

49 FR 7562-02
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RULES and REGULATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

42 CFR Part 37

Amendment to Specifications for Medical Examinations of Underground Coal Miners

Thursday, March 1, 1984

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control, PHS, HHS.

ACTION: Final rule.

SUMMARY: This rule adopts the 1980 revision of the International Labor Office (ILO) system for classifying radiographs (X-rays) of the pneumoconioses. The 1980 system has now become the recognized international standard for classifying this type of disease. Adoption of the revised classification system enables X-ray readers in the Department's medical surveillance program for underground coal miners to classify miners' chest X-rays more accurately in accordance with the latest standards.

EFFECTIVE DATE: April 2, 1984.

FOR FURTHER INFORMATION CONTACT: Ms. Mitzie Martin, Chief, Receiving Center Section, Examinations Processing Branch, Division of Respiratory Disease Studies, NIOSH, 944 Chestnut Ridge Rd., Morgantown, WV 26505. Phone (304) 291-4301 or FTS 923-4301.

SUPPLEMENTARY INFORMATION: This final rule implements revisions proposed in a Notice of Proposed Rulemaking (NPRM) published in the Federal Register on January 12, 1983 (48 FR 1321), to amend Part 37 of Title 42, Code of Federal Regulations. The NPRM proposed to adopt the 1980 revision of the ILO system for classifying X-rays of the pneumoconioses. Interested persons were invited to comment on the proposed amendment. Only two comments were received and are discussed below.

Discussion of Comments

An engineering consultant requested that information be presented on the apparent differences in the disease prevalence rates obtained from each classification

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system's separate interpretations of coal miners' chest X-rays. A direct comparison was made of film interpretations from systems developed by the ILO in 1959 and by a Working Committee of the International Union Against Cancer in 1968 and published in the Journal of the American Medical Association, June 26, 1972, Vol. 220, No. 13. The removal of category Z (suspect pneumoconiosis) resulted in the later (1968) system having a significantly greater proportion of positive cases. Since 1968, there have been two revisions (1971 and 1980). With these later revisions, the profusion scale for pneumoconioses has remained intact, extending even to the subcategories of the pneumoconioses. In fact, many of the same examples of mid-category cases have been carried through to the 1980 revision. Thus, no dramatic differences which could be attributed to changes in classification systems exist. NIOSH also performed two reading trials. The first trial involved films from round two of the National Coal Study (1973-1975), while the second trial involved films from a surface mine study conducted in 1972.

Both trials showed no appreciable difference between classification systems in the profusion of coal workers' pneumoconiosis (CWP) in the samples studied. For this reason, rereading all films on file would be costly and of little value. Differences in prevalence of CWP between rounds of examinations are mostly attributable to two factors: Reader variability and a true difference in disease.

All film pairs, triads, etc., involved in assessing change in disease (progression) over a specific timeframe have been and will continue to be interpreted using the 1980 classification system.

The second comment was from a representative of a radiology organization suggesting several technical changes in the language of the proposed rule, all of which have been incorporated in the final rule.

The Department of Health and Human Services has determined that this amendment will not significantly impact on a substantial number of small entities and, therefore, does not require preparation of a regulatory flexibility analysis under the Regulatory Flexibility Act, Pub. L. 96-354.

The Department also has determined that this amendment is not a "major rule" under Executive Order 12291 because it will not have an annual effect on the economy of \$100 million or more, result in significant adverse effects in competition, nor otherwise meet the thresholds established in the Executive Order.

Therefore, preparation of a regulatory impact analysis is not required.

List of Subjects in 42 CFR Part 37

Health care, Lung diseases, Medical research, Mine Safety and Health, Miners, X-rays.

Part 37 of Title 42, Code of Federal Regulations, is hereby amended as set forth below.

Dated: November 22, 1983.

James F. Dickson,

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Acting Assistant Secretary of Health.

Approved: February 8, 1984.

Margaret M. Heckler,

Secretary.

PART 37--[AMENDED]

42 CFR Part 37 is amended as follows:

1. the authority citation for Part 37 reads as follows:

Authority: Sec. 203, 83 Stat. 763; 30 U.S.C. 843.

2. In the Table of Contents, the title of § 37.51 is revised to read as follows:

* * * * *

37.51 Proficiency in the use of systems for classifying the pneumoconioses.

* * * * *

3. In § 37.2, paragraph (f) is revised to read as follows:

§ 37.2 Definitions.

