HRD-77-71
5-10-77

REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

Delays In Setting Workplace Standards For Cancer-Causing And Other Dangerous Substances

Department of Labor

Department of Health, Education, and Welfare

Although workers are exposed to thousands of toxic substances, hundreds of which may cause cancer, Government efforts to develop standards under the Occupational Safety and Health Act of 1970 have produced standards for only 15 substances. The bleak occupational health conditions which the Congress sought to improve still exist and may be getting worse. This report discusses several problems and offers recommendations to help resolve them.

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HRD-77-71

MAY 10, 1977

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

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To the President of the Senate and the
Speaker of the House of Representatives

This report discusses several administrative weaknesses which have caused delays in developing standards to protect workers from cancer-causing and other dangerous substances. In addition to recommending numerous actions to speed up standards development, the report recommends that the two responsible agencies--the Departments of Labor and Health, Education, and Welfare--determine whether more funds should be allocated to developing health standards and to informing and educating employers and employees on toxic substances.

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We made our review because of widespread congressional and public interest in the Government's activities under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651) and because of the need for prompt, effective action to protect workers from dangerous substances in workplaces. We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

AGC00021

Copies of the report are being sent to the Director of the Office of Management and Budget, the Secretary of Labor, and the Secretary of Health, Education, and Welfare.

Elmer B. Staats

Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

DELAYS IN SETTING WORKPLACE STANDARDS FOR CANCER-CAUSING AND OTHER DANGEROUS SUBSTANCES

Department of Labor
Department of Health, Education, and Welfare

D I G E S T

American workers are exposed to thousands of toxic substances in the places where they work. The National Institute for Occupational Safety and Health has identified about 1,500 substances that may cause cancer. Many others may cause respiratory diseases, nervous disorders, or other serious problems. Each year an estimated 390,000 new cases of occupational diseases appear, and an estimated 100,000 workers die from them. (See p. 9.)

Standards need to be developed faster to protect workers who are exposed to these serious hazards. The situation warrants immediate and continuing attention of the Secretary of Labor; the Secretary of Health, Education, and Welfare; and the Congress.

Labor's Occupational Safety and Health Administration was given the job of issuing and enforcing standards to protect workers from such hazards. (See p. 2.)

The National Institute for Occupational Safety and Health, which is in the Department of Health, Education, and Welfare (HEW), was created to do research and other work and to provide Labor with recommended standards and supporting scientific information. (See p. 5.)

Since 1970, Labor has established standards for 15 substances out of thousands of dangerous substances, in spite of HEW's estimate that 1,500 are suspected to be cancer-causing. At this rate, the Congress objective of protecting workers from such hazards will not materialize any time soon. In addition to

about 13,000 known toxic chemicals in common use, about 500 new chemicals are introduced each year. The need for standards may be growing faster than they are being issued. (See p. 9.)

DELAYS IN ISSUING STANDARDS

Health standards may limit the fumes, dust, or particles from a substance permitted in the air in the workplace and may contain various other measures to protect workers from the substance. HEW's recommendations and supporting information are usually issued as "criteria documents." Exceptions include a special project to expedite standards to require various protective measures for 387 substances or groups of substances.

As of September 1976, HEW had submitted 53 criteria documents to Labor. It took HEW an average of 22 months to complete each document. (This time has since been reduced to 14-1/2 months, according to HEW.) Labor had issued standards on only two of the substances covered by the completed criteria documents. Labor had the remaining documents for up to 51 months, or for an average of 18 months. HEW had recommended that at least nine of the substances covered by the completed criteria documents be treated as cancer-causing agents. Many others may also cause serious illness. (See p. 11.)

As of September 1976, HEW had completed its work on many substances in the special project, having sent recommendations to Labor to add various protective measures to 203 of the 387 standards. However, Labor had not issued standards on any of these substances. Labor had HEW's recommendations for 67 of these standards for more than a year. (See p. 12.)

IMPROVED MANAGEMENT COULD REDUCE DELAYS

The following problems contributed to delays in completing standards and GAO is recommending ways the Secretaries of Labor and HEW can help resolve them.

--Neither agency had reliable data for setting priorities--that is, determining which substances are most hazardous and developing standards for them. They had not agreed on the type and source of needed data and had assigned different priorities to the same substances. (See p. 17.)

--Labor did not have an adequate management information system and controls to identify and resolve problems delaying completion of standards. (See p. 23.)

--Labor seldom used its authority to issue emergency temporary standards to protect employees from grave danger. (See p. 26.)

--Labor did not promptly issue standards to provide needed protection on the basis of the best available evidence. (See p. 32.)

--Neither agency had an adequate policy and guidelines on the evidence needed to regulate a substance as a cancer-causing agent. (See p. 45.)

--Labor and HEW personnel had not worked effectively as a team on individual projects. Also, Labor had not placed enough reliance on HEW to carry out its basic mission under the act. (See p. 56.)

--A requirement to evaluate the inflationary impact of proposed standards was causing considerable delays. (See p. 61.)

--HEW has had difficulty making sure that its laboratory and field research is, to the extent practicable, directed to developing data needed for recommending standards to Labor. (See p. 67.)

NEED TO ASSESS PROGRESS AND CONSIDER ALTERNATIVES FOR PROTECTING WORKERS

Improvements such as those recommended by GAO can speed up the issuance of health standards, but it appears that many decades will pass before standards will be completed for many

of the toxic substances that threaten the health of workers.

Labor and HEW have not thoroughly assessed what is needed in the way of health standards, how long it will take to produce them with current funding levels, and whether increased funds could effectively be used to produce more standards. Such an assessment is needed to enable the agencies and the Congress to consider such alternatives as increasing funds for health standards development and/or putting more emphasis on informing and educating employers and workers about toxic substances. (See p. 72.)

The Secretaries of Labor and HEW should:

--Estimate, based on the best available data, the total needs for health standards and how long it will take to complete them with existing funding levels.

--Determine whether and to what extent additional funds can be used effectively to (1) speed up standards development and (2) increase efforts to inform, educate, and train employers and employees on toxic substances.

GAO also recommends that:

--If more funds can be used effectively, the Secretary of Labor allocate more funds to health standards development and health information, education, and training activities.

--The Secretary of HEW require that decisions on how much effort to devote to standards development, as opposed to other HEW worker protection programs, be based partly on Labor's ability to promptly act on recommended standards.

LABOR AND HEW COMMENTS

GAO requested Labor's comments before completing this report, but Labor refrained, stating that it would comment later. (See app. I.)

HEW provided extensive comments and suggestions for GAO's consideration, but did not specify whether it agreed or disagreed with most of GAO's recommendations. (See app. II.) Concerning the rate of progress in issuing standards, HEW cited the large number of toxic substances already covered by its recommendations to the Department of Labor. HEW also said that it will have recommended standards for about 5,000 substances by 1981. (See p. 74.)

