50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. Recipient's Accession No. PB91-152405
4. Title and Subtitle NIOSH Testimony on Occupational Exposure to Cadmium by R. W. Niemeier, May 7, 1990			5. Report Date 1990/05/07
			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 concerns the support of NIOSH for the assessment of OSHA that exposure to cadmium (7440439) is associated with the increased incidence of lung cancer and kidney dysfunction. Because cadmium is a potential occupational carcinogen and because OSHA estimates that the total cancer risk is 2.1 excess deaths per 1000 at an 8 hour time weighted average exposure of 1 microgram/cubic meter, NIOSH maintains that occupational exposures to cadmium should be reduced to the lowest feasible level. NIOSH strongly supports the use of engineering controls and work practices instead of the use of personal protective equipment, including respiratory protection, for controlling exposures to cadmium. Specific comments addressed include the control of confounding factors in kidney dysfunction analysis, the number of workers exposed to cadmium, the industries in which cadmium exposure occurs, standards for the construction industry, engineering and work practice controls, analytical methods for determining exposures, monitoring intervals, medical surveillance provisions, proteinuria and medical removal, return to work, and reproductive effects.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms NIOSH-Publication, NIOSH-Author, NIOSH-Testimony, Niemeier-R-W, Cadmium-poisoning, Cadmium-compounds, Construction-workers, Regulations, Standards, Epidemiology, Reproductive-hazards, Toxic-effects

c. COSATI Field/Group

18. Availability Statement	19. Security Class (This Report)	21. No. of Pages 24
	22. Security Class (This Page)	22. Price

(See ANSI-Z39.18) *See Instructions on Reverse* **OPTIONAL FORM 272(4-77)** (Formerly NTIS-35) Department of Commerce

PB91-152405

NIOSH Comments to DOL

COMMENTS 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

U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health

May 7, 1990

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*	Ceiling
Cadmium fume	100 $\mu g/m^3$**	300 $\mu g/m^3$
Cadmium dust	200 $\mu g/m^3$	600 $\mu g/m^3$

*Permissible exposure limit
**Micrograms of cadmium per cubic meter of air

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

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

	PEL	EL***	AL****
Alternative 1	1 $\mu g/m^3$	5 $\mu g/m^3$	0.5 $\mu g/m^3$
Alternative 2	5 $\mu g/m^3$	25 $\mu g/m^3$	2.5 $\mu g/m^3$

***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 and kidney dysfunction. In the criteria document on cadmium, NIOSH recommended that workers not be exposed to cadmium or its compounds at concentrations greater than 40 $\mu g/m^3$ as an 8-hr TWA and 200 $\mu g/m^3$ during any 15-minute period [NIOSH 1976]. This standard was recommended by NIOSH to prevent the chronic health effects of 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.

More recently, a NIOSH Current Intelligence Bulletin (CIB) 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 upon 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 and because 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 $\mu g/m^3$, NIOSH maintains the position that occupational exposures to cadmium should be reduced to the lowest feasible level [NIOSH 1984a]. Although NIOSH recognizes that 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, the level of excess cancer deaths estimated by OSHA for either proposed limit would still be excessive. For example, 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 300,000 workers are potentially exposed to cadmium-type compounds [see Appendices 1-4]. At a standard of 1 $\mu g/m^3$, excess deaths for these potentially exposed workers could exceed 600.

NIOSH strongly supports the use of engineering controls and work practices instead of the use 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]. As OSHA states, the "...effectiveness of engineering controls does not depend to any degree on human behavior, and the operation of equipment is not as vulnerable to human error as is personal protective equipment" (55 FR 4109). For this reason, NIOSH is concerned with the routine use of respirators for protection against exposure to cadmium; for example, during brief duration jobs/tasks, where respiratory protection is less expensive than engineering controls or "where feasible engineering controls result in only a negligible reduction in exposure" (55 FR 4108).

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)

NIOSH recognizes that respiratory protection may be required as supplementary protection for workers when engineering controls are not feasible for reducing exposures to below the OSHA TWA 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 in its most recent comments to the docket on methods of compliance, a detailed explanation of the problems associated with respirator use [NIOSH 1989a].

NIOSH agrees with the OSHA assessment that occasional 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 voluntary. For the same reasons, NIOSH does not support the OSHA proposed exemption for voluntary respirator users (55 FR 4112).

