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October 6, 1977

Mr. Hal Hollister, Director
Division of Operational and
Environmental Safety
U. S. Energy Research & Development
Administration
Washington, D. C. 20545

Dear Mr. Hollister:

Draft Criteria For Occupational Exposure
To Vinyl Compounds

In accordance with your memorandum of September 8, 1977, the following comments resulted from our review of the proposed standard for occupational exposure to vinyl compounds.

The proposed standard is applicable to seven compounds, i.e., vinyl chloride, vinylidene chloride, 1,2-dichloroethylene, vinyl bromide, vinyl fluoride, vinylidene fluoride and vinyl acetate. We have noted that only vinyl acetate has been used on an intermittent basis at this location and, therefore, have no experience in the monitoring/surveillance aspect of vinyl compounds. A brief review of the proposed standard, however, requires special comment because of a number of inconsistencies that would invalidate the proposed standard.

1) Section 1910.1000 of the OSHA Standards has already promulgated an emergency standard for vinyl chloride with environmental concentration not to exceed 1 ppm. The proposed standard of 0.1 mg/M^3 (.04 ppm equivalent) is a reduction by a factor of 25 and biological or epidemiological evidence was not cited in the document to merit this change. The only epidemiological evidence cited in previous vinyl chloride literature was the confirmed angiosarcoma cases associated to workers involved in reactor vessel cleaning at alleged vapor concentration exposures of approximately 5000 ppm. The writer at this time questions a sampling pump that will sample enough air to reflect a ceiling concentration of 0.1 mg/M^3 in a 15 minute period.

RSV 0011232

2) A similar situation exists for vinylidene chloride in the proposed reduction from 10 ppm to a proposed .25 ppm where a ceiling measurement during a 15 minute period is specified; also for 1,2-dichloroethylene where a 40 time decrease in concentration is proposed. In either case, carcinogenic potentials at the existing standards have not been noted.

3) Please note Section 4, Item 6, lines 410 through 413 that cites chemical cartridges or cannisters not be worn by employes exposed to vinyl chloride or vinylidene chloride even for evacuation or escape because of the poor warning properties of these compounds. Yet lines 436 through 438 under respirator selection, recommends gas mask with full face piece or backmounted organic vapor cannister etc. for exposures to less than or equal to 64 mg/M^3. This is contradictory.

4) Note further lines 611 through 617 where half masks are satisfactory for use in concentrations less than or equal to 17,500 mg/M^3. At these concentrations, irritation/damage to the eyes and the use of a half mask appears inconsistent with accepted industrial hygiene practice.

With the noted deficiencies, it can only be concluded that the document lacks credibility and should be returned to NIOSH for modification and re-writing.

If additional information is needed, please advise.

Very truly yours,

Original Signed By
A. G. BARNETT

A. G. Barnett
Manager, Safety and
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AGB:ar

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MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : Assistant Secretary of Labor
Occupational Safety and Health Administration
Department of Labor

DATE MAR 11 1974

FROM : Director, National Institute for
Occupational Safety and Health

SUBJECT: Recommended Occupational Health Standard for the Manufacture of Synthetic Polymer from Vinyl Chloride

On January 22, 1974, representatives from the B. F. Goodrich Chemical Company informed NIOSH that the deaths of several employees of their Louisville, Kentucky, plant might have been related to occupational exposures. An immediate industrial hygiene walk-through survey of the facility was conducted by NIOSH and resulted in developing and transmitting to affected companies recommendations for precautionary monitoring and control procedures for polymerization processes involving vinyl chloride. On February 1, 1974, NIOSH/CDC conducted a briefing for other Federal agencies with health research responsibilities at which it was disclosed that four employees of the plant in question had died of angiosarcoma of the liver. Because of the extremely low incidence of this disease, estimated to be on the order of 20 to 30 deaths per year in the United States, the history of four cases in a five-year period in one plant was considered of great importance. It was concluded at the briefing that a new occupational cancer had been discovered: angiosarcoma of the liver. It was further concluded that this disease was associated with the manufacture of polyvinyl chloride and that vinyl chloride was the prime etiological candidate in producing the disease.

