testimony.

Kjellstrom T [1986]. Effects on bone, on vitamin D, and calcium metabolism. Friberg L, Elinder C-G (eds.). In: Cadmium and Health: A Toxicological and Epidemiological Appraisal. Volume II. Effects and Response. Boca Raton, FL: CRC Press, Inc. Submitted with NIOSH testimony.

Knudson RJ, Lebowitz MD, et al. [1983]. Changes in the normal maximal expiratory flow-volume curve with growth and aging. Am Rev Respir Dis 127:725-734. Submitted with NIOSH comments.

Kowal NE, Johnson DE [1979]. Normal levels of cadmium in diet, urine, blood, and tissues of inhabitants of the United States. J Toxicol Environ Health  $\underline{5}$ :995-1014. Submitted with NIOSH testimony.

Lauwerys RR, Bernard A, et al. [1984]. Characterization of cadmium proteinuria in man and rat. Environ Health Perspect <u>54</u>:147-152. Submitted with NIOSH comments.

NIOSH [1976]. A recommended standard for occupational exposure to cadmium. Cincinnati, OH: U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, DHEW (NIOSH) Publication No. 76-192. Submitted with NIOSH comments.

NIOSH [1978]. Engineering control technology assessment for the plastics and resins industry. Prepared for NIOSH by Enviro Control, Inc., Rockville, MD, under contract no. 210-76-0122. Cincinnati, OH: U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, DHEW (NIOSH) Publication No. 78-159, NTIS PB 82-151-283. Submitted with NIOSH testimony.

NIOSH [1980]. Control technology assessment of the pesticides manufacturing and formulating industry. Prepared for NIOSH by SRI International, Menlo Park, CA, under contract no. 210-77-0093. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health. Submitted with NIOSH testimony.

NIOSH [1983a]. Comments of the National Institute for Occupational Safety and Health on the Occupational Safety and Health Administration proposed rule on health standards; methods of compliance: 29 CFR Part 1910, docket no. H-160, June 1983. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health. Submitted with NIOSH comments.

NIOSH [1984a]. Current intelligence bulletin #42: Cadmium. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 84-116. Submitted with NIOSH comments.

NIOSH [1984b]. NIOSH technical report: Control technology assessment: Metal plating and cleaning operations. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 85-102. Submitted with NIOSH comments.

NIOSH [1984c]. Indepth survey report: Control technology for Richard Klinger Inc, June 25, 1984. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, NIOSH Report No. 144-15b. Submitted with NIOSH testimony.

NIOSH [1987a]. NIOSH respirator decision logic. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 87-108. Submitted with NIOSH comments.

NIOSH [1987b]. A recommended standard for occupational exposure to radon progeny in underground mines. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 88-101. Submitted with NIOSH comments.

NIOSH [1987c]. NIOSH guide to industrial respiratory protection. Morgantown, WV: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 87-116. Submitted with NIOSH comments.

NIOSH [1989a]. Comments of the National Institute for Occupational Safety and Health on the Occupational Safety and Health Administration proposed rule on health standards; methods of compliance: 29 CFR Part 1910, docket no. H-160, October 2, 1989. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health. Submitted with NIOSH comments.

NIOSH [1989b]. Letter dated October 2, 1989, from Laurence D. Reed, Acting Associate Director for Policy Development, Division of Standards Development and Technology Transfer, NIOSH, to John Martonik, Occupational Safety and Health Administration, U.S. Department of Labor, transmitting a NIOSH evaluation of the OSHA proposed analytical methods for cadmium. Submitted with NIOSH comments.

NIOSH [1989c]. Draft NIOSH medical screening recommendations. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, Reviewed in Cincinnati, Ohio, April 11-12, 1990. Submitted with NIOSH comments.

NIOSH [1990]. Testimony of the National Institute for Occupational Safety and Health on the Occupational Safety and Health Administration proposed rule on occupational exposure to 4,4'-methylenedianiline (MDA): 29 CFR Parts 1910 and 1926, docket no. H-040, March 20, 1990. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health. Submitted with NIOSH testimony.

PACE [1990]. Analysis of OSHA's preliminary conclusions concerning the technological feasibility of achieving a 5 or a 1  $\mu g$  Cd/m³ permissible exposure limit for cadmium fume and dust. Cambridge, MA: Putnam, Hayes & Bartlett, Inc. OSHA docket.

Roels HA, Lauwerys RR, et al. [1981]. In Vivo measurement of liver and kidney cadmium in workers exposed to this metal: Its significance with respect to cadmium in blood and urine. Environ Res 26:217-240. Submitted with NIOSH testimony.

Roels H, Djubgang J, et al. [1982]. Evolution of cadmium-induced renal dysfunction in workers removed from exposure. Scand J Work Environ Health 8:191-200. Submitted with NIOSH comments.

Roels HA, Lauwerys RR, et al. [1989]. Health significance of cadmium induced renal dysfunction: a five-year follow up. Br J Ind Med  $\underline{46}$ :755-764. Submitted with NIOSH comments.

Rosenberg J, Fiserova-Bergerova V, et al. [1989]. Biological monitoring IV: Measurements in urine. Applied Industrial Hygiene  $\underline{4}(4)$ :F-16 - F21. Submitted with NIOSH testimony.

Rudolf G, Gebhart J, et al. [1988]. Mass deposition from inspired polydisperse aerosols. Ann Occup Hyg  $\underline{32}$ :919-938. Submitted with NIOSH testimony.

Savitz DA [1986]. Changes in spanish surname cancer rates relative to other whites, Denver area, 1969-71 to 1979-81. AJPH  $\underline{76}(10):1210-1215$ . Submitted with NIOSH testimony.

Takenaka S, Oldiges H, et al. [1983]. Carcinogenicity of cadmium chloride aerosols in W rats. JNCI 70(2):367-371. OSHA docket.

Thun MJ, Schnorr TM, et al. [1985]. Mortality among a cohort of U.S. cadmium production workers - an update. JNCI 74(2):325-333. OSHA docket.

Thun MJ, Osorio AM, et al. [1989]. Nephropathy in cadmium workers: assessment of risk from airborne occupational exposure to cadmium. Br J Indust Med 46:689-697. Submitted with NIOSH comments.

USPSTF [1989]. Guide to clinical preventive services: An assessment of the effectiveness of 169 interventions. Baltimore, MD: Williams & Wilkins. Submitted with NIOSH testimony.

WHO [1980]. Recommended health-based limits in occupational exposure to heavy metals. Geneva, Switzerland: World Health Organization. WHO Technical Report Series 647. Submitted with NIOSH comments.