Tear Sheet

Contents

ABBREVIATIONS

GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
NIOSH	National Institute for Occupational Safety and Health
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration

CHAPTER 1

INTRODUCTION

The Congress passed the Occupational Safety and Health Act of 1970 (29 U.S.C. 651) to assure, so far as possible, safe and healthful working conditions for every worker in the Nation. The act authorizes the Secretary of Labor to develop and enforce safety and health standards. Because of the critical need for health standards, we reviewed health standards development under the act.

Occupational safety standards are to prevent injuries from mechanical, fire, electrical, housekeeping, and other hazards. Occupational health standards are to prevent illnesses from exposure to toxic substances and harmful physical agents. Health standards may require (1) limits on employee exposure to substances (e.g., a limit on the amount of dust, fumes, or particles from a substance that can be in the air) and (2) such work practices as wearing protective clothing, posting warning labels, assuring adequate ventilation, and providing medical examinations.

The Department of Health, Education, and Welfare's (HEW's) Public Health Service estimates that each year 390,000 new cases of occupational illnesses appear and as many as 100,000 workers die from occupational illness.

In its report on the occupational safety and health bill, 1/ the Senate Committee on Labor and Public Welfare stated:

> "In the field of occupational health the view is particularly bleak, and, due to the lack of information and records, may well be considerably worse than we currently know.
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> "Occupational diseases which first commanded attention at the beginning of the Industrial Revolution are still undermining the health of workers. Substantial numbers, even today, fall victim to ancient industrial poisons such as lead and mercury. Workers in the dusty trades still contract various respiratory diseases. Other materials long in

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1/S. Rep. No. 91-1282 (1970) on S. 2193, which was enacted as the 1970 act.

"industrial use are only now being discovered to have toxic effects. In addition, technological advances and new processes in American industry have brought numerous new hazards to the workplace. Carcinogenic chemicals, lasers, * * * beryllium metal, epoxy resins, pesticides, among others, all present incipient threats to the health of workers. Indeed, new materials and processes are being introduced into industry at a much faster rate than the present meager resources of occupational health can keep up with. It is estimated that every 20 minutes a new and potentially toxic chemical is introduced into industry. New processes and new sources of energy present occupational health problems of unprecedented complexity.

"Recent scientific knowledge points to hitherto unsuspected cause-and-effect relationships between occupational exposures and many of the so-called chronic diseases--cancer, respiratory ailments, allergies, heart disease, and others. In some instances, the relationship appears to be direct: asbestos, ionizing radiation, chromates, and certain dye intermediaries, among others, are directly involved in the genesis of cancer. In other cases, occupational exposures are implicated as contributory factors. The distinction between occupational and nonoccupational illnesses is growing increasingly difficult to define."

In its report, the Committee said that many occupational health hazards were not covered by standards. The 1970 act contains several provisions for developing and issuing standards.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

The act authorizes the Secretary of Labor to establish national occupational safety and health standards, promote safety and health through employer and employee information and education programs, and enforce compliance with standards through workplace inspections with citations and penalties

for violations. The Secretary 1/ delegated these responsibilities to the Occupational Safety and Health Administration (OSHA) which was created on April 28, 1971.

Section 6(a) of the act required that the Secretary, within 2 years, adopt any national consensus or established Federal standard unless the standard would not improve safety and health conditions for designated employees. This was done to establish as rapidly as possible standards with which industry was familiar. Because these standards did not cover all hazards and may not have been as effective or up-to-date as desirable, the act authorized the Secretary to set new standards and modify or revoke existing standards.

Section 6(b) provides that the Secretary may determine the need for a safety or health standard on the basis of information developed by or available to OSHA, or information submitted by

--an interested person,

--a representative of any organization of employers or employees,

--a nationally recognized standards-producing organization,

--the Secretary of Health, Education, and Welfare,

--HEW's National Institute for Occupational Safety and Health (see p. 5), or

--a State or a political subdivision.

Section 6(b) states that, after determining that a standard is needed, the Secretary may request the recommendations of an advisory committee appointed under section 7 of the act. The Secretary must provide the advisory committee with any proposals of his own or of the Secretary of Health, Education, and Welfare, and pertinent factual material including the results of research, demonstrations, and experiments. The advisory committee must give the Secretary its recommendations within 90 days or within some time period established by the Secretary, but the period cannot be longer than 270 days.

1/Unless otherwise stated, the title "Secretary" as used in this report refers to the Secretary of Labor.

Section 6(b) requires that the Secretary, before finally setting a permanent standard, 1/ publish a proposed standard in the Federal Register, afford interested parties time to comment, and, if requested, conduct hearings on the proposal. If an advisory committee is appointed and the Secretary decides that a standard should be issued, the proposed standard must be published within 60 days after the committee submits its recommendations or after a period set for submitting such recommendations.

Section 6(b) states that interested persons shall be given 30 days to submit written data or comments on a proposed standard. On or before the last day of the comment period, any interested person filing written objections may request a public hearing on the objections.

Within 60 days after the comment period or 60 days after any hearings, the Secretary must either issue a final standard or determine that a standard should not be issued.

In addition to health and safety considerations, the Secretary is required to consider the feasibility of proposed standards and their environmental effect. Also, as discussed in chapter 8, the Secretary is required by an Executive order to evaluate the inflationary impact of proposed standards.

Section 6(c) requires that an emergency temporary standard be issued if the Secretary determines that (1) employees are exposed to grave danger because of toxic substances or agents or new hazards and (2) an emergency standard is needed to protect employees from the danger. An emergency temporary standard takes effect immediately and remains in effect until superseded by a permanent standard developed under section 6(b), which must be issued within 6 months.

OSHA is headed by the Assistant Secretary of Labor for Occupational Safety and Health. Standards development is centralized at Washington, D.C., headquarters. The following table shows OSHA's funding levels for standards development and other activities for fiscal years 1972 through 1977.

1/Although referred to as "permanent" these standards may be revised or revoked.

Fiscal year	Total funds (millions)	Standards development		All other activities (note a)	
		Amount (millions)	Percent of total	Amount (millions)	Percent of total
1972	$ 36.5	$ 2.2	6	$ 34.3	94
1973	69.4	3.0	4	66.4	96
1974	70.4	4.4	6	66.0	94
1975	102.3	4.8	5	97.5	95
1976 (note b)	109.8	c/6.7	6	103.1	94
1977 (est.)	130.8	c/10.9	8	119.9	92
Total	$519.2	$ 32.0	6	$487.2	94

a/Enforcement, training, education and information, safety and health statistics, and executive direction and administration.

b/Funds for transition quarter not included.

c/Large portions of the increases in funds for fiscal years 1976 and 1977 were for inflationary impact evaluations required by Executive Order 11821.