Because cadmium is a potential occupational carcinogen, NIOSH recommends the use of only the most protective respirator for use against carcinogens. These respirators are:

(1) 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 OSHA chooses to permit respirators other than the most protective respirators, NIOSH recommends the use of the assigned protection factors (APFs) in the NIOSH Respirator Decision Logic [NIOSH 1987c]. In particular, NIOSH recommends an APF of 50 for full facepiece powered air-purifying respirators--not 250 as OSHA has proposed.

2. <u>Medical Surveillance (55 FR 4124)</u>

Confidentiality

The proposed rule requires preplacement, annual, and termination medical examinations for employees who are exposed at or above the action level. Medical records generated by occupationally related medical screening should be confidential, as are other medical records; OSHA should specify the various responsibilities of the employer and the physician, especially with regard to confidentiality.

While biological monitoring cannot substitute for environmental sampling, NIOSH agrees with OSHA that employers should be informed of the results of biological monitoring tests that assess absorption by measuring the concentration of the substance (or a metabolite) in body fluids. In this case, blood and urine cadmium should be reported to employers, since this information is needed to ensure a "safe and healthful" workplace.

On page 4127, OSHA requires that employers maintain medical records. This is appropriate when the company employs medical professionals on site to maintain the records and ensure that confidentiality is not violated.

The employer is entitled to receive and maintain a copy of the physician's opinion regarding the suitability of the worker for continued work in the relevant exposure; the specific conditions responsible for any work restrictions should not be divulged to the employer without a signed release from the worker. While the welfare of a group of workers must occasionally be balanced against individual rights, NIOSH recommends that OSHA provide protection in the final rule against wrongful disclosure of medical information.

Medical screening requirements

The medical screening requirements in Section (1)(2)(ii)(B) of the proposed standard requires 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 may not be useful when screening for cadmium toxicity.

(2) cadmium-related musculoskeletal effects require long or high exposures (and perhaps dietary deficiencies and/or renal disease). Since other detectable effects occur much earlier and are detectable by more sensitive tests, it may not be necessary to screen the musculoskeletal system.

(3) If the complete blood count is normal, physical examination of the hematological system may not add useful information.

(4) the only established cadmium-related abnormality of the genitourinary system which could be detected by physical examination would be prostate cancer; the requirement for a rectal examination is probably not enhanced by a requirement for examination of the "genitourinary system."

In addition, some of the medical tests required under the proposed standard (e.g., liver enzymes, urine glucose, urine total protein, urine specific gravity, microscopic examination of urinary sediment) may not be useful in screening for cadmium-induced damage. Other tests (e.g., blood urea nitrogen, serum creatinine) may be worth obtaining in the baseline examination, but need not be repeated during periodic screening examinations of healthy workers.

The standard requires in Section (l)(ii)(4)(E) that certain actions be triggered by repeated diagnoses of upper or lower respiratory infections (presumably acute); such diagnoses are unlikely to be related to cadmium exposure at levels near either of the proposed PELs.

The questionnaire (Appendix d)

NIOSH recommends that a respiratory questionnaire be included in medical screening associated with cadmium exposure; questions 3-9 and 26 of the proposed questionnaire relate to the respiratory system. Many of the remaining questions are apparently included to help evaluate tests which may not be necessary (see above).

Pulmonary function tests

In Section (l)(4)(i)(C) OSHA states that pulmonary function test results are to be adjusted for the age and smoking habits of the person examined; it is not clear how this is to be done.

Section (l)(4)(iv) the proposed standard requires that when "...the FVC or the FEV_1 is less than 80% of predicted values, or the ratio of FEV_1/FVC times 100 is less than 75% of the predicted values, or the employee experiences difficulty breathing during the use of or fit testing for respirators, restriction from respirator use shall be considered and the physician will further evaluate the employee's ability to wear a respirator." OSHA should indicate what method of determining predicted values is to be used and consider alternative methods of determining that a specific result is abnormal [Knudson et al. 1983; Hankinson 1986].

