APPENDIX F

NIOSH OCCUPATIONAL HISTORY QUESTIONNAIRE FROM THE COAL WORKERS' X-RAY SURVEILLANCE PROGRAM

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APPENDIX G

TECHNICAL CONSIDERATIONS IN THE USE OF SPIROMETRY IN SCREENING AND SURVEILLANCE OF MINERAL-DUST-EXPOSED WORKERS

This appendix describes recommended procedures in the recording and performance (including interpretation) of spirometry in programs of screening and surveillance of mineral-dust-exposed workers.

G.1 RECOMMENDED PROCEDURES AND QUALITY CONTROL

Spirometry tests should be conducted in accordance with the American Thoracic Society (ATS) recommended spirometry standards and the recommendations of the European Respiratory Society (ERS) [ATS 1987; ERS 1993]. These standards establish both the minimum equipment requirements and the procedures to use in administering the test. A quality control (QC) program is also a critical component of the spirometry screening program. The QC program should include adoption of a procedures manual describing the proper calibration, use, and maintenance of all equipment; requirements for record maintenance of calibration checks; and technician training and monitoring. When screening information is being collected from multiple sites, a central system for reviewing test quality is needed.

If spirometry results are to be interpreted longitudinally, the central quality control monitoring center should also attempt to identify "survey" biases. A survey bias is an unexplained change in a group's mean FEV_1 between surveys (which take place at different times and perhaps different locations). A record of calibration checks should be maintained and is particularly useful when a survey bias is suspected to eliminate instrumentation errors as the source.

G.2 INTERPRETATION

G.2.1 Test Reproducibility

The first step in interpreting spirometry is to assess the quality of the test. The lack of a sufficient number of acceptable trials or a reproducible test should be carefully considered during the interpretation

^{*}This material is currently being prepared for publication as an appendix to a book entitled *Health Screening and* Surveillance of Workers Exposed to Mineral Dust (Geneva, Switzerland: World Health Organization, 1995 [in press]). Printed with permission from the World Health Organization.

interpretation. The presence of excessive flow oscillations in the spirogram, resulting in the curve being eliminated due to a "cough," may indicate a functional structural disorder. The lack of a reproducible test may result from disease and has been shown to be associated with an increased risk of mortality from lung disease in cohorts who are occupationally exposed [Eisen et al. 1985; Kellie et al. 1987]. In addition, shorter individuals may have more difficulty in meeting reproducibility criteria than taller individuals. Therefore, an individual's results may be interpreted even though the test was not considered reproducible by ATS standards [ATS 1987].

G.2.2 Comparison with Reference Values

The recommended method of interpreting a single observation of lung function involves the comparison of an individual's observed values of FEV_1 , with a reference value derived from cross-sectional data which takes into account the subject's height (as the main determinant of differences between individual sizes), as well as gender and age. Both ATS and ERS have recently published statements on interpretation of spirometry results [ATS 1991; ERS 1993]. The cutoff values selected to separate individuals for whom no intervention is warranted (presumed "normals") from those for whom a preventive intervention is recommended or required (presumed "abnormals") should be chosen to reflect the goals of screening the program. For purposes of screening where early identification of abnormality is the goal, these test cutoffs may be different from those generally used in clinical practice, which focuses on disease diagnosis and confirmation. Test sensitivity (the ability of a cutoff point for test interpretation to accurately identify a truly abnormal individual), test specificity (the ability of a test cutoff point to accurately identify individuals without disease), and the predictive value of positive and negative test results vary depending on the specific cutoff values adopted and on the extent of disease in the screened population.

G.2.3 Selection of Reference Values

Reference values should be selected based on methodological, epidemiological, and statistical criteria. Reference values are derived from regression equations generated from lung function data gathered in healthy (often non-smoking) populations. Published reference values vary as a result of technical reasons and population differences in groups studied. These differences may relate to socioeconomic, psychosocial, and other factors. The ATS, for example, does not recommend a universal reference value. Instead, it recommends that, to the extent possible, reference values be selected from those obtained using comparable equipment in a population with comparable age, physical characteristics, socio-economic background, and ethnic characteristics [ATS 1991]. By contrast, the ERS guidelines recommend the use of one equation for males and one for females, based on pooled data collected in several countries. Almost all reference values are based on the individual's age and height.