OSHA records do not show how much of its standards development funds were allocated to safety or health standards. Available information indicated that about one-half of the funds for fiscal year 1976 were allocated to safety standards and one-half to health standards.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

The 1970 act created the National Institute for Occupational Safety and Health (NIOSH) in HEW to do occupational safety and health research and related work. Although NIOSH cannot set standards under the act, one of its main responsibilities is to provide OSHA with recommended new or revised standards and scientific information and criteria for standards.

Concerning the need to establish NIOSH within HEW, the Senate report (see p. 1) on the bill which became the 1970 act said:

"In order to provide occupational health and safety research with the visibility and status it merits, * * * the bill establishes within the Department of Health, Education, and Welfare a new Institute * * *. The Institute will * * * have the responsibility for conducting research into all phases of occupational health and safety on an in-house and contract basis * * *.

"On the basis of its research the Institute will formulate recommended occupational health and safety standards and transmit them to the Secretaries of Labor and Health, Education, and Welfare for appropriate further action in accordance with the procedures established by section 6 of the bill for the promulgation of mandatory standards.

"The new Institute would perform all of the research now conducted by the Bureau of Occupational Safety and Health (BOSH) * * *. In the past, BOSH, notwithstanding its limited resources, has performed extremely valuable work in the field of occupational health and safety. The establishment of a special Institute * * * is not intended as any criticism of BOSH, but stems from the need to elevate the status of occupational health and safety research and to increase greatly the funds devoted for that purpose."

NIOSH forwards recommended standards and related information to the Secretary of Labor. Also, the recommended standards are distributed to various professional and industrial organizations, unions, and universities and made available to the general public. The publications, which are issued considerably in advance of OSHA's issuance of standards, provide employers and employees with information on the effects of exposure to hazardous conditions and how to improve employee protection. This can stimulate voluntary action by employers and give employees a basis for petitioning the Secretary of Labor to issue standards.

NIOSH obtains its information (either directly or by grants or contracts) by compiling and reviewing research literature and other data, and by conducting laboratory and field research.

NIOSH is headed by a director and is part of HEW's Center for Disease Control, Public Health Service. It is headquartered in Rockville, Maryland, and has a laboratory and other facilities in Cincinnati, Ohio, and Morgantown, West Virginia. Following are the annual NIOSH funding levels for fiscal years 1972 through 1977.

Activity	Fiscal year funding levels (note a) 1972	1973	1974	1975	1976 (note b)	1977	Total
	(millions)						
Surveillance	$ 1.1	$ 1.2	$ 1.7	$ 1.6	$ 2.0	$ 2.4	$10.0
Criteria documentation	0.9	1.7	4.9	4.0	5.7	5.7	22.9
Industrywide studies	2.6	2.3	1.7	3.4	4.0	6.0	20.0
Laboratory research and services	8.5	8.4	10.4	12.1	13.3	17.8	70.5
Coal mine safety and health research (note c)	6.1	5.0	8.4	4.3	4.4	4.4	32.6
Technical assistance	2.7	2.7	3.9	3.4	3.8	4.3	20.8
Personnel development	2.9	2.5	2.4	3.2	4.5	6.1	21.6
Program direction	0.8	1.3	2.1	2.1	2.1	2.1	10.5
Total	$25.6	$25.1	$35.5	$34.1	$39.8	$48.8	$208.9

a/Amounts for fiscal years 1972-1975 are expenditures. Amounts for fiscal years 1976 and 1977 are as budgeted.

b/Funds for transition quarter not included.

c/NIOSH carries out HEW's responsibilities (except for payment of black lung benefits) under the Federal Coal Mine Health and Safety Act of 1969.

Several of the activities listed above can result in input to standards development. Information available for fiscal year 1976 indicated that about 70 percent of NIOSH's standards development effort for that year involved health rather than safety hazards.

SCOPE OF REVIEW

We made our review at OSHA and NIOSH headquarters and at the NIOSH facilities in Cincinnati. Our objectives were to evaluate whether the agencies had

--adequate data and priority systems for directing health standards development to the most serious hazards;

--procedures and controls to insure that laboratory and field research were planned and directed to obtain data for needed health standards; and

--policies, procedures, and controls to help insure timely development and issuance of health standards.

We reviewed the law and OSHA and NIOSH policies and procedures related to developing and issuing standards. We reviewed records and interviewed agency representatives on the development and use of recommendations and supporting information completed by NIOSH through September 1976. We also reviewed records and interviewed NIOSH representatives on the planning, management, and use of laboratory and field research in Cincinnati.

CHAPTER 2

FASTER STANDARDS DEVELOPMENT NEEDED TO PROTECT WORKERS

Although workers are exposed to thousands of toxic substances, hundreds of which may cause cancer, standards have been established for only 15 substances since the 1970 act was passed. Thus, the bleak occupational health conditions which the Congress sought to improve still exist and may be getting worse.

If the Congress occupational health objective is to be reached in the foreseeable future by establishing and enforcing standards, the Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health must greatly increase their development of standards. Unless the rate improves, it will take more than a century to establish needed standards for substances already identified as hazards. The problem is compounded because potentially dangerous substances are being introduced faster than standards are being established for existing substances.

We identified a number of administrative weaknesses which have contributed to delays in developing standards. Improvements in these areas, which are discussed in chapters 3 through 9, warrant the attention of the Congress and the Secretaries of Labor and Health, Education, and Welfare.

However, such improvements may not be enough. OSHA and NIOSH had not adequately evaluated the total needs for health standards, how long it will take to produce them with current staff and funds, and whether increased staff and funds could be used effectively to increase their production. (See ch. 10.)

THE OCCUPATIONAL HEALTH PROBLEM

It is not known how many of the Nation's estimated 80 million workers are exposed to toxic substances and other health hazards in their workplaces. Several sources say that about 2 million chemical compounds exist today; information on toxicity may be available for 100,000; about 13,000 known toxic chemicals are commonly used; and about 500 new substances are introduced each year.

In 1975, NIOSH published a list identifying about 1,500 substances as suspected carcinogens (cancer-causing agents).

The Public Health Service estimates that each year 390,000 new cases of occupational diseases appear and 100,000 workers die from them. NIOSH has reported or predicted grave consequences of exposure to specific substances. For example:

--About 300,000 of the 1 million current and former asbestos workers can be expected to die of cancer.

--Thousands of coke-oven workers in the steel industry are inhaling toxic substances emitted from the ovens. The lung-cancer rate for these workers is 10 times the rate for other steel workers.

--About 1.5 million workers are exposed to inorganic arsenic. The lung-cancer death rate among such workers is from 2 to 8 times the national average.

65-MONTH EFFORT PRODUCES STANDARDS FOR ONLY 15 SUBSTANCES

The 1970 act became effective in April 1971. In May 1971, OSHA, as authorized in the act (see p. 3), adopted (1) standards that had been established under the Walsh-Healy Act (41 U.S.C. 35 et seq.) and other Federal laws and (2) certain standards that had been developed by consensus groups. These included exposure limits for about 400 toxic substances or groups of substances. It has been recognized that many of these standards, which consist solely of exposure limits, need revising to update the exposure limits and to include work practices, employee medical examinations, and other measures to help protect workers.