#### DRAFT 16-July-1990 DRAFT

#### Appendix A.

Interpretation of an Individual Worker's Longitudinal Change in  $FEV_1$  For repeat examinations, the observed decline in  $FEV_1$  ( $\Delta_0 FEV_1$ ) will be calculated by fitting a least squares line to the observed  $FEV_1$  values over time. The slope of this line, in ml/year, is compared with expected annual decline in  $FEV_1$  Table 7 or 8. The upper limit of the expected annual decline is determined using Equation 1 or 2 (males) or 3 or 4 (females), or is obtained from Table 7 (males) or 8 (females). For males and females 35 years of age or older the "10" should be added to Equations 1 and 2. The  $\Delta_2 FEV_1$  (ml/yr) is based on the last observed  $FEV_1$  and the total number of years of observation ( $T_{yrs}$ ), according to the equation:

- (1)  $\Delta_{E}FEV_{1}$  (m1/yr) = 1.282\*(7.48 + 288.4/T<sub>yrs</sub>) + .03\*FEV<sub>1</sub>/T<sub>yrs</sub>; males < 35 yrs
- (2)  $\Delta_{E}FEV_{1}$  (ml/yr) 1.282\*(4.25 + 210.1/T<sub>yrs</sub>) + .03\*FEV<sub>1</sub>/T<sub>yrs</sub>; females < 35 yrs
- (3)  $\Delta_{\text{E}} \text{FEV}_1 \text{ (ml/yr)} = 1.282*(7.48 + 288.4/T_{yrs}) + .03*FEV}_1/T_{yrs} + 10; \text{ males} \ge 35$
- (4)  $\Delta_{\rm E} {\rm FEV_1}$  (ml/yr) = 1.282\*(4.25 + 210.1/T<sub>yrs</sub>) + .03\*FEV<sub>1</sub>/T<sub>yrs</sub> + 10; females  $\geq$  35 Note: If (.C3\*FEV<sub>1</sub>) < 100 ml then 100 ml is used instead.

An excessive annual decline in FEV<sub>1</sub> (ml/yr) will be suspected if the  $\Delta_0$ FEV<sub>1</sub> (ml/yr) is greater than the  $\Delta_2$ FEV<sub>1</sub> (ml/yr). Any worker whose FEV<sub>1</sub> is below the LLN or who has a suspected excessive annual decline in FEV<sub>1</sub> ( $\Delta_0$ FEV<sub>1</sub> >  $\Delta_2$ FEV<sub>1</sub>) will be referred for a clinical evaluation which should include, at a minimum, a repeat examination. Notice that for repeat examinations the 90 percent confidence interval (1.282) in the calculation of the  $\Delta_2$ FEV<sub>1</sub> is used instead of the 95 percent confidence interval (1.645). Software to perform the linear regression for estimating the annual decline in FEV<sub>1</sub> is available from NIOSH.