3. <u>Monitoring Frequency (55 FR 4121)</u>

NIOSH recommends that initial and periodic (at least quarterly) monitoring be conducted for all workers who may be exposed to cadmium [NIOSH 1987a]. NIOSH does not support the OSHA position that periodic monitoring is not required 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). NIOSH contends that exposure levels will vary because of changes in the process, and the measurement of these exposure levels will be inaccurate because some exposure scenarios are of short duration (e.g., welding) and because of inherent sampling variability and measurement inaccuracies. Therefore, periodic monitoring should not be discontinued under any circumstance for workers who may be exposed to cadmium.

NIOSH suggests that part of the OSHA discussion on exposure monitoring in the preamble is not appropriate to cadmium (55 FR 4098). OSHA states that "...at least two methods and types of monitoring devices, charcoal tubes and passive dosimeters, are currently available to take these measurements." NIOSH is not aware of any sampling device using charcoal tubes or passive dosimeters that could measure airborne particulate such as cadmium.

4. <u>Sampling and Analytical Methods (55 FR 4138)</u>

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

As a result of recent discussions by NIOSH scientists concerning limits of detection, NIOSH suggests 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 bracket the low (i.e., near the action level) samples with known concentrations.

IV. NIOSH EVALUATION OF OSHA RISK ASSESSMENT

Regarding its risk assessment, OSHA requested comments regarding the quality of the Takenaka [1983] and Thun [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

Both studies appear to be sound studies and appropriate as a source 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). It is generally informative, when possible, to perform risk assessments based upon both animal and human data as OSHA has done.

It is noteworthy that the risk estimates derived from these two studies are similar. For the cadmium proposed rule, it is not clear which data set should be preferred to perform this assessment. However, from a protective policy viewpoint, NIOSH agrees with the OSHA choice of the data set (Takenaka) that yields the highest estimate of risk (i.e., errs on the side of protecting the worker's health).

Multistage Model

For its risk assessment, NIOSH agrees with the OSHA reliance on the multistage model for 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 best model.

Particle Size

OSHA did not take account of the effects of changes in particle size distribution on the risk assessment, and asked for comments on whether different lung disease risks would be posed by different size particles, and whether regulation is warranted by 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., Rudoph et al. [1988], Ann Occup Hyg 32:919-938). Thus, one would expect that the risk of lung cancer among workers exposed to cadmium exposure would vary depending on the particle size distribution. However, NIOSH suggests that the information currently available may be inadequate to form the basis for a standard based upon particle size distribution.

Assumptions Involved in Absolute and Relative Risk Models

OSHA requested comments concerning an OSHA assumption inherent to its use of the NIOSH study in its risk modeling (55 FR 4078). This assumption is that the relative effects of cadmium exposure were constant across the age groups. An additional assumption inherent to this assessment which was not discussed by OSHA, is that the effect of cadmium exposure is not dependent on dose rate. Thus, an individual exposed to 0.1 mg/m^3 for 10 years is assumed to have the same risk as an individual exposed to 1 mg/m^3 for a year in this analysis.

