Because of the importance of its contents to respirator users as well as to respirator manufacturers, the complete text of a letter from NIOSH to all respirator manufacturers is reproduced below. The letter went out on August 25, 1980.

PLAINTIFF'S EXHIBIT KRC-229h

NOTICE TO ALL RESPIRATOR MANUFACTURERS

The purpose of this letter is to express the concerns of the National Institute for Occupational Safety and Health (NIOSH) regarding the use of air-purifying respirators against asbestos and other carcinogenic substances and to announce a course of action to address these concerns.

First, the present requirements of 30 CFR, Part 11 preclude MSHA/NIOSH from voiding approval of dust, fume, and mist respirators for use against asbestos and other carcinogenic substances without following appropriate administrative procedures. Section 11.130(f) of Subpart K mentions respirators with replaceable filters, designed as respiratory protection against asbestos-containing dusts and mists. Section 11.130(h) mentions single-use dust respirators designed as respiratory protection against pneumoconiosis and fibrosis-producing dusts, or dusts and mists, including but not limited to aluminum, asbestos, coal, flour, iron ore, and free silica.

However, we are deeply concerned about the use of dust, fume, and mist respirators, and other air-purifying respirators, against carcinogenic substances. Our concerns are based on two major issues: 1) the ability of the filter media to effectively remove the carcinogenic substance during the entire period of use, and 2) the questionable face fit of at least some dust, fume, and mist respirators, particularly the single-use type.

Excessive leakage of a substance such as asbestos into the respirator due to either ineffective filtration or leakage around a poor seal is unacceptable and presents a potentially serious hazard to the wearer. The possibility of the development of lung cancer or mesothelioma, in the case of asbestos exposure, cannot be ignored when both filtration efficiency and adequate face seal are questionable.

On the issue of asbestos, the Institute wishes to state that although asbestos can produce fibrosis, this effect pales in significance in comparison to the known human and animal carcinogenicity of this fibrous material. It is not our position that single-use dust respirators will provide adequate protection against the cancer causing potential of asbestos. In light of the present knowledge concerning the carcinogenicity of asbestos, the listing of asbestos as an example of a "fibrosis-producing dust" in Section 11.130(h) can only be viewed as misleading. In the document entitled "Workplace Exposure to Asbestos: Review and Recommendations," the Institute concluded that "there is *no* asbestos exposure level below which clinical effects do not occur; significant disease can occur following very short (1 day to three months) exposure periods; worker exposures to asbestos must be controlled to the maximum extent possible; and human occupational exposures to all commercial asbestos fiber types have been associated with high rates of lung cancer and mesothelioma."

The above concerns, focused largely on asbestos, also apply to other carcinogenic substances referenced in 30 CFR, Part 11. Sections 11.130(a)(1) and 11.130(b) refer to dust, fume, and mist respirators, either with replaceable or reusable filters, designed as respiratory protection against dusts such as arsenic, cadmium, and chromium, all of which are suspected human carcinogens. Section 11.130(d) refers to respirators, with replaceable filters, designed as respiratory protection against dust, fumes, and mists of beryllium and radionuclides, which can produce cancer. Based on the facts that the air-purifying components of these devices are tested not against the carcinogens themselves but rather against other materials (*i.e.,* do the filters effectively remove the carcinogenic agent during the entire period of recommended use?) and that the face seals of many of these devices are marginal or inadequate, we are concerned about their use against carcinogenic substances. Respirators with low protection factors may not provide adequate protection against carcinogens.

Accordingly, NIOSH intends to undertake a study of the use of air-purifying respirators against asbestos and other carcinogenic substances in an effort to resolve our concerns. In order to effectively accomplish this goal, it is essential that the respirator manufacturers and others engaged in respirator research provide NIOSH with all relevant data in their possession. We herewith request: 1) all data relating to the efficiency of your devices in removing contaminants, particularly any data involving actual testing against carcinogenic agents; and 2) any data pertaining to calculation of protection factors for your devices. In essence, because of the potential health consequences the Institute believes that the approval of air-purifying respirators for use against asbestos and other carcinogens should be based on their demonstrated effectiveness and not on a policy adopted when the carcinogenicity of certain chemicals and other substances was unrecognized.

Your assistance in this very important assessment is vital. If you have any questions please write or telephone (301) 443-3680.

Sincerely yours,

Jon R. May, Ph.D.

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