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157 2.89 3.01 3.13 3.25 3.02 2.97 2.92 2.87 2.82 2.77 2.73 2.68 2.38 2.33 2.29 2.25 2.20 2.16 2.12 2.07 2.03 1.98 1.94 1.90 1.85
     158 2.94 3.06 3.18 3.29 3.08 3.04 2.99 2.94 2.89 2.84 2.79 2.75 2.44 2.40 2.35 2.31 2.27 2.22 2.18 2.13 2.09 2.05 2.00 1.96 1.92
     159 2.99 3.11 3.22 3.34 3.15 3.10 3.06 3.01 2.96 2.91 2.86 2.81 2.50 2.46 2.41 2.37 2.33 2.28 2.24 2.20 2.15 2.11 2.06 2.02 1.98
     160 3.04 3.15 3.27 3.39 3.22 3.17 3.12 3.06 3.03 2.98 2.93 2.88 2.56 2.52 2.48 2.43 2.39 2.35 2.30 2.26 2.21 2.17 2.13 2.08 2.04
     161 3.08 3.20 3.32 3,44 3.29 3.24 3.19 3.14 3.10 3.05 3.00 2.95 2.63 2.58 2.54 2.50 2.45 2.41 2.36 2.32 2.28 2.23 2.19 2.15 2.10
     162 3.13 3.25 3.37 3.48 3.36 3.31 3.26 3.21 3.16 3.12 3.07 3.02 2.69 2.64 2.60 2.56 2.51 2.47 2.43 2.38 2.34 2.29 2.25 2.21 2.16
     163 3.18 3.29 3.41 3.53 3.43 3.38 3.33 3.26 3.23 3.18 3.14 3.09 2.75 2.71 2.66 2.62 2.58 2.53 2.49 2.44 2.40 2.36 2.31 2.27 2.23
     164 3.22 3,34 3.46 3,58 3.49 3.45 3.46 3,35 3.30 3.25 3.26 3.16 2.81 2.77 2.72 2.68 2.64 2.59 2.55 2.51 2.46 2.42 2.37 2.33 2.29
     165 3.27 3.39 3.51 3.62 3.56 3.51 3.47 3.42 3.37 3.32 3.27 3.22 2.87 2.83 2.79 2.74 2.70 2.66 2.61 2.57 2.52 2.48 2.44 2.39 2.35
     166 3.32 3.44 3.55 3.67 3.63 3.58 3.53 3.49 3.44 3.39 3.34 3.29 2.94 2.89 2.85 2.80 2.76 2.72 2.67 2.63 2.59 2.54 2.50 2.45 2.41
     167 3.36 3.48 3.60 3.72 3.70 3.65 3.60 3.55 3.51 3.46 3.41 3.36 3.00 2.95 2.91 2.87 2.82 2.78 2.74 2.69 2.65 2.60 2.56 2.52 2.47
     168 3.41 3.53 3.65 3.77 3.77 3.72 3.67 3.62 3.57 3.53 3.48 3.43 3.06 3.02 2.97 2.93 2.88 2.84 2.80 2.75 2.71 2.67 2.62 2.58 2.53
     169 3.46 3.58 3.69 3.81 3.84 3.79 3.74 3.69 3.64 3.59 3.55 3.50 3.12 3.08 3.03 2.99 2.95 2.90 2.86 2.82 2.77 2.73 2.68 2.64 2.60
     170 3.51 3.62 3.74 3.66 3.90 3.66 3.81 3.76 3.71 3.66 3.61 3.57 3.18 3.14 3.10 3.05 3.01 2.97 2.92 2.88 2.53 2.79 2.75 2.70 2.66
     171 3.55 3.67 3.79 3.91 3.97 3.93 3.88 3.83 3.78 3.73 3.68 3.64 3.25 3.20 3.16 3.11 3.07 3.03 2.96 2.96 2.96 2.86 2.81 2.76 2.72
     172 3.60 3.72 3.84 3.95 4.04 3.99 3.95 3.90 3.85 3.80 3.75 3.70 3.31 3.26 3.22 3.16 3.13 3.60 3.05 3.00 2.96 2.91 2.87 2.83 2.78
     173 3.65 3.77 3.88 4.00 4.11 4.06 4.01 3.97 3.92 3.87 3.82 3.77 3.37 3.33 3.28 3.24 3.19 3.15 3.11 3.06 3.02 2.98 2.93 2.89 2.84
     174 3.69 3.81 3.93 4.05 4.18 4.13 4.08 4.03 3.99 3.94 3.89 3.84 3.43 3.39 3.34 3.30 3.26 3.21 3.17 3.13 3.08 3.04 2.99 2.95 2.91
     175 3.74 3.86 3.98 4.10 4.25 4.20 4.15 4.10 4.05 4.01 3.96 3.91 3.49 3.45 3.41 3.36 3.32 3.27 3.23 3.19 3.14 3.10 3.06 3.81 2.97
     176 3.79 3.91 4.02 4.14 4.32 4.27 4.22 4.17 4.12 4.07 4.03 3.98 3.56 3.51 3.47 3.42 3.38 3.34 3.29 3.25 3.21 3.16 3.12 3.07 3.03
     177 3.84 3.95 4.07 4.19 4.38 4.34 4.29 4.24 4.19 4.14 4.09 4.05 3.62 3.57 3.53 3.49 3.44 3.40 3.35 3.31 3.27 3.22 3.18 3.14 3.09
     178 3.88 4.00 4.12 4.24 4.45 4.40 4.36 4.31 4.26 4.21 4.16 4.11 3.68 3.64 3.59 3.55 3.50 3.46 3.42 3.37 3.33 3.29 3.24 3.20 3.15
     179 3.93 4.05 4.17 4.28 4.52 4.47 4.42 4.38 4.33 4.28 4.23 4.18 3.74 3.70 3.65 3.61 3.57 3.52 3.48 3.44 3.39 3.35 3.30 3.26 3.22
     180 3.98 4.09 4.21 4.33 4.59 4.54 4.49 4.44 4.40 4.35 4.30 4.25 3.80 3.76 3.72 3.67 3.63 3.58 3.54 3.50 3.45 3.41 3.37 3.32 3.28
     181 4-02 4-14 4-26 4-38 4-66 4-61 4-56 4-51 4-46 4-42 4-37 4-32 3-87 3-82 3-78 3-73 3-69 3-65 3-60 3-56 3-52 3-47 3-43 3-38 3-34
     182 4.07 4.19 4.31 4.42 4.73 4.66 4.63 4.58 4.53 4.48 4.44 4.39 3.93 3.88 3.84 3.80 3.75 3.71 3.66 3.62 3.58 3.53 3.49 3.45 3.40
     183 4.12 4.24 4.35 4.47 4.79 4.75 4.70 4.65 4.60 4.55 4.50 4.46 3.99 3.95 3.90 3.86 3.81 3.77 3.73 3.68 3.64 3.60 3.55 3.51 3.46
     184 4-17 4-28 4-40 4-52 4-86 4-81 4-77 4-72 4-67 4-62 4-57 4-52 4-05 4-01 3-96 3-92 3-88 3-83 3-79 3-74 3-79 3-66 3-61 3-57 3-53