As of September 30, 1976, OSHA had established permanent standards on 15 toxic substances: vinyl chloride, asbestos, and 13 other chemicals 1/ considered to be carcinogens. Based on the past rate of progress, it will take over 100 years to establish needed standards on existing substances. Also, the estimated 500 new

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1/One package of standards was issued covering 14 chemicals. The standard for one of the chemicals was vacated by a court decision. (See p. 33.)

substances being introduced might require more standards than are being issued each year.

DELAYS IN DEVELOPING AND ISSUING STANDARDS

NIOSH's recommendations to OSHA for health standards usually are included in "criteria documents." These documents contain scientific data on the effects of exposure to a substance, the extent of employee exposure, and other supporting information. The documents are lengthy, formal publications. For example, a document on cotton dust contains 159 pages; a document on chloroform has 120 pages.

In 1974 the two agencies started a project--referred to as the "standards completion project"--to revise most of the estimated 400 standards adopted by OSHA in May 1971 (see p. 10). The plan was to supplement the exposure limits by adding requirements, where appropriate, for work practices, medical examinations, and other measures to protect employees from the substances. NIOSH was to provide recommendations and support for the revisions, but in most cases the required NIOSH effort on each standard was to be far less than the effort usually involved in developing a criteria document. NIOSH continued to develop criteria documents on other substances.

Criteria documents

As of September 30, 1976, NIOSH had submitted 53 criteria documents 1/ to OSHA. The time taken by NIOSH to complete each of the criteria documents ranged from 1 to 50 months and averaged 22 months. NIOSH, however, told us that the time had been reduced to an average of 14 1/2 months for 13 documents recently completed.

OSHA had issued final standards on only two of the substances (asbestos 2/ and vinyl chloride) covered by the 53 criteria documents completed through September 30, 1976. As of that date, OSHA had the other 51 documents for up to 51 months, or for an average of 18 months. OSHA had published proposed standards on only nine of the substances covered by the 51 documents. OSHA took an average of 26 months

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1/Includes recommendations which were not in the form of criteria documents for vinyl chloride and a pesticide known as kepone.

2/The existing standard does not treat asbestos as a carcinogen. A revised standard is being developed treating it as a cancer-causing substance.

to publish the nine proposed standards after receipt of the criteria documents. As of September 30, 1976, an average of 13 months had passed since the proposed standards were published; none of the nine had been issued as final.

The schedule beginning on page 14 shows how long it took NIOSH to develop each of the 51 documents and how long OSHA had each document as of September 30, 1976. As indicated in the schedule, at least nine of the documents deal with suspected carcinogens; many others deal with substances that may cause other severe and irreversible effects. The effects shown in the schedule generally do not include all of the potential ones noted in the criteria documents.

NIOSH estimates indicate that large numbers of employees are exposed to the substances covered by the criteria documents. For example, NIOSH estimated that

--2 million workers are exposed to benzene,

--1.5 million are exposed to inorganic arsenic,

--175,000 are exposed to hexavalent chromium, and

--1.2 million are exposed to crystalline silica.

Standards completion project

Under the plan for the standards completion project, 100 revised standards were to have been completed by August 30, 1976. The entire project covering 387 of the estimated 400 adopted standards was planned for completion by July 1977.

As of September 30, 1976, NIOSH had given OSHA its recommendations for 203 of the standards. Of these, OSHA had

--71 recommendations for less than 6 months,

--65 for 7 to 12 months,

--36 for 13 to 18 months, and

--31 for more than 18 months.

OSHA had not issued in final any of these revised standards.

Complete information was not available on how many workers are exposed to the 203 substances or groups of substances, or how severe the ill effects are of such exposure. Estimates on some of the substances indicate a significant need for improving the standards. For example:

--More than 1 million workers are exposed to aniline, which causes deficient oxygenation of blood resulting in skin discoloration. Eye contact with the substance may cause eye damage.

--About 30,000 workers are exposed to diethylamine, which has been shown to cause skin and eye damage.

--About 10,000 workers are exposed to ethylamine. Suspected effects are skin burns and eye damage.

NIOSH believes the hazardous nature of these and other substances in the project warrant development of complete standards.

CONCLUSION

Faster standards development is needed to protect workers exposed to toxic substances that may cause cancer or other serious illnesses. The situation warrants immediate and continuing attention of the Secretary of Labor, the Secretary of Health, Education, and Welfare, and the Congress. Our findings and views on problems that warrant attention are presented in the remainder of this report.

NIOSH CRITERIA DOCUMENTS FOR WHICH STANDARDS HAD NOT

BEEN ISSUED AS OF SEPTEMBER 30, 1976

Harmful substance or agent	Date started by NIOSH	Date submitted to OSHA	Months in NIOSH	Date OSHA proposed standard	Months in OSHA	Months in NIOSH and OSHA	Effects or suspected effects
Beryllium	Feb. 1971 e/	June 1972	16	Oct. 1975	51	67	Lung cancer
Hot environments	June 1971 a/	June 1972	12	None	51	63	Heat stroke, exhaustion
Carbon monoxide	July 1971 a/	Aug. 1972	13	None	49	62	Enhanced heart irregularity
Noise	Jan. 1972 a/	Aug. 1972	7	Oct. 1974	49	56	Hearing loss
Ultraviolet radiation	June 1971	Dec. 1972	18	None	45	63	Eye and skin damage
Inorganic lead	June 1971 f/	Jan. 1973	19	Oct. 1975	44	63	Anemia and abdominal pain
Coke-oven emissions	July 1972 a/	Feb. 1973	7	July 1975	43	50	Lung cancer
Chromic acid	June 1972 a/	July 1973	13	None	38	51	Skin, nasal ulcers
Tolune	June 1972 a/	July 1973	13	Oct. 1975	38	51	Central nervous system depressant
Toluene diisocyanate	June 1972 a/	July 1973	13	None	38	51	Decreased breathing capacity
Trichloroethylene	June 1972 a/	July 1973	13	Oct. 1975	38	51	Central nervous system depressant
Inorganic mercury	June 1971	Aug. 1973	26	None	37	63	Tremor; gum and mouth inflammation
Inorganic arsenic	July 1972	Jan. 1974 b/	18	Jan. 1975	32	50	Lung cancer
Sulfur dioxide	July 1972	Feb. 1974	19	Nov. 1975	31	50	Respiratory tract damage
Sulfuric acid	July 1972	June 1974	23	None	27	50	Lung damage; blindness; skin disfigurement
Ammonia	June 1973 a/	July 1974	13	Nov. 1975	26	39	Respiratory tract damage
Benzene	May 1971 g/	July 1974	38	None	26	64	Cancer (leukemia)
Chloroform	Oct. 1973 a/	Sept. 1974	11	None	24	35	Liver or kidney cancer
Cotton dust	June 1971 a/	Sept. 1974	39	None	24	63	Lung damage
Crystalline silica	Mar. 1972 a/	Nov. 1974	32	None	22	54	Lung damage
Identification system for hazardous materials	Sept. 1971 a/	Dec. 1974	39	None	21	60	None c/
Xylene	June 1973 a/	May 1975	23	None	16	39	Central nervous system depressant
Inorganic fluorides	June 1973 a/	June 1975	24	None	15	39	Bone damage, digestive system irregularity
Sodium hydroxide	June 1973 a/	Sept. 1975	27	None	12	39	Respiratory tract, eye, skin damage
Zinc oxide	June 1973 a/	Oct. 1975	28	None	11	39	Transitory fever; throat irritation
Carbon tetrachloride	Apr. 1973 h/	Dec. 1975	32	None	9	41	Liver cancer
Emergency egress from elevated workstations	June 1973 a/	Dec. 1975	30	None	9	39	Injury from jumping or falling
Hexavalent chromium	June 1973 a/	Dec. 1975	30	None	9	39	Lung cancer
Kepone d/	Nov. 1975	Jan. 1976	2	None	8	10	Nervous system damage; liver cancer
Phosgene	June 1973 a/	Feb. 1976	32	None	7	39	Severe tissue damage; lung irritation
Nitric acid	Apr. 1973 a/	Mar. 1976	35	None	6	41	Chronic bronchitis, dental erosion
Oxides of nitrogen	Apr. 1973 a/	Mar. 1976	35	None	6	41	Lung damage
Hydrogen fluoride	June 1973 a/	Mar. 1976	33	None	6	39	Eye, skin, respiratory tract injury
Isopropyl alcohol	Nov. 1974	Mar. 1976	16	None	6	22	Mucous membrane irritant

