Dragon, Karen E. (CDC/NIOSH/EIDIV)

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Sent: Friday, September 08, 2006 2:49 PM
To: NIOSH Docket Office (CDC)
Subject: Comments on the Draft Revised Website "NIOSH Safety and Health Topic: Chest Radiography"
Attachments: NIOSH.pdf

Attached are the comments of the Coalition for Litigation Justice, Inc. on the draft revised website entitled "NIOSH Safety and Health Topic: Chest Radiography."

<<NIOSH.pdf>>

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SUBMISSION OF THE COALITION FOR LITIGATION JUSTICE, INC., IN RESPONSE TO THE REQUEST FOR COMMENTS ON NIOSH'S DRAFT REVISED WEBSITE "NIOSH SAFETY AND HEALTH TOPIC: CHEST RADIOGRAPHY"

We wish to express our appreciation to NIOSH for the thoughtful consideration given to our comments submitted in January of this year. The incorporation of comments from our Coalition, and other stakeholders, has improved the website pages regarding Chest Radiography. We appreciate the opportunity to again offer comments on the overall issue of Chest Radiography and to reiterate and expand on some of our earlier comments.

I. RECOMMENDATIONS FOR THE B READER PROGRAM

A. Establish an Audit Program

We appreciate your consideration of our request for implementation of a B Reader audit program. In the case of ILO classifications made for litigation or contested proceedings, we find ourselves in disagreement with your position that "one of the most important components of reliable classification is selection of readers who are mainstream in their classification tendencies."

The problem faced by NIOSH does not concern B Readers who are mainstream in their classification tendencies. Instead, the problem NIOSH needs to address concerns doctors who accurately apply the ILO system when seeking B Reader certification and recertification, but who then choose to misread the films in an attempt to advance the litigation interests of claims that have no merit. The recent abuses by NIOSH certified B Readers in interpreting normal chest radiographs as evidence of silicosis described in our previous comments, and that were documented in the opinion by Judge Janis Graham Jack, were so egregious

that the Judge characterized them as raising "great red flags of fraud." We are confident that short of developing and implementing some type of audit program, these abuses will continue.

We also take exception with your response that "It may be entirely appropriate for the courts, to make use of this guidance in an effort to establish quality of B Reader ILO classifications and qualifications of expert B Reader witnesses." It is the NIOSH imprimatur that is conferred upon the individual that successfully completes the B Reader process, and as the certifying body, it is NIOSH that has a duty and obligation to ensure that persons certified use the credential correctly. To attempt to pass on this responsibility to the courts, or any other organization, is to abrogate NIOSH's public health responsibility.

NIOSH has developed and implemented stringent quality assurance programs, to include field audits of approved devices, for its approval program for respiratory protective devices. It cannot be correct that NIOSH can develop quality assurance and audit programs for respirator certification but that NIOSH cannot implement a similar program for physicians being certified to interpret chest x-rays. We encourage NIOSH to revisit its decision not to implement an audit program for B Readers.

B. Assist in Establishing a Panel of Experts in Pneumoconiosis Radiology to Serve as Court Appointed Experts

We appreciate and are sensitive to the fact that NIOSH does not want to become directly involved in the legal system. Nevertheless, NIOSH can still play a role in establishing a panel of experts in pneumoconiosis radiology to serve as court appointed experts. A unique service that assists federal and state judges in locating

highly qualified independent scientific experts is offered by the American Association for the Advancement for Science (AAAS). Due to its success the Court Appointed Scientific Expert (CASE) program of AAAS, which began in 2001 as a demonstration project for federal district judges, was expanded in 2004 to state trial courts and assists in selecting experts on a case-by-case basis for judges. We recommend that NIOSH contact Deborah Runkle at CASE for additional information and to explore interest in assisting CASE in putting in place an expert panel on the radiology of the pneumoconiosis to assist the courts in obtaining independent scientists to provide medical opinions regarding chest radiography.

http://www.aaas.org/spp/case/case.htm

II. SPECIFIC COMMENTS FOR THE CHEST RADIOGRAPHY WEBPAGES

A. Webpage "Recommended Practices for Reliable Classification of Chest Radiographs by B Readers"

1. Subheading "Contested Proceedings – Remuneration"

Remuneration for ILO classifications in contested proceedings should be according to usual and customary charges for classification in other settings.

2. Subheading "Contested Proceedings – Reader Selection"

It is unlikely that parties to a contested proceeding will be able to agree to a selection procedure at random using the largest pool of B Readers available.

3. Subheading "Contested Proceedings – Number of Readers and Summary Classification"

It is unlikely that parties to a contested proceeding will be able to agree to the number of readers and a summary classification decision logic. This procedure

would be practicable if using an independent panel of experts to serve as court appointed experts as recommended in II. B. above.