     185 4.21 4.33 4.45 4.57 4.93 4.88 4.84 4.79 4.74 4.69 4.64 4.59 4.11 4.07 4.03 3.98 3.94 3.89 3.85 3.81 3.76 3.72 3.68 3.63 3.59
     186 4-26 4-38 4-50 4-61 5-00 4-95 4-90 4-86 4-81 4-76 4-71 4-66 4-17 4-13 4-99 4-04 4-00 3-96 3-91 3-87 3-83 3-78 3-74 5-69 3-65
     187 4.31 4.42 4.54 4.66 5.07 5.02 4.97 4.92 4.88 4.83 4.78 4.73 4.24 4.19 4.15 4.11 4.06 4.02 3.97 3.93 3.89 3.84 3.80 3.76 3.71
     188 4-35 4-47 4-59 4-71 5-14 5-09 5-04 4-99 4-94 4-90 4-85 4-80 4-30 4-26 4-21 4-17 4-12 4-08 4-04 3-99 3-95 3-91 3-86 3-82 3-77
     189 4.40 4.52 4.64 4.75 5.21 5.16 5.11 5.06 5.01 4.96 4.92 4.87 4.36 4.32 4.27 4.23 4.19 4.14 4.10 4.05 4.01 3.97 3.92 3.88 3.84
     190 4.45 4.57 4.68 4.80 5.27 5.23 5.18 5.13 5.08 5.03 4.98 4.94 4.42 4.38 4.34 4.29 4.25 4.20 4.16 4.12 4.07 4.03 3.99 3.94 3.90
     191 4.49 4.61 4.73 4.85 5.34 5.29 5.25 5.20 5.15 5.10 5.05 5.00 4.48 4.44 4.40 4.35 4.31 4.27 4.22 4.18 4.13 4.09 4.85 4.00 3.96
     192 4.54 4.66 4.78 4.90 5.41 5.36 5.31 5.27 5.22 5.17 5.12 5.07 4.55 4.50 4.46 4.42 4.37 4.33 4.28 4.24 4.20 4.15 4.11 4.07 4.02
     193 4-59 4-71 4-82 4-94 5-48 5-43 5-38 5-38 5-38 5-29 5-24 5-19 5-14 4-61 4-56 4-52 4-48 4-43 4-39 4-35 4-30 4-26 4-21 4-17 4-13 4-08
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Ht(cm)\Age 17 19 21 23 25 27 29 31 33 35 37 39 41 43 45 47 49 51 53 55 57 59 61 63 65
      157 2.52 2.62 2.73 2.83 2.52 2.48 2.43 2.38 2.34 2.29 2.25 2.20 2.10 2.06 2.01 1.97 1.92 1.88 1.83 1.79 1.74 1.70 1.65 1.61 1.56
     158 2.56 2.67 2.77 2.87 2.58 2.53 2.48 2.44 2.39 2.34 2.30 2.25 2.15 2.11 2.06 2.02 1.97 1.93 1.88 1.84 1.79 1.75 1.70 1.66 1.61
     159 2.61 2.71 2.81 2.92 2.63 2.58 2.54 2.49 2.44 2.40 2.35 2.30 2.20 2.16 2.11 2.07 2.02 1.98 1.93 1.89 1.84 1.84 1.75 1.71 1.66
      160 2.65 2.75 2.85 2.96 2.68 2.63 2.59 2.54 2.50 2.45 2.40 2.36 2.26 2.21 2.17 2.12 2.08 2.03 1.98 1.94 1.89 1.85 1.80 1.76 1.71
      161 2.69 2.79 2.90 3.80 2.73 2.69 2.64 2.59 2.55 2.50 2.46 2.41 2.31 2.26 2.22 2.17 2.13 2.08 2.04 1.99 1.95 1.90 1.86 1.81 1.77
      162 2.73 2.84 2.94 3.84 2.79 2.74 2.69 2.65 2.60 2.55 2.51 2.46 2.36 2.31 2.27 2.22 2.18 2.13 2.09 2.04 2.00 1.95 1.91 1.86 1.82
      163 2,77 2,88 2,96 3,66 2,84 2,79 2,75 2,70 2,65 2.61 2,56 2,52 2,41 2,36 2,32 2,27 2,23 2,18 2,14 2,09 2,05 2,00 1,96 1,91 1,87
     164 2.82 2.92 3.02 3.13 2.89 2.84 2.80 2.75 2.71 2.66 2.61 2.57 2.46 2.42 2.37 2.33 2.28 2.24 2.19 2.15 2.10 2.06 2.01 1.96 1.92
     165 2.86 2.96 3.07 3.17 2.94 2.90 2.85 2.81 2.76 2.71 2.67 2.62 2.51 2.47 2.42 2.38 2.33 2.29 2.24 2.20 2.15 2.11 2.06 2.02 1.97
     166 2.90 3.00 3.11 3.21 3.00 2.95 2.90 2.86 2.81 2.77 2.72 2.67 2.56 2.52 2.47 2.43 2.38 2.34 2.29 2.25 2.20 2.16 2.11 2.07 2.02
     167 2.94 3.05 3.15 3.25 3.05 3.00 2.96 2.91 2.86 2.02 2.77 2.73 2.61 2.57 2.52 2.48 2.43 2.39 2.34 2.30 2.25 2.21 2.16 2.12 2.07
      168 2.99 3.09 3.19 3.29 3.10 3.06 3.01 2.96 2.92 2.87 2.82 2.78 2.67 2.62 2.58 2.53 2.49 2.44 2.40 2.35 2.31 2.26 2.22 2.17 2.13
      169 3.03 3.13 3.23 3.34 3.15 3.11 3.06 3.02 2.97 2.92 2.68 2.63 2.72 2.67 2.63 2.58 2.54 2.49 2.45 2.40 2.36 2.31 2.27 2.22 2.18
      170 3,07 3,17 3.28 3.38 3.21 3.16 3,11 3.07 3,02 2.98 2.93 2.88 2.77 2.72 2.68 2.63 2.59 2.54 2.50 2.45 2.41 2.36 2.32 2.27 2.23
     171 3.11 3.21 3.32 3.42 3.26 3.21 3.17 3.12 3.07 3.03 2.98 2.94 2.82 2.78 2.73 2.68 2.64 2.59 2.55 2.50 2.46 2.41 2.37 2.32 2.28
      172 3.15 3.26 3.36 3.46 3.31 3.27 3.22 3.17 3.13 3.08 3.03 2.99 2.87 2.83 2.78 2.74 2.69 2.65 2.60 2.56 2.51 2.47 2.42 2.38 2.33
     173 3.20 3.30 3.40 3.51 3.36 3.32 3.27 3.23 3.18 3.13 3.09 3.04 2.92 2.88 2.83 2.79 2.74 2.70 2.65 2.61 2.56 2.52 2.47 2.43 2.38
      174 3.24 3.34 3.44 3.55 3.42 3.37 3.32 3.28 3.23 3.19 3.14 3.09 2.97 2.93 2.88 2.84 2.79 2.75 2.70 2.66 2.61 2.57 2.52 2.48 2.43
      175 3.28 3.38 3.49 3.59 3.47 3.42 3.38 3.33 3.28 3.24 3.19 3.15 3.03 2.98 2.94 2.89 2.85 2.80 2.76 2.71 2.66 2.62 2.57 2.53 2.48