Harmful substance or agent	Date started by NIOSH	Date submitted to OSHA	Months in NIOSH	Date OSHA proposed standard	Months in OSHA	Months in NIOSH and OSHA	Effects or suspected effects
Ethylene dichloride	Apr. 1974 a/	Mar. 1976	23	None	6	29	Liver, kidney, lung, heart damage
Methyl alcohol	Nov. 1974	Mar. 1976	16	None	6	22	Blindness
Methylene chloride	Jan. 1974 a/	Mar. 1976	26	None	6	32	Central nervous system damage
Chlorine	June 1973 a/	May 1976	35	None	4	39	Skin, eye, respiratory tract irritant
Acetylene	Apr. 1975	June 1976	14	None	3	17	Asphyxia
Malathion	Mar. 1975	June 1976	15	None	3	18	Nervous system damage
Parathion	July 1972	June 1976	47	None	3	50	Nervous system damage
Phenol	July 1973 a/	June 1976	35	None	3	38	Skin, respiratory tract irritant
Logging	June 1974 a/	July 1976	25	None	2	27	High fatality and injury rates
1,1,1 - Trichloroethane	Jan. 1975 a/	July 1976	18	None	2	20	Central nervous system depressant
Tetrachloroethylene	Dec. 1974 a/	July 1976	19	None	2	21	Central nervous system depressant
Carbon dioxide	May 1975	Aug. 1976	15	None	1	16	Respiratory impairment
Cadmium	June 1972 a/	Aug. 1976	50	None	1	51	Kidney damage, emphysema
Epichlorohydrin	June 1975	Sept. 1976	15	None		15	Mutation, cancer, sterility
Allyl chloride	June 1975	Sept. 1976	15	None		15	Liver, kidney, and respiratory tract damage
Carbaryl	Feb. 1975	Sept. 1976	19	None		19	Nervous system damage
Methyl parathion	Jan. 1975	Sept. 1976	20	None		20	Central nervous system depressant

a/NIOSH records did not show the starting dates for developing these criteria documents. The dates shown were either estimated by NIOSH officials or were the starting dates for the contracts under which the documents were developed.

b/NIOSH submitted a revised criteria document to OSHA in June 1975.

c/This document is designed to allow for the identification of hazardous materials in the workplace and informing the workers of the hazards.

d/NIOSH sent OSHA a recommended standard on kepone but it was not in the form of a formal criteria document.

e/NIOSH submitted revised recommendations to OSHA in December 1975.

f/NIOSH submitted revised recommendations to OSHA in August 1975.

g/NIOSH submitted revised recommendations to OSHA in August 1976.

h/NIOSH submitted revised recommendations to OSHA in June 1976.

AGENCY COMMENTS

On March 4, 1977, we requested comments from the Departments of Labor and HEW on the contents of this report. By letter of April 12, 1977, (app. I), the Assistant Secretary for Administration and Management, Department of Labor, told us that the Department preferred not to comment at that time because of (1) the serious issues which must be considered and (2) the recent appointment of a new Assistant Secretary for Occupational Safety and Health.

HEW commented on the report contents by letter of April 12, 1977 (see app. II). Those comments are dealt with in various chapters of this report.

HEW said that our conclusion that the bleak occupational safety and health conditions still exist and may be getting worse cannot necessarily be drawn from the fact that standards have been developed for only 15 substances since the 1970 act was passed. HEW said that both OSHA and NIOSH have other programs that have helped ameliorate occupational health problems.

We recognize that OSHA and NIOSH have other programs to help eliminate or reduce safety and health hazards. The agencies, however, have placed major emphasis on the development and enforcement of standards as the primary means of achieving the act's objective. Also, NIOSH has not evaluated the extent that its programs have improved working conditions. While recognizing that such programs may have had an impact, our concern is that major reliance is being placed on standards and that new hazards may be accumulating faster than standards are being issued.

HEW said that the facts presented in this chapter do not support including NIOSH in the statement that OSHA and NIOSH must significantly increase their development of health standards if the Congress occupational health objective is to be achieved in the foreseeable future by establishing and enforcing standards. HEW's rationale was that NIOSH neither sets nor enforces standards, that NIOSH had developed recommendations for more than 1,000 substances, and that NIOSH had significantly reduced the average time required to complete criteria documents.

We recognize that NIOSH has developed and submitted to OSHA far more recommended health standards than OSHA has promulgated. As discussed in later chapters, increasing the rate of OSHA's progress will require action by both agencies to insure closer cooperation and coordination.

CHAPTER 3

NEED FOR JOINT EFFORT TO OBTAIN DATA AND SET PRIORITIES

Neither the Occupational Safety and Health Administration nor the National Institute for Occupational Safety and Health have adequate data for deciding which of the thousands of toxic substances should be given priority in developing standards. Therefore, the agencies have not insured that their efforts are directed to the most significant problems first.