For ethnic groups where reference values may not be available, some adjustment to the caucasian values may be possible. For example, the ERS recommends that for subjects of African descent, the predicted values be multiplied by 0.87. This procedure is not recommended by the ATS, nor does it appear justified based on a recent analysis of published data on over 30,000 men and women of sub-Saharan African descent [White et al. 1994]. Some variability between ethnic groups may be due to differences in trunk length relative to standing height [ERS 1993].

G.2.4 Criteria for Abnormal FEV₁ Based on Reference Value Comparisons

Although the 95th percentile[†] is often used as the lower limit of normal (LLN) for purposes of clinical interpretation, this may not be appropriate for screening and surveillance. In some circumstances, where the purposes of cross sectional screening would be better met by a more sensitive indication of potential abnormality, the 85th or 90th percentile, or another cutoff, might be selected as the LLN or level that stimulates further monitoring, investigation, or other action. The LLN is available or can be calculated from data published for most reference values. For example, the ERS recommends that the LLN approximating the 95th percentile can be estimated by subtracting 0.84 L (males) or 0.62 L (females) from the predicted value.

G.2.5 Criteria for Abnormal FEV₁ Based on Change Over Time

A comparison of an individual's current FEV_1 with his/her own FEV_1 determined in the past may be of some benefit, particularly for those workers whose FEV_1 is above that predicted. A quality control program is especially important if longitudinal changes are to be assessed. Because of considerable short-term variability in FEV_1 , a year-to-year change of greater than 15% should occur before a change in FEV_1 is considered significant. For longer periods of observation, adjustment for the expected annual decline in FEV_1 is appropriate. Therefore, the LLN for the follow-up FEV_1 is computed by taking 85% of the baseline value minus the expected decline over the time period. An individual's expected decline over the time period is dependent on his/her age, but for practical considerations, a constant value of 25 ml/year is often recommended. For example, an individual whose initial FEV_1 is 4.00 L would be considered to have an accelerated decline in FEV_1 if his/her FEV_1 is below 3.15 L, 10 years after the baseline value was determined (0.85 × 4.00 L --10 years × 0.025 L). This approach to interpretation of longitudinal test performance has been presented in more detail recently [Hankinson and Wagner 1993].

To increase the sensitivity of screening spirometry, comparisons of an individual's FVC and FEV₁/FVC% with the appropriate LLNs can also be conducted. However, because the FVC is usually a more difficult parameter to accurately determine (more effort-dependent than the FEV₁), the FVC and FEV₁/FVC% comparisons should be optional.

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[†]The "normal 95th percentile" used by Knudson et al. [1983] is equivalent to the ATS [1991] definition of LLN as the 5th percentile.

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APPENDIX H

THE BLACK LUNG BENEFITS PROGRAM

The Black Lung Benefits Program, initially established in 1969 as part of the Federal Coal Mine Health and Safety Act (Public Law 91-173), * is intended to provide compensation for coal miners who are partially or totally disabled from their normal coal mine employment. Standards for determining coal miners' total disability or death due to pneumoconiosis are based on criteria such as length of employment, radiographic evidence of pneumoconiosis, and/or values for pulmonary function tests or arterial blood-gas tests that are below predicted normal values [29 CFR 718].

The initial program established in 1969 was administered by the Social Security Administration and used public funds to compensate disabled coal miners. It was intended that the second phase of the program would be administered by the U.S. Department of Labor and structured according to general principles of workers' compensation. However, the number of claims filed under the initial program far exceeded estimates, and the Black Lung Benefits Act of 1972 was enacted to provide simplified interim eligibility criteria for claims filed with the Social Security Administration and to delay the transfer of responsibility to the U.S. Department of Labor for processing and paying claims until 1973. The Social Security Administration continues to administer funds for claims filed before July 1, 1973.

In 1978, the Black Lung Benefits Reform Act of 1977 was enacted, which again mandated the use of interim criteria based on the presumption of eligibility to resolve old, unapproved claims. In addition, the Black Lung Benefits Revenue Act of 1977 was enacted, which created the Black Lung Disability Trust Fund, to be financed by an excise tax on coal that is mined and sold in the United States.