      176 3.32 3.43 3.53 3.63 3.52 3.48 3.43 3.58 3.34 3.29 3.25 3.20 3.08 3.03 2.99 2.94 2.90 2.85 2.81 2.76 2.72 2.67 2.63 2.58 2.54
      177 3.36 3.47 3.57 3.67 3.57 3.53 3.48 3.44 3.39 3.34 3.30 3.25 3.13 3.08 3.04 2.99 2.95 2.90 2.86 2.81 2.77 2.72 2.68 2.63 2.59
      178 3.41 3.51 3.61 3.72 3.63 3.58 3.54 3.49 3.44 3.40 3.35 3.30 3.18 3.13 3.09 3.84 3.00 2.95 2.91 2.86 2.82 2.77 2.73 2.68 2.64
      179 3.45 3.55 3.66 3.76 3.68 3.63 3.59 3.54 3.50 3.45 3.40 3.36 3.23 3.19 3.14 3.10 3.05 3.01 2.96 2.92 2.87 2.83 2.78 2.73 2.<del>6</del>9
      180 3.49 3.59 3.70 3.80 3.73 3.69 3.64 3.59 3.55 3.50 3.46 3.41 3.28 3.24 3.19 3.15 3.10 3.06 3.01 2.97 2.92 2.88 2.63 2.79 2.74
      181 3.53 3.64 3.74 3.84 3.79 3.74 3.69 3.65 3.60 3.55 3.51 3.46 3.33 3.29 3.24 3.20 3.15 3.11 3.06 3.02 2.97 2.93 2.88 2.84 2.79
      182 3.58 3.68 3.78 3.88 3.84 3.79 3.75 3.79 3.65 3.61 3.56 3.51 3.38 3.34 3.29 3.25 3.20 3.16 3.11 3.07 3.02 2.98 2.93 2.89 2.84
      183 3.62 3.72 3.82 3.93 3.89 3.84 3.80 3.75 3.71 3.66 3.61 3.57 3.44 3.39 3.35 3.30 3.26 3.21 3.17 3.12 3.08 3.03 2.99 2.94 2.90
      184 3.66 3.76 3.87 3.97 3.94 3.90 3.85 3.86 3.76 3.71 3.67 3.62 3.49 3.44 3.40 3.35 3.31 3.26 3.22 3.17 3.13 3.08 3.04 2.99 2.95
      185 3.70 3.80 3.91 4.01 4.00 3.95 3.90 3.86 3.81 3.76 3.72 3.67 3.54 3.49 3.45 3.40 3.36 3.31 3.27 3.22 3.18 3.13 3.09 3.04 3.00
      186 3.74 3.85 3.95 4.05 4.05 4.00 3.96 3.91 3.86 3.82 3.77 3.72 3.59 3.55 3.50 3.46 3.41 3.36 3.32 3.27 3.23 3.18 3.14 3.09 3.05
      187 3.79 3.89 3.99 4.10 4.10 4.05 4.01 3.96 3.92 3.87 3.82 3.78 3.64 3.60 3.55 3.51 3.46 3.42 3.37 3.33 3.28 3.24 3.19 3.15 3.10
     188 3.83 3.93 4.03 4.14 4.15 4.11 4.06 4.01 3.97 3.92 3.88 3.83 3.69 3.65 3.60 3.56 3.51 3.47 3.42 3.38 3.33 3.29 3.24 3.20 3.15
     189 3.87 3.97 4.08 4.18 4.21 4.16 4.11 4.07 4.02 3.98 3.93 3.88 3.74 3.70 3.65 3.61 3.56 3.52 3.47 3.43 3.38 3.34 3.29 3.25 3.20
     190 3.91 4.02 4.12 4.22 4.26 4.21 4.17 4.12 4.07 4.03 3.98 3.94 3.80 3.75 3.71 3.66 3.62 3.57 3.53 3.48 3.43 3.39 3.34 3.30 3.25
     191 3.95 4.06 4.16 4.26 4.31 4.27 4.22 4.17 4.13 4.08 4.03 3.99 3.85 3.80 3.76 3.71 3.67 3.62 3.58 3.53 3.49 3.44 3.40 3.35 3.31
     192 4.00 4.10 4.20 4.31 4.36 4.32 4.27 4.23 4.18 4.13 4.09 4.04 3.90 3.85 3.81 3.76 3.72 3.67 3.63 3.58 3.54 3.49 3.45 3.40 3.36
     193 4-04 4-14 4-25 4-35 4-42 4-37 4-32 4-28 4-23 4-19 4-14 4-09 3-95 3-90 3-86 3-81 3-77 3-72 3-68 3-63 3-59 3-54 3-50 3-45 3-41
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LOWER LIMIT OF NORMAL (LLN) FOR FEV1/FVC% FOR MALES
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Ht(cm)\Age	17	19	21	23	25	27	29	31	33	35	37	39	41	43	45	47	49	51	53	55	57	59	61	63	65
																				70.3					
158 7	74.4	74.4	74.4	74.4	73.0	72.8	72.6	72.5	72.3	72.1	71.9	71.7	71.5	71,4	71.2	71.0	70.8	70.6	70.4	<b>70.3</b>	70.1	69.9	69.7	69.5	69.3
																				70.3					
168	74.3	74.3	74.3	74.3	73.0	72.8	72.6	72.5	72.3	72.1	71.9	71.7	71.5	71.4	71.2	71.0	70.8	70.6	70.4	70.3	70.1	69.9°	69.7	69.5	69.3
161	74.2	74.2	74.2	74.2	73.0	72.8	72.6	72.5	72.3	72.1	71.9	71.7	71.5	71.4	71.2	71.0	70.8	70.6	70.4	70.5	70.1	69.9	69.7	69.5	69.3
162	74.1	74.1	74.1	74.1	73.0	72.8	72.6	72.5	72.3	72.1	71.9	71.7	71.5	71.4	71.2	71.0	70.8	70.6	70.4	70.3	70.1	69.9	69.7	69.5	69.3
																				70.3					
																				70.3					
																				70.3					
166	73.9	73.9	73.9	73.9	73.0	72.8	72.6	72.5	<i>7</i> 2.3	72.1	71.9	71,7	71.5	71.4	71.2	71.0	70.8	70.6	70.4	70.3	70.1	69.9	69.7	69.5	69.3
																				70.3					
																				70.3					
169 7	73.6	73.6	73.6	73.6	73.0	72.8	72.6	72.5	<i>7</i> 2.3	72.1	71.9	71.7	71.5	71.4	71.2	71.0	70.8	70.6	70.4	70.3	70.1	69.9	69.7	69.5	69.3
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193 4	7Z. V	12.0	72.0	72.0	/3.0	(Z.B	12.6	(Z.)	12.5	12.1	77.9	71.7	/1.5	71.4	11.2	/1.0	7U.5	₩.6	/Ų.4	70.3	/U,1	6Y.Y	6Y. /	DY.5	oy.5