NIOSH, with the assistance of expert consultants from both industry and organized labor, began development of a recommended occupational health standard. These and other activities were discussed in more detail at the OSHA Informal Fact-Finding Hearing on Possible Hazards of Vinyl Chloride Manufacture and Use on February 15, 1974. It was also during this Hearing that Professor Cesare Maltoni of Bologna, Italy, presented the preliminary results of his research which showed induction of angiosarcoma of the liver and other organs, as well as the production of other cancers in rats exposed to vinyl chloride. The results of these studies identify vinyl chloride as a carcinogen and further confirm its role in inducing the cancers observed in the B. F. Goodrich workers.

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Since the OSHA Hearing, NIOSH has learned of at least five additional cases of angiosarcoma of the liver. Two of these cases were diagnosed in the current working population at the same Louisville facility, while the other three involved deceased workers, one each from the Louisville facility, Union Carbide's South Charlestown plant, and Goodyear's Niagara plant.

Although vinyl chloride must be considered as a carcinogenic agent, the immediate problem appeared to be concentrated in polymerization facilities. Consequently, the attached NIOSH recommended standard only applies to such operations. This is not to say, however, that appropriate standards should not be developed for other exposures to the basic chemical. NIOSH is implementing further evaluation of the data, coupled with field observations, to determine exposure potentials in pre- and post-polymerization operations. You will be informed as further data and plans are developed.

As previously indicated, NIOSH considers this to be a most serious problem and strongly urges that expedited rulemaking be implemented by OSHA to insure that the health of exposed workers is promptly and adequately safeguarded.

We feel that, except where employers experience problems in obtaining air supplied respirators or environmental monitoring equipment, the attached recommendations can be implemented as soon as a standard is promulgated. The medical surveillance requirements which will be supplied in one to two weeks could also be implemented immediately with the possibility that some employers would need a short period of time for their medical staff or consultants to make arrangements for any special laboratory tests.

You should be aware that the consultants from industry who worked with us proposed that the recommended standard contain the concept of an allowable "working level" for vinyl chloride gas in the atmosphere, which they identified as a time weighted average of 50 ppm. They recommended that where workers were exposed to concentrations in excess of this level they should wear air-supplied respirators.

This concept of an allowable "working level" might seem justifiable in that Professor Maltoni found no liver tumors at 50 ppm, but there is the possibility that tumors might have been produced if a larger number of animals had been exposed at that concentration. Based on theoretical considerations, there is probably no threshold for carcinogenesis although it is possible that with very low concentrations, the latency period might be extended beyond the life expectancy. In view of these considerations and our inability to describe a safe exposure level as required in section 20(a)(3) of the Occupational Safety and Health Act, we rejected the concept of a threshold limit for vinyl chloride gas in the atmosphere.

Consequently, our recommendations as contained in the attached document are such that where any employee is exposed to measurable concentrations of vinyl chloride, as determined by the recommended sampling and analytical method, he shall wear an air supplied respirator. This recommendation is based on some preliminary information that the standard chemical cartridge respirators are inefficient in protecting against vinyl chloride. NIOSH is implementing a study to evaluate the degree of protection afforded by different types of respirators using vinyl chloride as the test gas. As information becomes available, it will be forwarded to OSHA as recommendations for alternative respirator usage. The employer is also required to develop a Control Plan to reduce airborne concentrations of vinyl chloride to levels not detectable by the recommended method.

As you will note in reviewing the recommended standard, there are references to the "sampling and analytical method recommended by the Director." This method, in the form of a compliance sampling data sheet, will be forwarded to OSHA within a week. We now estimate that the level of sensitivity of our recommended method will be around one part per million, specifically for vinyl chloride.

The Office of Research and Standards Development, which is directed by Mr. Vernon E. Rose, has had lead responsibility in developing this recommended standard. As your professional staff review and evaluate our document, questions or requests for additional information should be directed to Mr. Rose.

Marcus M. Key, M.D.
Assistant Surgeon General

Attachment