In 1981, the Black Lung Benefits Revenue Act of 1981 and the Black Lung Benefits Amendments of 1981 were enacted. The amendments tightened the eligibility standards, eliminated certain presumptions, and temporarily increased the excise tax on coal to reduce the debt of the Trust Fund to the U.S. Treasury, which was more than \$1.5 billion in 1981 and \$2.8 billion in 1985. In 1985 and 1987, budget-related laws were passed, but further changes were made in the eligibility criteria or adjudication procedures. By the end of 1991, the Trust Fund's cumulative debt to the U.S. Treasury was \$3.3 billion. Tables H-1 through H-4 provide information on the number of beneficiaries and the costs of the Black Lung Benefits Program. An in-depth review and evaluation of the Federal Black Lung Benefits Program was performed by Prunty and Solomons [1989].

^{*}This Act was later amended by the Federal Mine Safety and Health Act of 1977 [30 USC 901-945].

	Cum (July 1	ulative decisions— l, 1973, to Decembe	all levels [*] r 31, 1991)	
Claim category	Approved	Denied	Total number of decisions	Approval rate (%)
Section 435 claims filed, 7/1/73 to 2/28/78	56,080	63,725	119,805	46.8
Section 727 claims filed, 3/1/78 to 3/31/80	20,494	41,044	61,538	33.3
Section 718 (PRE) claims filed, 1/1/82 to present	4,125	28,529	32,654	12.6
Section 718 (POST) claims filed, 1/1/82 to present	5,890	77,804	83,694	7.0
Part B denials— denied claims inherited from SSA	21,867	45,917	67,784	32.3
SSA [†] approvals— claims approved by SSA under the 1977 amendments	15,931	710	16,641	95.7
Subtotal	124,387	257,729	382,116	32.6
Medical only	116,738	1,656	118,394	98.6
Grand total	241,125	259,385	500,510	48.2

Table H-1. Summary of claims activity, U.S. Department of Labor's Black Lung Benefits Program, fiscal year 1991 and cumulative, July 1, 1973, to December 31, 1991

Source: DOL [1992].

*Refers to the most recent decision (any level—Division of Coal Mine Workers' Compensation, Administrative Law Judge, Benefits Review Board).

[†]SSA = Social Security Administration.

Year	Program obligations (in billions)
1982	\$1.79
1983	2.15
1984	2.50
1985	2.83
1986	2.88
1987	2.95
1988	2.99
1989	3.05
1990	3.05
1991	3.26

Table H-2. Department of Labor's Black Lung Benefits Programobligations for fiscal years 1982-91

Source: DOL [1992].

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				Number of UK	Number of beneficiaries, by year	y year			
Class of beneficiary	1983	1984	1985	1986	1987	1988	1989	1990	1991
Primary beneficiaries:									
Minors	\$64.181	\$62,785	\$60,906	\$59,004	\$56,688	\$54,339	\$51,588	\$45,587	\$45,842
Widows	35,178	36,495	37,827	39,049	40,702	41,901	42,923	43,500	43,842
Others	813	854	887	1,119	766	1,054	1,110	1,153	1,18(
Total primary beneficiaries	100,172	100,134	99,620	99,172	98,387	97,294	95,621	93,240	90,870
Dependents of primary beneficiaries:									
Dependents of minors	63.040	60.275	58,113	54,747	52,237	49,343	46,053	42,846	39,800
Dependents of widows	2.398	2.298	2,306	2,207	2,199	2,079	2,002	1,902	1,82
Dependents of others	433	409	398	424	466	440	511	503	ŝ
Total dependents	65,871	62,982	60,817	57,378	54,902	51,862	48,566	45,251	42,13
Total of all beneficiaries	166,043	163,116	160,437	156,550	153,289	149,156	144,187	138,491	133,001

Table H-3. Black lung benefit claims by class of beneficiary, 1983-91

Source: DOL [1992]. * Active claims (including those paid by an RMO), cases paid by the Trust Fund, cases in interim pay status, cases being offset as a result of concurrent Federal or State benefits, and cases temporarily suspended.