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148 2.17 2.27 2.32 2.29 2.27 2.24 2.21 2.19 2.16 2.14 2.11 2.08 2.01 1.99 1.96 1.94 1.91 1.89 1.86 1.84 1.81 1.78 1.76 1.73 1.71
      149 2.20 2.30 2.35 2.33 2.30 2.27 2.25 2.22 2.20 2.17 2.14 2.12 2.05 2.02 2.00 1.97 1.94 1.92 1.89 1.87 1.84 1.82 1.79 1.77 1.74
      150 2.23 2.33 2.39 2.36 2.33 2.31 2.28 2.24 2.23 2.20 2.18 2.15 2.08 2.05 2.03 2.00 1.96 1.95 1.93 1.90 1.88 1.85 1.83 1.80 1.77
      151 2.26 2.36 2.42 2.40 2.37 2.34 2.32 2.29 2.27 2.24 2.21 2.19 2.11 2.09 2.06 2.04 2.01 1.99 1.96 1.94 1.91 1.88 1.86 1.83 1.81
      152 2.29 2.40 2.46 2.43 2.40 2.38 2.35 2.33 2.30 2.27 2.25 2.22 2.15 2.12 2.10 2.07 2.04 2.02 1.99 1.97 1.94 1.92 1.89 1.87 1.84
      153 2.32 2.43 2.49 2.46 2.44 2.41 2.39 2.36 2.33 2.31 2.28 2.26 2.18 2.15 2.13 2.10 2.08 2.05 2.03 2.00 1.98 1.95 1.93 1.90 1.88
      154 2.35 2.46 2.52 2.50 2.47 2.45 2.42 2.39 2.37 2.34 2.32 2.29 2.21 2.19 2.16 2.14 2.11 2.09 2.06 2.04 2.01 1.98 1.96 1.93 1.91
      155 2.38 2.49 2.56 2.53 2.51 2.48 2.45 2.43 2.40 2.36 2.35 2.32 2.25 2.22 2.20 2.17 2.15 2.12 2.09 2.07 2.04 2.02 1.99 1.97 1.94
      156 2.41 2.52 2.59 2.57 2.54 2.51 2.49 2.46 2.44 2.41 2.38 2.36 2.26 2.25 2.23 2.20 2.18 2.15 2.13 2.10 2.06 2.05 2.03 2.00 1.98
      157 2.45 2.55 2.63 2.60 2.57 2.55 2.52 2.50 2.47 2.44 2.42 2.39 2.31 2.29 2.26 2.24 2.21 2.19 2.16 2.14 2.11 2.06 2.86 2.03 2.01
      158 2.48 2.58 2.66 2.63 2.61 2.58 2.56 2.53 2.50 2.48 2.45 2.43 2.35 2.32 2.30 2.27 2.25 2.22 2.19 2.17 2.14 2.12 2.89 2.07 2.04
      159 2.51 2.61 2.69 2.67 2.64 2.62 2.59 2.56 2.54 2.51 2.49 2.46 2.38 2.35 2.33 2.30 2.28 2.25 2.23 2.20 2.18 2.15 2.13 2.10 2.08
      160 2.54 2.64 2.73 2.70 2.68 2.65 2.62 2.60 2.57 2.55 2.52 2.49 2.41 2.39 2.36 2.34 2.31 2.29 2.26 2.24 2.21 2.18 2.16 2.13 2.11
      161 2.57 2.68 2.76 2.74 2.71 2.68 2.66 2.63 2.61 2.58 2.55 2.53 2.45 2.42 2.40 2.37 2.35 2.32 2.29 2.27 2.24 2.22 2.19 2.17 2.14
      162 2,60 2.71 2.80 2.77 2.74 2.72 2.69 2.67 2.64 2.61 2.59 2,56 2,48 2.46 2.43 2.40 2.38 2.35 2.33 2.30 2.28 2.25 2.23 2.20 2.18
      163 2.63 2.74 2.83 2.80 2.78 2.75 2.73 2.70 2.67 2.65 2.62 2.60 2.51 2.49 2.46 2.44 2.41 2.39 2.36 2.34 2.31 2.29 2.26 2.23 2.21
      164 2.66 2.77 2.86 2.84 2.81 2.79 2.76 2.73 2.71 2.68 2.66 2.63 2.55 2.52 2.50 2.47 2.45 2.42 2.39 2.37 2.34 2.32 2.29 2.27 2.24
      165 2.70 2.80 2.90 2.87 2.85 2.82 2.80 2.77 2.74 2.72 2.69 2.67 2.58 2.56 2.53 2.50 2.48 2.45 2.43 2.40 2.38 2.35 2.33 2.30 2.28
      166 2.73 2.63 2.93 2.91 2.68 2.66 2.63 2.80 2.78 2.75 2.73 2.70 2.61 2.59 2.56 2.54 2.51 2.49 2.46 2.44 2.41 2.39 2.36 2.33 2.31
      167 2.76 2.86 2.97 2.94 2.92 2.89 2.86 2.84 2.81 2.79 2.76 2.73 2.65 2.62 2.60 2.57 2.55 2.52 2.49 2.47 2.44 2.42 2.39 2.37 2.34
      168 2.79 2.89 3.00 2.96 2.95 2.92 2.90 2.87 2.85 2.82 2.79 2.77 2.68 2.66 2.63 2.60 2.58 2.55 2.53 2.50 2.48 2.45 2.43 2.40 2.38
      169 2.82 2.92 3.04 3.01 2.98 2.96 2.93 2.91 2.88 2.85 2.83 2.80 2.71 2.69 2.66 2.64 2.61 2.59 2.56 2.54 2.51 2.49 2.46 2.43 2.41
      170 2.85 2.96 3.07 3.04 3.02 2.99 2.97 2.94 2.91 2.89 2.86 2.84 2.75 2.72 2.70 2.67 2.65 2.62 2.60 2.57 2.54 2.52 2.49 2.47 2.44
      171 2.58 2.99 3.10 3.08 3.05 3.03 3.00 2.97 2.95 2.92 2.90 2.87 2.78 2.76 2.73 2.70 2.68 2.65 2.63 2.60 2.56 2.55 2.53 2.50 2.48
      172 2.91 3.02 3.14 3.11 3.09 3.06 3.03 3.01 2.98 2.96 2.93 2.90 2.81 2.79 2.76 2.74 2.71 2.69 2.66 2.64 2.61 2.59 2.56 2.53 2.51
      173 2.94 3.05 3.17 3.15 3.12 3.09 3.07 3.04 3.02 2.9V 2.96 2.94 2.85 2.82 2.80 2.77 2.75 2.72 2.70 2.67 2.64 2.62 2.59 2.57 2.54
      174 2.98 3.08 3.21 3.18 3.15 3.13 3.10 3.08 3.05 3.02 3.00 2.97 2.88 2.86 2.83 2.80 2.78 2.75 2.73 2.70 2.68 2.65 2.63 2.60 2.58
      175 3.01 3.11 3.24 3.21 3.19 3.16 3.14 3.11 3.08 3.06 3.05 3.01 2.91 2.89 2.86 2.84 2.81 2.79 2.76 2.74 2.71 2.69 2.66 2.63 2.61
      176 3.04 3.14 3.27 3.25 3.22 3.20 3.17 3.14 3.12 3.09 3.07 3.04 2.95 2.92 2.90 2.87 2.85 2.82 2.80 2.77 2.74 2.72 2.69 2.67 2.64
      177 3.07 3.17 3.31 3.28 3.24 3.23 3.20 3.18 3.15 3.13 3.10 3.07 2.98 2.96 2.93 2.91 2.88 2.85 2.83 2.80 2.78 2.75 2.73 2.70 2.68
      178 3.10 3.21 3.34 3.32 3.29 3.26 3.24 3.21 3.19 3.16 3.13 3.11 3.01 2.99 2.96 2.94 2.91 2.89 2.86 2.84 2.81 2.79 2.76 2.74 2.71
     179 3.13 3.24 3.38 3.35 3.33 3.30 3.27 3.25 3.22 3.20 3.17 3.14 3.05 3.02 3.00 2.97 2.95 2.92 2.90 2.87 2.84 2.82 2.79 2.77 2.74
      180 3.16 3.27 3.41 5.39 3.36 3.33 3.31 3.28 3.26 3.23 3.20 3.18 3.08 3.06 3.03 3.01 2.98 2.95 2.93 2.90 2.88 2.85 2.83 2.80 2.78
     181 3.19 3.30 3.45 3.42 3.39 3.37 3.34 3.32 3.29 3.26 3.24 3.21 3.11 3.09 3.06 3.04 3.01 2.99 2.96 2.96 2.96 2.91 2.89 2.86 2.84 2.81
     182 3.23 3.33 3.48 3.45 3.43 3.40 3.38 3.35 3.32 3.30 3.27 3.25 3.15 3.12 3.10 3.07 3.05 3.02 3.00 2,97 2,94 2,92 2,89 2.87 2.84
     183 3.26 3.36 3.51 3.49 3.46 3.44 3.41 3.38 3.36 3.33 3.31 3.28 3.18 3.16 3.13 3.11 3.06 3.05 3.03 3.00 2.98 2.95 2.93 2.90 2.88
     184 3.29 3.39 3.55 3.52 3.50 3.47 3.44 3.42 3.39 3.37 3.34 3.31 3.22 3.19 3.16 3.14 3.11 3.09 3.06 3.04 3.01 2.99 2.96 2.94 2.91
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LOWER LIMIT