The two agencies have a common goal and face the same problems, but they have made independent efforts to get data and set priorities. They have not agreed on the type and source of data needed and, in many cases, have assigned different priorities to the same substances. Several NIOSH criteria documents for recommended standards were not promptly acted on by OSHA because OSHA considered them to be low priority.

The agencies, therefore, had not effectively implemented section 6(g) of the act, which requires that OSHA, in determining the priorities for standards development, consider (1) the urgency of the need for standards for particular industries, trades, crafts, occupations, businesses, workplaces, or work environments and (2) NIOSH's recommendations for standards.

DATA NOT ADEQUATE FOR PRIORITY DECISIONS

In August 1976 we reported to the Congress 1/ that OSHA's data on the extent, severity, and causes or potential causes of occupational health problems were not adequate for OSHA to establish priorities and set standards for the thousands of toxic substances. That report pointed out the following:

--OSHA's data were based on work-related illnesses as reported by employers, and, because of difficulty in associating illnesses with working conditions, understated the number of illnesses occurring.

1/"Better Data On Severity And Causes Of Worker Safety And Health Problems Should Be Obtained From Workplaces," HRD-76-118, Aug. 12, 1976.

--The data did not specify the severity and causes (e.g., the names of the toxic substances) of reported illnesses.

--Even if these problems were corrected, the data could not be relied upon because the effects of some hazards may not show up as reported illnesses for several years after employee exposure. Many workers might be exposed for a long time before preventive action would be taken.

In the August 1976 report we concluded that the magnitude of the health hazard problem made it imperative that OSHA establish a program to obtain needed data on employers' use of toxic substances, the number of workers exposed, and the effects of such exposure. We recommended that OSHA consult with NIOSH and start a program for reviewing existing data on toxic substances to identify those substances that warrant reporting by employers. We also recommended that the program provide for setting standards to include, as appropriate:

--Provisions for obtaining information from employers on employees' exposure to identified substances and physical agents and the effects of the exposure on employee health.

--Requirements for employers to provide periodic medical examinations for exposed employees where a possible risk of harm exists, plus any other protective measures as may be prescribed on the basis of available data.

--Monitoring, recording, and reporting of exposure levels.

The Department of Health, Education, and Welfare agreed that OSHA should conduct the recommended program in consultation with NIOSH. The Department of Labor, although agreeing with our assessment of OSHA's data needs, disagreed with our recommendation, stating that the legal authority to initiate such a program is not clearly established. Labor did not say what, if anything, should be done. In our opinion OSHA has authority under the act to implement our recommendations. The Senate report on the bill which became the 1970 act (see p. 1) said that:

"The committee also expects that the Secretary of Labor and the Secretary of Health, Education, and Welfare will make every effort, through the authority to

issue regulations and other means, to obtain complete data regarding the occurrence of illnesses, including those resulting from occupational exposure which may not be manifested until after the termination of such exposure."

In February 1977 OSHA headquarters officials said that OSHA had not decided how it would get better data for establishing priorities for health standards.

NIOSH has tried since 1971 to obtain data from workplaces for use in setting priorities for standards development. A major effort involved visiting 4,700 selected employer establishments to identify the substances used and the number of workers exposed. The plan is to project the results nationwide. As of November 1976, this effort was not complete. NIOSH researchers told us they were concerned that the data may not be adequate for setting priorities because (1) much of the data were already about 4 years old and (2) the data may not be representative because certain employer establishments were excluded from the sample.

Although NIOSH and OSHA need the same kind of data for the same purpose--to decide on priorities for standards--they had not reached agreement on what data they need, how and from where the data should be obtained, and which agency would be primarily responsible for obtaining the data.

SEPARATE PRIORITIES FOR THE SAME PURPOSE

In September 1975 NIOSH established a priority list of 50 substances, which superseded a 1973 priority list of 471 substances. NIOSH believed that the smaller list would be better for maintaining control in developing criteria documents and programing the related research. Although the act refers to OSHA's determination of priorities for standards development (see p. 17), OSHA had not officially established a priority list as of February 1977. OSHA had an unofficial list with 220 substances.

NIOSH's selection of the 50 substances was based mainly on the subjective views of senior NIOSH officials. NIOSH did not determine that each of the 50 substances posed a greater problem than the thousands of other toxic substances.

NIOSH's priority ranking of the 50 substances was based partly on (1) limited survey data, estimates, and "best guesses" concerning the numbers of workers exposed and

(2) several scientists' opinions on the relative severity of the effects of substances on workers. NIOSH officials said other factors considered were whether (1) the substances were potential carcinogens, (2) the American Conference of Governmental Industrial Hygienists had recommended new exposure limits, and (3) OSHA already had standards or was working on new or revised standards. Officials could not tell us how NIOSH weighted the factors.

The head of OSHA's health standards staff told us that he did not know how the 220 substances on OSHA's unofficial priority list were selected. OSHA did not determine that each of the 220 substances posed a greater problem than other toxic substances.

OSHA's ranking of the 220 substances was based on such factors as (1) whether OSHA had standards on the substances, (2) whether the American Conference of Governmental Industrial Hygienists had recommended new exposure limits, (3) potential carcinogenicity, (4) volume of production, and (5) presence and ranking of the substances on the original priority list established by NIOSH in 1973.

Of the top 50 substances on OSHA's unofficial priority list, 39 were not on NIOSH's priority list and were not covered by NIOSH criteria documents completed or in process.

At least six of NIOSH's completed criteria documents were shelved by OSHA because OSHA considered them to be low priority. These documents covered ultraviolet radiation, hot environments, inorganic fluorides, sodium hydroxide, xylene, and zinc oxide. The documents were in process in NIOSH an average of 25 months and, as of September 30, 1976, had been with OSHA an average of 20 months.

In addition to the priority list of 50 substances, NIOSH has established a listing of about 140 suspected carcinogens that may warrant quick action, outside of the regular criteria development process, because of their potential danger to workers. NIOSH plans to develop information on these substances and possibly establish recommended work practices.

NIOSH also has decided to devote part of its effort to developing standards covering certain industries or industrial processes, as opposed to separate standards on individual substances or groups of substances. NIOSH believes this approach is desirable for some industries or processes that expose employees to more than one toxic substance. As of September 30, 1976, NIOSH was developing a

criteria document for the coal gasification industry. NIOSH told us it plans to issue criteria documents for the cement industry, foundries, welding and brazing, the roofing industry, the printing industry, and slaughtering and rendering plants.

OSHA did not participate in NIOSH's decision to develop industry or industrial process standards, nor did it help in the selection of the industries or processes to be addressed. NIOSH invited OSHA to comment on the decisions to develop such recommendations. An OSHA official told us that OSHA did not respond because it did not have sufficient data to evaluate the NIOSH decisions.

CONCLUSION

OSHA and NIOSH need better data to decide on priorities for health standards development. The two agencies have a common goal. NIOSH recommendations cannot become standards unless accepted by OSHA.