Appendix H

309

		Benefit rates by ty	pe of beneficiary	
Period	Claimant	Claimant and 1 dependent	Claimant and 2 dependents	Claimant and 3 or more dependents
7/1/73 to 9/30/73	\$169.80	\$254.70	\$297.10	\$339.50
10/1/73 to 9/30/74	177.60	226.40	610.80	355.20
10/1/74 to 9/30/75	187.40	281.10	328.00	374.80
10/1/75 to 9/30/76	196.80	295.20	344.40	393.50
.0/1/76 to 9/30/77	205.40	308.10	359.50	410.80
0/1/77 to 9/30/78	219.90	329.80	384.80	439.70
0/1/78 to 9/30/79	232.00	348.00	405.90	463.90
0/1/79 to 9/30/80	254.00	381.00	444.50	508.00
0/1/80 to 9/30/81	279.80	419.60	489.60	559.50
0/1/81 to 9/30/82	293.20	439.80	513.10	586.40
0/1/82 to 12/31/83	304.90	457.30	533.60	609.80
/1/84 to 12/31/84*	317.10	475.60	554.90	634.20
/1/85 to 12/31/86	328.20	492.30	574.30	656.40
/1/87 to 12/31/87	338.00	507.00	591.50	676.00
/1/88 to 12/31/88	344.80	517.20	603.40	689.60
/1/89 to 12/31/89	358.90	538.30	628.10	717.80
/1/90 to 12/31/90	371.80	557.70	650.60	743.60
/1/91 to 12/31/91	387.10	580.60	677.40	774.10

Table H-4. Monthly black lung benefit rates, 1973-91

Source: DOL [1992].

^{*}These benefit rates include the additional 0.5% increase that was granted retroactively to January 1, 1984. The rates in effect before the retroactive payments (1/1/84 through 6/30/84) were \$315.60 for a claimant only, \$473.30 for a claimant and one dependent, \$552.20 for a claimant and two dependents, and, \$631.10 for a claimant and three or more dependents.

APPENDIX I

CONFIDENCE LIMIT ON MINIMUM ACCURATELY QUANTIFIABLE (MAQ) CONCENTRATION OF RESPIRABLE COAL MINE DUST

The lowest concentration of respirable coal mine dust that can be accurately quantified is estimated here. The accuracy criterion to be used is one that has been referred to as the NIOSH Accuracy Criterion, namely: "... measurements by the method will come within 25% of corresponding true air concentrations at least 95% of the time" [Busch and Taylor 1981]. Therefore, the accuracy A itself is defined as the largest percentage of deviation from the true concentration to be found among 95% of measurements; it is given in terms of bias and total imprecision relative standard deviation (rsd) implicitly by

 Φ [(bias + A)/rsd] - Φ [(bias - A)/rsd] = 95%

where Φ is the accumulative normal function. Note that the (true) rsd may be denoted by its approximation, the coefficient of variation (CV). The function A (bias, rsd) is shown, together with a planar approximation, in Figure I-1. Then the confidence limit on the minimum (concentration) accurately quantifiable (MAQ) is defined as the smallest concentration at which the 95% confidence limit on accuracy is better than 25%.

If the method were unbiased and the imprecision perfectly known, MAQ equals approximately eight times the method imprecision. Therefore, in this case MAQ differs only slightly from the limit of quantitation (LOQ). LOQ as defined by the American Chemical Society and by NIOSH [NIOSH 1994] is the concentration corresponding to 10 times the method imprecision (i.e., the use of MAQ avoids introducing a second arbitrary number (10) in addition to the value 25%).

Conditions of the calculation:

The pump uncertainty-induced imprecision (rsd_{pump}) is assumed to be less than 1% [Bartley et al. 1994].

The samplers considered are the traditional 10-mm nylon cyclone operated at 1.7 L/min and the Higgins-Dewell cyclone at 2.2 L/min.

The intersampler imprecision (rsd_{samp}) is assumed to be less than 5% [Bartley et al. 1994].