 $\mathbf{q}$ 

NORMAL

(LLN) FOR FEV $_{
m 1}$ 

FOR

FEMALES

<sup>\*</sup> One note on Knudson et al. LLN for females less than 40 years old. The 95<sup>th</sup> percentile for this age group is 70.3%, while the value for females older than 40 years is 77.9%. The 1.645\*SEE or the 95 percent confidence limit for the less than 40 years age group is located at approximately 77 percent of the mean FEV<sub>1</sub> for this age group. If the 70.3 value is used, then a female's LLN for the FEV<sub>1</sub> will increase between the ages of 39 and 40. Most other studies, and even the males for this same study, usually exhibit a decrease in the 95<sup>th</sup> percentile for the older age groups. Therefore, we chose to use the same percentile (77.9%) for all females older than 20 years.

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Nt(cm)\Age 17 19 21 23 25 27 29 31 33 35 37 39 41 43 45 47 49 51 53 55 57 59 61 63 65
      148 74.8 75.9 77.5 77.2 76.9 76.5 76.2 75.9 75.6 75.2 74.9 74.6 74.2 73.9 73.6 73.3 72.9 72.6 72.3 72.0 71.6 71.3 71.0 70.7 70.3
      149 74.7 75.8 77.3 77.0 76.7 76.4 76.0 75.7 75.4 75.1 74.7 74.4 74.1 73.8 73.4 73.1 72.8 72.5 72.1 71.8 71.5 71.2 70.8 70.5 70.2
      150 74.5 75.6 77.2 76.9 76.5 76.2 75.9 75.6 75.2 74.9 74.6 74.3 73.9 73.6 73.3 73.0 72.6 72.3 72.0 71.7 71.3 71.0 70.7 70.3 70.0
      151 74.4 75.5 77.0 76.7 76.4 76.1 75.7 75.4 75.1 74.7 74.4 74.1 73.8 73.4 73.1 72.8 72.5 72.1 71.8 71.5 71.2 70.8 70.5 70.2 69.9
      152 74.2 75.3 76.9 76.5 76.2 75.9 75.6 75.2 74.9 74.6 74.3 73.9 73.6 73.3 73.0 72.6 72.3 72.0 71.7 71.3 71.0 70.7 70.4 70.0 69.7
      153 74.1 75.1 76.7 76.4 76.1 75.7 75.4 75.1 74.8 74.4 74.1 73.8 73.5 73.1 72.8 72.5 72.2 71.8 71.5 71.2 70.8 70.5 70.2 69.9 69.5
      154 73.9 75.0 76.6 76.2 75.9 75.6 75.2 74.9 74.6 74.3 73.9 73.6 73.3 73.0 72.6 72.3 72.0 71.7 71.3 71.0 70.7 70.4 70.0 69.7 69.4
      155 73.8 74.8 76.4 76.1 75.7 75.4 75.1 74.8 74.4 74.1 73.8 73.5 73.1 72.8 72.5 72.2 71.8 71.5 71.2 70.9 70.5 70.2 69.9 69.6 69.2
     156 73.6 74.7 76.2 75.9 75.6 75.3 74.9 74.6 74.3 74.0 73.6 73.3 73.0 72.7 72.3 72.0 71.7 71.3 71.0 70.7 70.4 70.0 69.7 69.4 69.1
     157 73.5 74.5 76.1 75.7 75.4 75.1 74.8 74.4 74.1 73.8 73.5 73.1 72.8 72.5 72.2 71.8 71.5 71.2 70.9 70.5 70.2 69.9 69.6 69.2 68.9
     158 73.3 74.4 75.9 75.6 75.3 74.9 74.6 74.3 74.0 73.6 73.3 73.0 72.7 72.3 72.0 71.7 71.4 71.0 70.7 70.4 70.1 69.7 69.4 69.1 68.7
      159 73.2 74.2 75.8 75.4 75.1 74.8 74.5 74.1 73.8 73.5 73.2 72.8 72.5 72.2 71.8 71.5 71.2 70.9 70.5 70.2 69.9 69.6 69.2 68.9 68.6
      160 73.0 74.1 75.6 75.3 74.9 74.6 74.3 74.0 73.6 73.3 73.0 72.7 72.3 72.0 71.7 71.4 71.0 70.7 70.4 70.1 69.7 69.4 69.1 68.8 68.4
      161 72.8 73.9 75.4 75.1 74.8 74.5 74.1 73.8 73.5 73.2 72.8 72.5 72.2 71.9 71.5 71.2 70.9 70.6 70.2 69.9 69.6 69.2 68.9 68.6 68.3
      162 72.7 73.8 75.3 75.0 74.6 74.3 74.9 73.7 73.3 73.0 72.7 72.3 72.0 71.7 71.4 71.0 70.7 70.4 70.1 69.7 69.4 69.1 68.8 68.4 68.1
      163 72.5 73.6 75.1 74.8 74.5 74.1 73.8 73.5 73.2 72.8 72.5 72.2 71.9 71.5 71.2 70.9 70.6 70.2 69.9 69.6 69.3 68.9 68.6 68.3 68.0
      164 72.4 73.5 75.0 74.6 74.3 74.0 73.7 73.3 73.0 72.7 72.4 72.0 71.7 71.4 71.1 70.7 70.4 70.1 69.7 69.4 69.1 68.8 68.4 68.1 67.8
      165 72.2 73.3 74.5 74.5 74.2 73.8 73.5 73.2 72.8 72.5 72.2 71.9 71.5 71.2 70.9 70.6 70.2 69.9 69.6 69.3 68.9 68.6 68.3 68.0 67.6
      166 72.1 73.1 74.6 74.3 74.0 73.7 73.3 73.0 72.7 72.4 72.0 71.7 71.4 71.1 70.7 70.4 70.1 69.8 69.4 69.1 68.8 68.5 68.1 67.8 67.5
      167 71.9 73.0 74.5 74.2 73.8 73.5 73.2 72.9 72.5 72.2 71.9 71.6 71.2 70.9 70.6 70.2 69.9 69.6 69.3 68.9 68.6 68.3 68.0 67.6 67.3
      168 71.8 72.8 74.3 74.0 73.7 73.3 73.0 72.7 72.4 72.0 71.7 71.4 71.1 70.7 70.4 70.1 69.8 69.4 69.1 68.8 68.5 68.1 67.8 67.5 67.2
      169 71.6 72.7 74.2 73.8 73.5 73.2 72.9 72.5 72.2 71.9 71.6 71.2 70.9 70.6 70.3 69.9 69.6 69.3 69.0 68.6 68.3 68.0 67.7 67.3 67.0
      170 71.5 72.5 74.0 73.7 73.4 73.0 72.7 72.4 72.1 71.7 71.4 71.1 70.7 70.4 70.1 69.8 69.4 69.1 68.8 68.5 68.1 67.8 67.5 67.2 66.8
      171 71.3 72.4 73.8 73.5 73.2 72.9 72.5 72.2 71.9 71.6 71.2 70.9 70.6 70.3 69.9 69.6 69.3 69.0 68.6 68.3 68.0 67.7 67.3 67.0 66.7
      172 71.2 72.2 73.7 73.4 73.0 72.7 72.4 72.1 71.7 71.4 71.1 70.8 70.4 70.1 69.8 69.5 69.1 68.8 68.5 68.2 67.8 67.5 67.2 66.8 66.5
      173 71.0 72.1 73.5 73.2 72.9 72.6 72.2 71.9 71.6 71.2 70.9 70.6 70.3 69.9 69.6 69.3 69.0 68.6 68.3 68.0 67.7 67.3 67.0 66.7 66.4
      174 70.8 71.9 73.4 73.0 72.7 72.4 72.1 71.7 71.4 71.1 70.8 70.4 70.1 69.8 69.5 69.1 48.8 68.5 68.2 67.8 67.5 67.2 66.9 66.5 66.2
      175 70.7 71.8 73.2 72.9 72.6 72.2 71.9 71.6 71.3 70.9 70.6 70.3 70.0 69.6 69.3 69.0 68.7 68.3 68.0 67.7 67.3 67.0 66.7 66.4 66.0
      176 70.5 71.6 73.1 72.7 72.4 72.1 71.7 71.4 71.1 70.8 70.4 70.1 69.8 69.5 69.1 68.8 68.5 68.2 67.8 67.5 67.2 66.9 66.5 66.2 65.9
      177 70.4 71.5 72.9 72.6 72.2 71.9 71.6 71.3 70.9 70.6 79.3 70.0 69.6 69.3 69.0 68.7 68.3 68.0 67.7 67.4 67.0 66.7 66.4 66.1 65.7
      178 70.2 71.3 72.7 72.4 72.1 71.8 71.4 71.1 70.8 70.5 70.1 69.8 69.5 69.2 68.8 68.5 68.2 67.8 67.5 67.2 66.9 66.5 66.2 65.9 65.6
      179 70.1 71.2 72.6 72.2 71.9 71.6 71.3 70.9 70.6 70.3 70.0 69.6 69.3 69.0 68.7 68.3 68.0 67.7 67.4 67.0 66.7 66.4 66.1 65.7 65.4
      180 69.9 71.0 72.4 72.1 71.8 71.4 71.1 70.8 70.5 70.1 69.8 69.5 69.2 68.8 68.5 68.2 67.9 67.5 67.2 66.9 66.6 66.2 65.9 65.6 65.2
     181 69.8 70.8 72.3 71.9 71.6 71.3 71.0 70.6 70.3 70.0 69.7 69.3 69.0 68.7 68.3 68.8 67.7 67.4 67.8 66.7 66.4 66.1 65.7 65.4 65.1
      182 69.6 70.7 72.1 71.8 71.4 71.1 70.8 70.5 70.1 69.8 69.5 69.2 68.8 60.5 68.2 67.9 67.5 67.2 66.9 66.6 66.2 65.9 65.6 65.3 64.9
      183 69.5 70.5 71.9 71.6 71.3 71.0 70.6 70.3 70.0 69.7 69.3 69.0 68.7 68.4 68.0 67.7 67.4 67.1 66.7 66.4 66.1 65.7 65.4 65.1 64.8
     184 69.3 70.4 71.8 71.5 71.1 70.8 70.5 70.2 69.8 69.5 69.2 68.8 68.5 68.2 67.9 67.5 67.2 66.9 66.6 66.2 65.9 65.6 65.3 64.9 64.6
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### DRAFT 16-July-1990 DRAFT