* * * * *

(f) "ILO-U/C Classification" means the classification of radiographs of the pneumoconioses devised in 1971 by an international committee of the International Labor Office and described in "Medical Radiography and Photography," volume 48, No. 3, December 1972. "ILO Classification" means the classification of radiographs of the pneumoconioses revised in 1980 by an international committee of the International Labor Office and described in "Medical Radiography and Photography" volume 57, No. 1, 1981, and in ILO publication 22 (revised 1980) from the ILO Occupational Safety and Health Series.

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4. In § 37.3, paragraph (b) (3) is revised to read as follows:

§ 37.3 Chest roentgenograms required for miners.

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* * * * *
(b) * * *

(b) (3) A third chest roentgenogram 2 years following the second chest roentgenogram if the miner is still engaged in underground coal mining and if the second roentgenogram shows evidence of category 1, category 2, category 3 simple pneumoconioses, or complicated pneumoconioses (ILO Classification).

* * * * *

5. § 37.7, paragraph (a) is revised to read as follows:

§ 37.7 Transfer of affected miner to less dusty area.

(a) Any miner who, in the judgment of the Secretary based upon the interpretation of one or more of the miner's chest roentgenograms, shows category 1 (1/0 , 1/1 , 1/2), category 2 (2/1 , 2/2 , 2/3), or category 3 (3/2 , 3/3 , 3/4) simple pneumoconioses, or complicated pneumoconioses (ILO Classification) shall be afforded the option of transferring from his or her position to another position in an area of the mine where the concentration of respirable dust in the mine atmosphere is not more than 1.0 mg/m³ of air, or in such level is not attainable in the mine, to a position in the mine where the concentration of respirable dust is the lowest attainable below 2.0 mg/m³ of air.

* * * * *

6. Section 37.50 is amended by revising paragraphs (a), (b), and (c) to read as follows:

§ 37.50 Interpreting and classifying chest roentgenograms.

(a) Chest roentgenograms shall be interpreted and classified in accordance with the ILO Classification system and recorded on a Roentgenographic Interpretation Form (Form CDC/NIOSH (M)2.8).

(b) Roentgenograms shall be interpreted and classified only by a physician who regularly reads chest roentgenograms and who has demonstrated proficiency in classifying the pneumoconioses in accordance with § 37.51.

(c) All interpreters, whenever interpreting chest roentgenograms made under the Act, shall have immediately available for reference a complete set of the ILO International Classification of Radiographs for Pneumoconioses, 1980.

Note.-- This set is available from the International Labor Office, 1750 New York Avenue, NW., Washington, D.C. 20006 (Phone: 202/376 -2315).

* * * * *

7. Section 37.51 is amended by revising the section heading and the introductory text of paragraph (a) (2), paragraphs (a) (2) (ii), and (b) (2) to read as follows:

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§ 37.51 Proficiency in the use of systems for classifying the pneumoconioses.

(a) * * *

(a) (2) Physicians who desire to be "A" readers must demonstrate their proficiency in classifying the pneumoconioses by either:

* * * * *

(ii) Satisfactory completion, since June 11, 1970, of a course approved by ALOSH on the ILO or ILO-U/C Classification systems or the UICC/Cincinnati classification system. As used in this subparagraph, "UICC/Cincinnati classification" means the classification of the pneumoconioses devised in 1968 by a Working Committee of the International Union Against Cancer.

(b) * * *

(b) (2) Proficiency in evaluating chest roentgenograms for roentgenographic quality and in the use of the ILO Classification for interpreting chest roentgenograms for pneumoconiosis and other diseases shall be demonstrated by those physicians who desire to be "**B**" readers by taking and passing a specially designed proficiency examination given on behalf of or by ALOSH at a time and place specified by ALOSH. Each physician must bring a complete set of the ILO standard reference radiographs when taking the examination. Physicians who qualify under this provision need not be qualified under paragraph (a) of this section.

* * * * *

8. In § 37.52, paragraph (b) is revised to read as follows:

§ 37.52 Method of obtaining definitive interpretations.

* * * * *

(b) Two interpreters shall be considered to be in agreement when they both find either stage A, B, or C complicated pneumoconiosis, or their findings with regard to simple pneumoconiosis are both in the same major category, or are within one minor category (ILO Classification 12-point scale) of each other. The higher of the two interpretations shall be reported.

[FR Doc. 84-5446 Filed 2-29-84; 8:45 am]

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