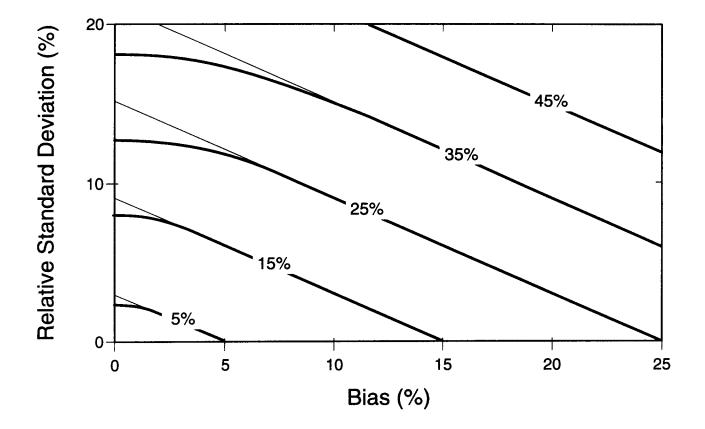


Figure I-1. Accuracy contours: fine lines represent linear approximation.

The maximum bias of each sampler is assumed to equal 7% as indicated by the coal mine dust size distributions of Mutmansky and Lee [1987] and the computation of Bartley et al. [1994].

The sampling time is assumed to equal 8 hr.

I.1 DETAILS OF THE CALCULATION

The confidence limit ${}_{95\%}A$ on the accuracy for obtaining the above results was computed by approximating the dependence of the true accuracy A on the intersampler variability rsd_{samp} and on the bias as linear. Details of this approximation have been published by Bartley et al. [1994]. Furthermore, regarding the data on S samplers (with $v_{rsd} = S-1$ degrees of freedom) reported in this paper, the uncertainties in both bias and in the overall imprecision were dominated by the intersampler variability. This results in the following expression for the accuracy confidence limit (hats over variables denote estimates):

$${}_{95\%} \mathbf{A} = \mathbf{\hat{A}} + 1.64 \mathbf{rsd}_{samp} \cdot \left[\frac{\mathbf{k}_1^2}{\mathbf{S}} + \frac{\mathbf{k}_2^2}{2\upsilon_{rsd}}\right]$$

where the constant k_1 and k_2 solve

$$k_1 = \partial A / \partial$$
 bias

$$k_1 - 1.64 \left[\frac{k_1^2}{S} + \frac{k_2^2}{2v_{rsd}} \right]^{1/2} = \frac{rsd_{samp}}{rsd} \cdot \frac{\partial A}{\partial rsd}$$

where rsd is the total imprecision given by

$$rsd = \sqrt{rsd^2_{weigh} + rsd^2_{samp}} = rsd^2_{pump}$$

The dependence of the accuracy A on the total imprecision rsd and bias is somewhat complicated but is given by

$$\frac{\partial A}{\partial rsd} = \frac{\Phi_{+} \frac{bias + A}{rsd} - \Phi_{-} \frac{bias - A}{rsd}}{\Phi_{+} + \Phi_{-}}$$
$$\frac{\partial A}{\partial \Delta} = \frac{\Phi_{-} - \Phi_{+}}{\Phi_{+} + \Phi_{-}}$$
$$\Phi_{\pm} = \exp\left[-\frac{1}{2}\left(bias \pm A\right)^{2}/rsd^{2}\right]$$

313

The weighing-induced imprecision is given by

$$rsd_{weigh} = \frac{\sigma_{weigh} \times 1,000 L/m^3}{Q 8 \times 60 min} / MAQ$$

where Q is the sampler flow rate.

Finally, using these expressions, the equation $_{95\%}A = 25\%$ is solved numerically for MAQ in terms of σ_{weigh} , giving the above results.

I.2 BIASLESS ACCURACY

The confidence limit on the accuracy is simple to calculate when the bias is known to be zero. This is consistent with the current MSHA practice for defining respirable dust by the sampler. Specifically, respirable dust is $1.38 \times$ that which is captured by the traditional 10-mm nylon cyclone at 2 L/min.