Table 7. Upper limits of estimated annual decline in  $FEV_1$  ( $\Delta_E FEV_1$ ) based on linear regression for males for several different time intervals ( $T_{yrs}$ ) by most recently observed  $FEV_1$  and age.

			Age	< 35	FEV	1			
Tyrs	<3.00	3.50	4.00	4.50	5.00	5.50	6.00	6.50	7.00
1	479	484	499	514	529	544	559	574	589
2	244	247	254	262	269	277	284	292	299
3	166	163	173	178	183	188	193	198	203
4	127	128	132	136	140	143	147	151	155
5	104	105	108	111	114	117	120	123	126
6	88	89	91	94	96	99	101	104	106
7	77	77	80	82	84	86	88	90	92
8	68	59	71	73	75	76	78	80	82
9	62	52	64	66	67	69	71	72	74
10	57	57	59	60	62	63	65	66	68
11	52	53	54	55	57	58	60	61	62
12	49	49	50	52	53	54	55	57	5 <b>8</b>
				Age					
1	489	494	509	524	539	554	569	584	599
2	254	257	264	272	279	287	294	302	309
3	176	178	183	188	193	198	203	208	213
4	137	138	142	146	150	153	157	161	165
5	114	115	118	121	124	127	130	133	136
6	98	99	101	104	106	109	111	114	116
7	87	87	90	92	94	96	98	100	102
8	78	79	81	83	85	86	88	90	92
3	72	72	74	76	77	79	81	82	84
10	67	67	69	70	72	73	75	76	78
11	52	63	64	65	67	68	70	71	72
12	59	59	60	62	63	54	65	67	68

### DRAFT 16-July-1990 DRAFT

Table 8. Upper limits of estimated annual decline in  $FEV_1$  ( $\Delta_E FEV_1$ ) based on linear regression for females for several different time intervals  $(T_{yrs})$  by most recently observed  $FEV_1$  and age.

Age < 35 FEV1													
Tyrs	<3.00	3.50	4,00	4.50	5.00	5.50	6,00	6,50	7.00				
1	375	380	395	410	425	440	455	470	485				
2	190	193	200	208	215	223	230	238	245				
3	129	130	135	140	145	150	155	160	165				
4	98	99	103	107	110	114	118	122	125				
5	79	80	83	86	89	92	95	98	101				
6	67	68	70	73	75	78	80	83	85				
7	58	59	61	63	65	67	70	7 <b>2</b>	74				
8	52	52	54	56	58	60	62	63	65				
9	46	47	49	50	52	54	55	<b>5</b> 7	59				
10	42	43	44	46	47	49	50	52	53				
11	39	39	41	42	44	45	46	48	49				
12	36	37	38	39	40	42	43	44	45				
				Age	≥ 35								
1	385	. 390	405	420	435	450	465	480	495				
2	200	203	210	218	225	233	240	248	255				
3	139	140	145	150	155	160	165	170	175				
4	108	109	113	117	120	124	128	132	135				
5	89	90	93	96	99	102	105	108	111				
6	77	78	80	83	85	88	90	93	95				
7	68	69	71	73	75	77	80	82	84				
8	62	62	64	66	68	70	72	73	75				
9	56	57	59	60	62	64	<b>6</b> 5	67	69				
10	52	53	54	56	57	59	60	62	63				
11	49	49	51	52	54	55	56	58	59				
12	46	47	48	49	50	52	53	54	55				