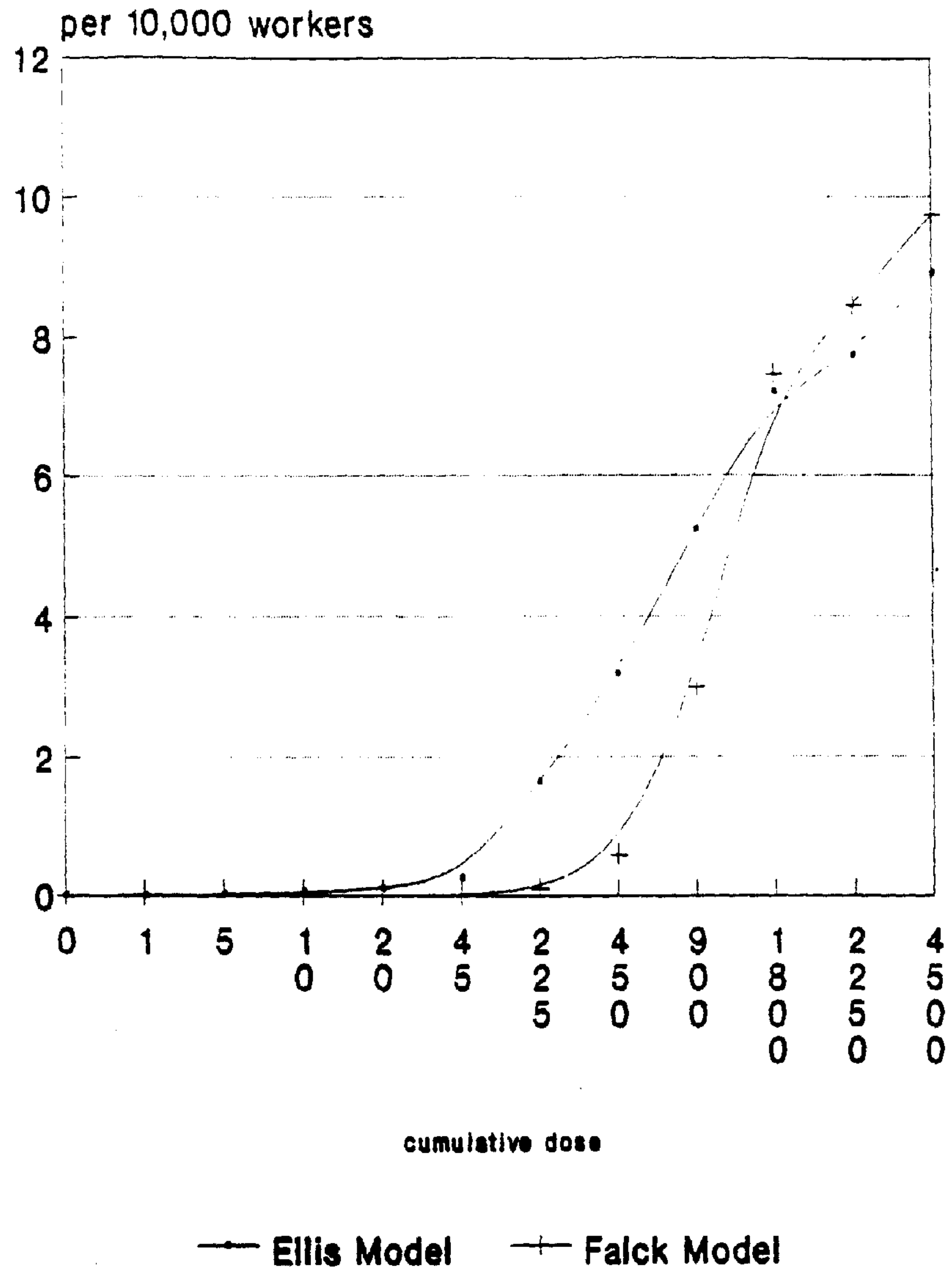
Actually, neither of these assumptions can be tested given the results as reported by Thun et al. [1985]. The assumption of the risk being constant with age (proportional hazards assumption) could be tested in the context of a Poisson regression or Cox proportional hazards model. However, it would not be possible to examine the assumption of a dose-rate effect given the limited epidemiologic information available.

Logistic Regression Analysis for Kidney Dysfunction

OSHA asked for comments on their use of logistic regression as a model for estimating risk of kidney dysfunction. The primary concern expressed in comments to OSHA regarding the use of this model is that this model may be inappropriate if a threshold exists for the effects of cadmium exposure on kidney function, because this model would predict some finite risk at any nonzero exposure level (55 FR 4083).

Actually, the logistic regression model may be an appropriate method for modeling effects which are believed to have a threshold level. 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 exposure concentrations. 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 have thus been described as belonging to a family of "tolerance" distribution models.

NIOSH is not familiar with the two-phase linear model that OSHA cited as an alternative used by Mason et al. (Ex. 8-669). However, because different



Based on Logistic Regression Models

Figure 1. Cadmium and nephrotoxicity results from OSHA risk assessment

individuals in the population would be expected to have different threshold levels, a single level for a "threshold" effect for the population may be impossible to determine.

Control of Confounding Factors in Kidney Dysfunction Analysis

OSHA requested information on whether the Falck study suggests that the effects of cadmium are independent of smoking, whether a one-tailed test should have been used, and whether OSHA's risk model appropriately captures the independent effect of cadmium exposure. The issue of whether a variable should be considered a confounder in an analysis is generally not decided on the basis of a statistical test. This principle has been emphasized by several authors [Rothman 1986; Kleinbaum, Kupper, Morgenstein, 1982]. The established method in a regression context for evaluating a confounder is to check whether the inclusion of the confounding variable in the regression model changes the regression coefficient for the predictor variable of interest (i.e., cadmium exposure). Furthermore, OSHA's use of a stepwise regression procedure for selecting confounding variables for inclusion in its modeling of Falck's study is not appropriate, because it is also based on criteria related to statistical significance.