In this case, the accuracy A is given by

$$\Phi$$
 [A/rsd] - Φ [-A/rsd] = 95%

which implies that

$$A = \Phi^{-1}$$
 [97.5%] rsd = 1.96 rsd

Since rsd_{samp} is the only uncertain quantity in rsd and therefore in A, and since A is monotonic in rsd_{samp} , the 95% confidence limit on A is computed simply by determining the 95% confidence limit on rsd_{samp} and substituting into the expression for A. In other words,

$$A_{95\%} = 1.96 \sqrt{rsd^2_{weigh} + \frac{rsd^2_{samp}}{\chi^2_{95\%}(\upsilon)/\upsilon} + rsd^2_{pump}}$$

With the number of degrees of freedom v = 7, $\chi^2 = 2.167$. Futhermore, rsd_{weigh} is given by

$$rsd_{weigh} = 1.38 \frac{\sigma_{weigh} \times 1000 \text{ L/m}^3}{O \ 8 \times 60 \text{ min}} / MAQ$$

where σ_{weigh} is the weighing imprecision, Q is the flow rate, and MAQ is the minimum accurately quantifiable concentration. Setting Q = 2.0 L/min and σ_{weigh} = 0.029 mg; MAQ is determined so as to give A_{95%} = 25%. The result is

$$MAQ = 0.46 \text{ mg/m}^3$$

I.3 RESULTS

Under these conditions, the confidence limit on the MAQ in terms of the imprecision in the coal dust weight measurements is given in Figure I-2. As seen from the graph, the value of MAQ depends strongly on the precision of the coal dust mass measurement. Several values of this precision may be found in the literature. A figure 0.081 mg was published in an early study of Parobeck et al. [1981] of weighing procedures employed in the past by the Mine Safety and Health Administration (MSHA) in which filters are preweighed by the filter manufacturer and postweighed by MSHA, using balances readable to 0.010 mg.

MSHA [Kogut 1994] has recently completed a study of the accuracy of weighing new "tamper-resistant" (and heavier) capsules. The filter manufacturer's balance, readable to 0.01 mg, was used for preweighing the filters and a 0.001 mg balance was used for the postweighing by MSHA. The results indicate imprecision equal to 0.029 mg (as well as a systematic error equal to -0.012 mg, which is considered negligible or correctable here).

The precision can likely be improved further. Bowman et al. [1984] reported imprecision equal to 0.010 mg, using a single 0.001 mg balance for both preweighing and postweighing. This value is consistent with a study of Vaughan et al. [1989] of repeat filter weighings. It should be noted that the actual attainable precision may depend strongly on the specific environment to which the filters are exposed between the two weighings.

These values are used in Table I-1.

σ _{weigh} (μg)	MAQ _{nylon} * (mg/m ³)	MAQ _{HD} † (mg/m ³)
81 [Parobeck et al. 1981]	1.83	1.42
29 [Kogut 1994]	0.66	0.51
10 [Bowman et al. 1984]	0.23	0.17

Table I-1. Minimum (concentration) accurately quantifiable(MAQ) at specific values of imprecision

^{*}Minimum concentration accurately quantifiable by the nylon sampler (CPSU) [30 CFR 74].

[†]Minimum concentration accurately quantifiable by the Higgins-Dewell sampler [Higgins and Dewell 1968].

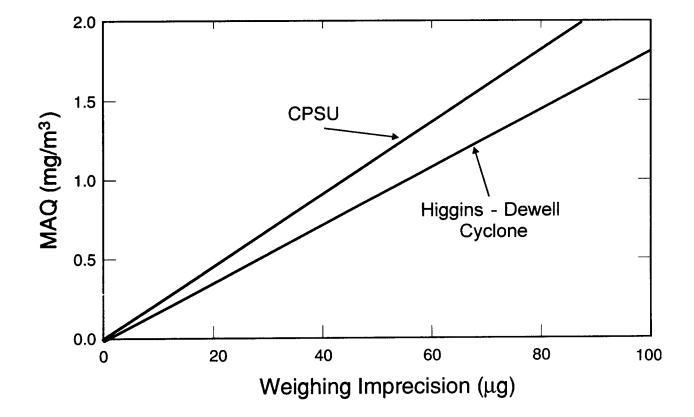


Figure I-2. Minimum accurately quantifiable (MAQ): CPSU and Higgins-Dewell cyclone.

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