Therefore, a single program for obtaining data on the numbers of workers exposed to the various substances and the effects of such exposure on workers' health would serve the needs of both agencies. The recommendations in our August 1976 report to the Congress on establishing a common data system (see p. 17) should be given further consideration by OSHA and NIOSH.

The two agencies should work together in establishing priorities for substances, industries, or industrial processes. Inconsistencies in priorities have contributed to delays in establishing standards.

RECOMMENDATIONS

We recommend that the Secretary of Labor and the Secretary of Health, Education, and Welfare instruct OSHA and NIOSH to:

--Establish a single program for obtaining and using data to set priorities for health standards development. The program should be along the lines recommended in our August 1976 report.

--Work together to develop uniform priorities for substances, industries, or industrial processes.

HEW COMMENTS

In its April 1977 letter, HEW told us that data from the NIOSH survey of workplaces are now available and that there are no other similar data available. HEW said these data represent about half the workforce and are certainly useful.

HEW said that NIOSH also uses data from (1) NIOSH's list of toxic substances, (2) the World Health Organization, and (3) various other sources.

HEW said that NIOSH has asked OSHA many times to assist in developing priorities but has received little or no response or recommendations from OSHA.

CHAPTER 4

TIMELY COMPLETION NOT EMPHASIZED BY OSHA--
POOR RECORDS AND LOOSE ACCOUNTABILITY

The Occupational Safety and Health Administration did not have an adequate management information system and controls to identify and resolve the problems which delayed completion of standards. The National Institute for Occupational Safety and Health has had some problems in this area in the past, but has developed a system which, in our opinion, should provide more effective control over the development of recommended standards.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

We reviewed NIOSH's official files for six criteria documents--dealing with ammonia, benzene, coke-oven emissions, inorganic arsenic, beryllium, and trichloroethylene--to find out if delays in their development had occurred and if so, why. For the most part, the absence of documented milestone and completion dates and the poor condition of the files precluded us from evaluating the progress of work on the documents.

NIOSH officials could not give us complete information on how long each criteria document was in process, whether work was delayed beyond expected completion dates, where in the organization the delays were occurring, and the problems causing the delays. In fact, NIOSH could not provide us with the starting dates for work on 46 criteria documents.

NIOSH told us that during 1976 it revised its progress reporting system to provide for setting 42 milestone target dates for each criteria document. The system requires progress reporting and justifications for not meeting planned milestone dates. NIOSH officials believe that this system will be effective in monitoring progress and stimulating greater effort. To assure better historical records, NIOSH said it would develop a special file for each criteria document.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

We interviewed OSHA officials to find out why issuance of standards was taking so long. We discussed 13 criteria documents.

The absence of estimated and actual completion dates and the lack of progress reports and other information in the records precluded us from pinpointing delays and problem areas.

In three cases--inorganic lead, carbon monoxide, and noise--project officers who took over the projects (after they had been in process for some time) said that their progress was delayed because previous project officers did not maintain records. In other cases, the records generally did not show whether work was delayed beyond expected completion dates, where in the organization delays were occurring, and what problems had caused delays. The following cases illustrate some of these conditions.

--OSHA received NIOSH's criteria document on coke-oven emissions in February 1973 and did not take action for more than 21 months. There was no record of what caused the delay and the project officer told us he did not know.

--OSHA completed a draft on benzene in December 1974 and sent it to the Office of the Solicitor for legal review. The project officer said that the draft was reviewed by various attorneys in that office until April 1975. There were no records of who reviewed the draft or what changes were proposed.

--OSHA received NIOSH's criteria document on chloroform in September 1974 and published an advance notice of proposed rule-making in December 1974. Since then, little progress has been made; a proposed standard has not been drafted. Reasons for the lack of action were not documented. The project officer told us that his work on chloroform (a carcinogen) had been disrupted in the past because he had to work on developing standards for safety showers and confined working spaces. In October 1976, he told us that the chloroform project was inactive because he had to work on developing a standard regarding itinerant farm workers.

OSHA does not have a project management and records system for planning milestone and completion dates, reporting progress, or justifying delays. The system only provides for recording the dates of advance notices of proposed rule-making, proposed standards, and other major events leading to a final standard. An OSHA official said that this information was kept merely to indicate the status of major events to outsiders.

An OSHA official said that starting in August 1976, project officers were to prepare weekly progress reports. We asked for copies but were told that the reports were not kept.

Several OSHA project officers and Solicitor's attorneys said that they received little direction from higher levels. A senior OSHA project officer said that he was held accountable for the contents of completed standards but not for meeting a target date.

CONCLUSION

More emphasis on timely completion of standards is needed from top OSHA officials. This can come about only with effective project planning and progress reporting. Better records are needed to provide a basis for management review and insure continuity of work when the project staff changes.

RECOMMENDATIONS TO THE SECRETARY OF LABOR

We recommend that the Secretary direct OSHA to establish project planning and progress reporting systems to provide for:

--Setting planned milestone and completion dates for each standards development project.

--Making regular periodic reports that compare planned and actual progress and explain any delays.

--Maintaining complete files on each project.

We recommend that the system be applied to each recommended standard received and to be received from NIOSH and to any standards development effort initiated or to be initiated by OSHA without a recommendation from NIOSH.

CHAPTER 5

OSHA'S APPROACH TO ISSUING STANDARDS IGNORES NEED FOR QUICK ACTION

The Occupational Safety and Health Administration's application of two provisions in the 1970 act has not been responsive to the need to protect workers from dangerous substances as soon as possible. These provisions relate to (1) issuance of emergency temporary standards to protect employees from grave dangers and (2) issuing standards, as soon as possible, on the basis of the best scientific data available.

LIMITED USE OF EMERGENCY STANDARDS

Many of the NIOSH criteria documents submitted to OSHA indicated to us that the toxic substances pose grave danger to workers. However, OSHA has not issued emergency temporary standards on most of these substances, as authorized in section 6(c)(1) of the act. (See p. 4.)

OSHA has issued five emergency temporary standards for (1) asbestos, (2) organophosphorous pesticides, (3) 14 carcinogenic chemicals, (4) vinyl chloride (another carcinogen), and (5) diving. The emergency standards on pesticides and 2 of the 14 chemicals were vacated by Federal court decisions. The emergency temporary standard on diving was stayed by a Federal court and withdrawn by OSHA.

OSHA decided to issue emergency temporary standards on the 14 chemicals and vinyl chloride because they had been shown to cause cancer in humans or animals or both. As shown in the table on pages 14 and 15, at least nine additional substances covered by completed NIOSH criteria documents have also been shown to cause cancer in animals or humans. As of September 30, 1976, OSHA had not issued emergency temporary standards or, for that matter, permanent standards on any of these nine substances.