Typographical and Other Relatively 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 (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 β is obtained by maximizing the first derivative of the log likelihood with respect to β." 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 a $EG5_j$ which should be E_j. The other likelihood expression has an $E_j\beta_j$, 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 $\beta \pm 1.645\ SE(\beta)$.

V. 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?**

   NIOSH recognizes that 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 1983; Thun 1985]:

   EXCESS CANCER DEATHS

	1 $\mu g/m^3$*	5 $\mu g/m^3$*
Thun	0.3 per 1000	1 per 1000
Takenaka	2 to 3 per 1000	10 to 15 per 1000

   *Proposed alternative TWA PELs.

   NIOSH is concerned that the estimate of excess cancer deaths for either proposed PEL would still be excessive. Therefore, NIOSH continues to recommend that occupational exposure to cadmium should be reduced to the lowest feasible level [NIOSH 1984a].

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

   NIOSH has performed an assessment of the relevant NIOSH studies regarding exposures to cadmium and the technological feasibility for controlling exposures to cadmium. Based on this assessment, NIOSH concludes that exposures to cadmium can generally be controlled by engineering and work practice techniques to within 1 to 2 $\mu g/m^3$ for these industries. Exposures can be reduced even further by the use of respiratory protection [NIOSH 1987b; NIOSH 1987c].

   For example, NIOSH has conducted a number of studies on cadmium exposures and feasibility for control [ECI 1982; NIOSH 1982a; NIOSH 1982b; NIOSH 1982c; NIOSH 1982d; NIOSH 1982e; NIOSH 1983b; NIOSH 1983c; NIOSH 1983d;

NIOSH 1984b; NIOSH 1984c; NIOSH 1984d; NIOSH 1984e; NIOSH 1985a; NIOSH 1985b; NIOSH 1986]. These studies are subject to certain limitations including the condition that the majority of these studies were conducted with reference to the then current NIOSH recommended exposure limit (REL) of 40 $\mu g/m^3$ of cadmium. The majority of the studies used analytical methods with limits of detection of greater than or equal to 10 $\mu g/m^3$. However, A number of observations are possible based on these studies. Operations involving cadmium pigments have high potential exposures although the magnitude of the potential exposures may be significantly decreased by appropriate engineering controls [NIOSH 1985b]. For some processes, respiratory protection programs were found to be necessary in reducing exposures for some cadmium pigment handling operations [NIOSH 1983c].

Welding, brazing, and silver-soldering operations may result in exposures over the proposed PEL, but engineering controls are available to reduce these exposures [NIOSH 1982a; NIOSH 1982b; NIOSH 1982c].

Cadmium-plating operations that were surveyed had very low exposure levels to cadmium. These levels were close to the limit of detection (1 $\mu g/m^3$) for the analytical method that was used [NIOSH 1984e]. NIOSH would project that local ventilation would control exposures to cadmium below the proposed PEL in cadmium-plating operations.

7. **How many workers are exposed to cadmium?**

and

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

Appendices 1 through 4 are the NIOSH National Occupational Exposure Survey (NOES) estimates for the number of United States workers who are potentially exposed to cadmium-type compounds [see Appendices 1-4]. 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 workers who are exposed to cadmium compounds (total workers = 221,000).

With these estimates, NIOSH has also provided the type and percentage use of the predominant methods for controlling exposure to cadmium by SIC code. 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?**

Because the health effects related to cadmium exposure are independent of the type of industry (i.e., general industry, construction, maritime, etc.), NIOSH suggests that the cadmium standard should apply to all sectors of industry including construction. There are several potential exposures to cadmium for construction workers, including the job tasks of demolition, renovation, repair, and clean-up workers. Moreover, in construction, there is the unique problem of material safety data sheets (MSDS) being unavailable in jobs such as the aforementioned, at multi-employer work sites, and where workers are mobile. Moreover, MSDSs may not be available during some operations, for example, during demolition work where old cadmium paint or cadmium metal may be encountered.