4. Subheading "Contested Proceedings – Blinding"

This is not conventional practice in litigation and it is improbable that the parties to a contested proceeding will be willing to consult with a B Reader without disclosing the alleged pneumoconiotic agent.

5. Subheading "Contested Proceedings – Notification"

We recommend adding to the end of the sentence "and recommend medical follow-up when appropriate".

B. Webpage "Classification of Chest Radiographs: Practices for Medical Diagnosis"

1. Subheading "The Role of Classification of Chest Radiographs in Medical Diagnosis"

We recommend adding a second paragraph that would read:

"It is important to remember that chest radiograph findings alone are insufficient for the diagnosis of pneumoconiosis. Other data, such as the medical and occupational history, the physical examination, additional types of chest imaging, various laboratory tests, and biopsy results should also be considered."

C. Webpage "Classification of Chest Radiographs: Practices for Epidemiologic Research"

1. Subheading "The Role of Classification of Chest Radiographs in Epidemiologic Research"

We recommend the last sentence of the first paragraph be deleted since a discussion of surveillance and hazard investigations seems out of place in the section on epidemiology.

D. Webpage "Classification of Chest Radiographs: Practices for Worker Monitoring and Surveillance"

1. Introductory Paragraph, 4th Sentence

We recommend that between the words "individual" and "may" the phrase "or the potential development of disease in coworkers" be inserted. This seems to be prudent public health advice based on a positive finding and makes broader use of the results of monitoring and surveillance.

2. Subheading "The Role of Classification of Chest Radiographs in Worker Monitoring and Surveillance"

In addition to these federal programs, state programs, such as the North Carolina Dusty Trades Program, and medical surveillance programs conducted by private industry and organized labor have been useful in the early detection of pneumoconioses and appropriate intervention. Indeed, with the possible exception of coal miners, probably far more workers are receiving periodic medical surveillance for the dust diseases through industry and labor efforts than through government programs.

3. Subheading "Special Considerations for Classification of Chest Radiographs in Worker Monitoring and Surveillance Programs"

In addition to safeguards for false positives, consideration should be given to obtaining a second interpretation on a percentage of normal films to guard against false negative readings.

E. Webpage "Classification of Chest Radiographs: Practices for Determining Government Program Eligibility"

1. Subheading "Federal Black Lung Benefits Program"

We recognize that the ILO Classification is dated "2000" in the title but was published in "2002". In other places in the text the ILO Guidelines are cited as "(ILO 2000)". We recommend that NIOSH be consistent throughout.

2. Subheading "The Energy Employees Occupational Illness Compensation Program"

It is our understanding that under the Act, claimants for silicosis are limited to those involved for 250 days or more during the mining of tunnels in Nevada or Alaska (See § 7384r of the Act). To avoid misinforming workers at other DOE sites regarding eligibility, the worksite criterion should be addressed.

> "(c) EXPOSURE TO SILICA IN THE PERFORMANCE OF DUTY—A covered employee shall, in the absence of substantial evidence to the contrary, be determined to have been exposed to silica in the performance of duty for the purposes of the compensation program if, and only if, the employee was present for a number of work days aggregating at least 250 work days during the mining of tunnels at a Department of Energy facility located in Nevada or Alaska for tests or experiments related to an atomic weapon."

F. Webpage "Classification of Radiographs: Practices in Contested Proceedings"

1. Subheading "Remuneration"

Again, remuneration in excess of standard billing for comparable services should be discouraged.

2. Subheading "Reader Selection"

As mentioned above, it is unlikely that the parties in a contested proceeding will be able to agree to a selection procedure at random using the largest pool of B Readers available.

3. Subheading "Number of Readers and Summary Classification

In contested proceedings, we agree that the initial interpretations should be obtained from independent readings, but we do not object to B Readers holding a conference to discuss a particular case after the individual interpretations are made.

a. Subheading 4.a. "Small Opacities"

Please justify why the higher reading of two independent readings of small opacities would be the final interpretation. It seems the difference could only be resolved by additional reading(s) of the case.

4. Subheading "Blinding"

This would be desirable but unlikely that it will be practiced in contested proceedings.

5. Subheading "Notification"

We suggest that notification come from the doctor interpreting the chest x-ray.

G. Webpage " Best Technical Practices "

1. Subheading "The Need for Good Quality Radiographic Techniques and Equipment"

In addition to the Coalworkers' X-ray Surveillance Program, guidance on technical quality is presented in Appendix A of the ILO Guidelines for Classification of Radiographs of Pneumoconioses with references to selected papers on producing quality radiographic images.

Date: September 8, 2006