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

Please see the NIOSH response to question 1.

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 1987c]. Both training and motivation are required for a respirator to be used properly [NIOSH 1987b]. NIOSH continues to recommend only the most protective respirators be worn when exposed to potential carcinogens [NIOSH 1987c]. 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; 1989].

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 $\mu g/m^3$?**

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 $\mu g/m^3$. NIOSH would be willing to evaluate any analytical method that is submitted to the OSHA docket.

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

Although it is not clear what is meant by "objective data," NIOSH suggests that air monitoring is the most appropriate means of estimating airborne exposure to cadmium. NIOSH further suggests that the use of "objective data" may not be appropriate for many of the exposures to cadmium, particularly in the construction, agricultural, and maritime industries, because of the variability of the conditions surrounding the exposure. For example, in the construction industry, 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 infrastructures. In the maritime industry, the exposure to cadmium may occur in enclosed or confined spaces such as inside storage tanks or submarines. In the agricultural industry, the exposure may occur outside during the application of fungicides containing cadmium or during the cutting of cadmium-coated metal. In all of these circumstances, the parameters of exposure (e.g., wind, humidity, temperature) are not only unpredictable from one exposure period to the next, but the parameters may change during an exposure period. Therefore, NIOSH urges that "objective data" not be used to estimate exposures to cadmium, particularly where the parameters of exposure 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 be required for all workers who are potentially exposed to cadmium. NIOSH suggests that under no circumstances should this frequency of monitoring be reduced. [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-molecule-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).

RBP is a better test than B2M, since 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 still in the urinary bladder [Bernard et al. 1987; Lauwreys et al. 1984]. Thus, measurements of B2M in acid urine specimens will result in falsely low values. However, since B2M testing is more widely available and more thoroughly studied, it is currently recommended for screening purposes.

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. 1985a; 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, though neither is completely reliable for this purpose.

Based on currently available data, it would appear that workers who maintain urinary cadmium levels below 10 μg/liter (approximately 10 μg/g creatinine) will not develop tubular kidney proteinuria [NIOSH 1976; WHO 1980; ACGIH 1989]. The action level for urinary cadmium chosen by OSHA (5 μg/gm creatinine) should help to protect workers against renal damage. NIOSH has no recommendations for concentrations of cadmium in blood.

There are insufficient data to evaluate whether limiting cadmium in blood or urine to the action levels proposed by OSHA will be protective against cancer. NIOSH has recommended that cadmium be considered a potential carcinogen and that exposures be reduced to the fullest extent possible [NIOSH 1984a].

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

Cadmium induced renal disease appears to be progressive and irreversible [Thun et al. 1989]. Medical removal is appropriate for employees with proteinuria and in most cases the worker would be ill-advised to return to a job involving cadmium exposure.

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 at intervals of 3 or 6 months is reasonable, proteinuria --and the need to avoid exposure -- may persist indefinitely.

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; this determination is not easily reduced to a formula based on level of "lung function loss."

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

Workers with preceding cadmium exposure should receive the same medical screening evaluations as new workers. However, the lack of baseline testing may make interpretation of the results more difficult.

31. **Questions regarding reproductive effects.**

NIOSH is not aware of data to suggest that cadmium exposure at the proposed PEL's would have adverse reproductive effects in humans.

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

The proposed standard appropriately requires termination medical examinations. At termination, the worker should be provided with a copy of the medical record and the exposure record (including use of respirators and other PPE.

The information obtained in termination medical examinations may be used to:

a. advise the worker regarding the advisability of future employment in jobs with cadmium exposure;

b. evaluate the need for future medical screening or medical treatment. The proposed standard requires that medical records be provided to the worker upon termination of employment. OSHA should also require that complete records regarding exposure and PPE (including respirator usage) be provided;

c. document the status of the worker's health at the time of termination in the event of workmen's compensation claims or litigation;

d. provide additional data for purposes of occupational health surveillance.

REFERENCES

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

Bernard AM, Vyskocil AA, Mahieu P, Lauwerys RR [1987]. Assessment of urinary retinol-binding protein index as an of proximal tubular injury. Clin Chem *33*(6):775-779.

ECI [1982]. Control technology assessment for coal gasification and liquefaction processes at Combustion Engineering Process Development Unit Windsor, Connecticut. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health, Division of Physical Sciences and Engineering, NIOSH Contract No. 210-78-0084.

Elinder CG, Edling C, Lindberg E, Kagedal B, Vesterberg O [1985a]. Assessment of renal function in workers previously exposed to cadmium. Br J Ind Med *42*:754-760.

Ellis KJ, Yuen K, Yasumura S, Cohn SH [1984]. Dose-response analysis of cadmium in man: body burden vs kidney dysfunction. Environ Res *33*:216-226.

Hankinson JL [1986]. Pulmonary function testing in the screening of workers: guidelines for instrumentation, performance, and interpretation. Journal of Occupational Medicine *28*(10):1081-1092.

Kleinbaum DG, Kupper LL, Morgenstern H [1982]. Epidemiologic research: Principles and quantitative methods. New York, NY: Van Nostrand Reinhold Company. Pages 254-257, 448, 455-456.

Knudson RJ, Lebowitz MD, Holberg CJ, Burrows B [1983]. Changes in the normal maximal expiratory flow-volume curve with growth and aging. Am Rev Respir Dis *127*:725-734.

Lauwerys RR, Bernard A, Roels HA, Buchet JP, Viau C [1984]. Characterization of cadmium proteinuria in man and rat. Environ Health Perspect *54*:147-152.

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.

NIOSH [1982a]. Health hazard evaluation report: Goodyear Aerospace Corporation, Akron, Ohio. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health, HETA 82-011-1143.

NIOSH [1982b]. Health hazard evaluation report: Neoplan USA Corporation, Lamar, Colorado. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health, HETA 82-061-1152.

NIOSH [1982c]. Health hazard evaluation report: N.P.C. Systems, Inc., Milford, New Hampshire. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health, HETA 81-212-1169.

NIOSH [1982d]. In-depth survey report of American Airlines Plating Facility. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health, Division of Physical Sciences and Engineering.

NIOSH [1982e]. In-depth survey report: Control technology for Trans World Airlines maintenance facility, Kansas City, Missouri. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health, Division of Physical Sciences and Engineering. Report No. 106-18.

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.

NIOSH [1983b]. Health hazard evaluation report: Hoover Company, I P, North Canton, Ohio. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health, HETA 82-127-1370.

NIOSH [1983c]. Health hazard evaluation report: Rubbermaid Incorporated, Wooster, Ohio. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, HETA 82-223-1340.

NIOSH [1983d]. Health hazard evaluation report: Saft America, Incorporated, St. Paul, Minnesota. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health, HETA 80-187-1395.

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.

NIOSH [1984b]. Health hazard evaluation report: General Motors Corporation, Framingham, Massachusetts. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health, HETA 81-433-1452.

NIOSH [1984c]. Health hazard evaluation report: Kennecott Smelter, Hurley, New Mexico. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, HETA 84-038-1513.

NIOSH [1984d]. Health hazard evaluation report: Rubbermaid Incorporated, Wooster, Ohio. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, HETA 84-230-1528.

NIOSH [1984e]. 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.

NIOSH [1985a]. Health hazard evaluation report: Metz Metallurgical, South Plainfield, New Jersey. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, HETA 82-222-1631.

NIOSH [1985b]. In-depth survey report: Control technology assessment of solid material handling, phase I - bag opening, emptying, and disposal at Rohm and Haas Delaware Valley, Inc. - Bristol Plant, Bristol, Pennsylvania. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, Division of Physical Sciences and Engineering, Engineering Control Technology Branch, Report No. 144-18b.

NIOSH [1986]. Health hazard evaluation report: City of Columbus Refuse Derived Fuel Power Plant, Columbus, Ohio. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, HETA 85-041-1709.

NIOSH [1987a]. 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.

NIOSH [1987b]. 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.

NIOSH [1987c]. 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.

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.

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.

Roels H, Djubgang J, Buchet JP, Bernard A, Lauwerys R [1982]. Evolution of cadmium-induced renal dysfunction in workers removed from exposure. Scand J Work Environ Health *8*:191-200.

Rothman KJ [1986]. Modern epidemiology. Boston, MA: Little, Brown and Company. Pages 301-302.

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

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