Criteria needed for applying emergency provisions

OSHA does not have written criteria on the conditions which warrant emergency temporary standards as authorized by the act. Although not required by the act to recommend emergency standards, NIOSH is the technical advisor to OSHA

and is cognizant of the gravity of the dangers of toxic substances. NIOSH has not developed criteria to provide such recommendations to OSHA.

Early in October 1976 NIOSH officials told us they had never recommended that OSHA issue an emergency temporary standard. They said, however, that a NIOSH criteria document provided a basis for OSHA to decide whether an emergency temporary standard was needed. For example, they explained that their identification of a substance as a carcinogen was, in their view, sufficient stimulus for OSHA to issue an emergency standard.

NIOSH officials agreed that it might be desirable to establish criteria for recommending emergency temporary standards and said that they would consider this further. By a memorandum dated October 27, 1976, the Director of NIOSH told OSHA that "we strongly recommend that OSHA establish emergency temporary standards for benzene, hexavalent chromium, and MOCA." 1/ NIOSH did not recommend emergency standards for other carcinogens because (1) the recommended exposure level in the criteria document was not much different than the existing standard, (2) permanent standards were close to being issued, or (3) they did not think OSHA's resources could handle the increased workload. The memo also stated that from time to time, NIOSH would be making additional recommendations for emergency temporary standards.

Such recommendations by NIOSH, however, will have little impact unless OSHA and NIOSH establish and use the same criteria. On November 30, 1976, NIOSH asked OSHA what its plans were to control exposures to benzene, MOCA, and hexavalent chromium. On December 27, 1976, OSHA told NIOSH that the permanent standards development procedures under section 6(b) of the act were the most effective mechanisms for developing standards and for providing long-range protection of the safety and health of the workers.

Information obtained from OSHA pointed out the following issues that should be resolved concerning the use of emergency temporary standards.

1/MOCA is a trade name for one of the 14 chemicals covered by OSHA's emergency temporary standard, which is now expired. See p. 33 for discussion of MOCA.

Definition and evidence of grave danger

In discussing with us why OSHA has not issued more emergency standards, the acting director of OSHA's standards development staff said that the term "grave danger" might be interpreted as something that causes death and that OSHA might have difficulty upholding an emergency standard unless there is direct evidence of human deaths attributable to workplace conditions.

Under this interpretation, workers may be exposed to a toxic substance whose deadly effects may not become apparent until many years after exposure. Also, the interpretation is not consistent with that of the U.S. Court of Appeals for the Fifth Circuit, as expressed in its January 9, 1974, decision on OSHA's emergency temporary standard on pesticides. Although vacating that standard, the court stated:

> "We reject any suggestion that deaths must occur before health and safety standards may be adopted. Nevertheless, the danger of incurable, permanent, or fatal consequences to workers, as opposed to easily curable and fleeting effects on their health, becomes important in the consideration of the necessity for emergency measures to meet a grave danger."

In October 1976 we asked an OSHA official why OSHA had not issued emergency temporary standards for either benzene or chloroform. He said that OSHA did not believe the evidence of these substances' carcinogenicity was strong enough to support such action.

NIOSH has concluded that exposure to benzene causes leukemia; both NIOSH and HEW's National Cancer Institute have concluded that exposure to chloroform can cause cancer, with a capacity to cause liver and kidney tumors. 1/ A NIOSH official said that the evidence of carcinogenicity of these substances was as strong as, or stronger than, that for the 14 chemicals for which OSHA issued emergency standards. OSHA does not have criteria on what kind of evidence would be strong enough to support issuing emergency temporary standards.

1/The National Cancer Institute's findings were cited by HEW's Food and Drug Administration as the reason for banning the use of chloroform in drugs or cosmetics in 1976 (21 C.F.R. 310.513 and 21 C.F.R. 700.18).

In October 1975, representatives of the United Steelworkers of America requested the Secretary of Labor to issue an emergency temporary standard for chromium compounds which are suspected carcinogens (hexavalent chromium). In April 1976, the Assistant Secretary of Labor for Occupational Safety and Health told the steelworker representatives:

> "* * * I certainly share your view that certain new evidence confirms a carcinogenic potential in some hexavalent chromium compounds and that there exists an urgent need to minimize occupational exposure to them to the greatest extent feasible * * *." (Underscoring added.)

The Assistant Secretary concluded, however, that the benefits of an emergency standard would not be substantial and would not warrant exercizing the emergency provision. The OSHA project officer told us that a standard on hexavalent chromium probably would not be issued before October 1977. NIOSH estimates that 175,000 workers are directly exposed to chromium compounds.

In January 1977 the Assistant Secretary said that, because of OSHA's lack of success in defending emergency temporary standards in court, OSHA does not plan to increase the use of the emergency provisions. He also said that OSHA would not use the provisions for any hazards that are already covered by standards.

OSHA's position that the emergency provision should not be applied to toxic substances already covered by standards is not, in our opinion, consistent with the act and its intent. In this regard, section 6(c)(1) states:

> "* * * The Secretary shall provide * * * for an emergency temporary standard to take immediate effect * * * if he determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger." (Underscoring supplied.)

In our opinion, the use of the term "new hazards" in the above quote does not prevent the application of emergency temporary standards to toxic or harmful substances or agents already covered by inadequate standards. The Senate report on the bill which became the 1970 act (see p. 1) makes this point even more clearly. It states:

> "* * * Because of the obvious need for quick response to new health and safety findings, section 6(c) mandates the Secretary to promulgate temporary emergency standards if he finds that such a standard is needed to protect employees who are being exposed to grave dangers from potentially toxic materials or harmful physical agents, or from new hazards for which no applicable standard has been promulgated."
> (Underscoring supplied.)

OSHA's interpretation will result in not applying the emergency provisions to grave dangers posed by toxic substances covered by inadequate standards. At least eight substances identified by NIOSH as carcinogens are covered by standards that provide exposure limits not designed to prevent cancer and that require no other employee protective measures.

In January 1977 (after our discussion with the Assistant Secretary as described on p. 29) OSHA announced that it intended to issue proposed regulations to provide for issuing emergency temporary standards immediately upon classifying a substance as a "confirmed" carcinogen. The announcement said that a substance would be classified as a confirmed carcinogen if positive evidence is found in either (1) humans, (2) two test animal species, or (3) under certain conditions, one test animal species. An OSHA official told us that it will be at least 6 months before these regulations are issued in final.

Effect of 6-month requirement

The act and its legislative history are not clear on whether an emergency temporary standard expires if not superseded within 6 months by a permanent standard as required by the act (see p. 4).

OSHA's unwritten interpretation is that the emergency standard cannot be in effect for more than 6 months. Under this interpretation, unregulated exposure of workers to a grave danger would be permitted after 6 months merely because OSHA could not meet the 6-month requirement.

In March 1976 the acting director of OSHA's standards development staff said that expected difficulty in meeting the 6-month requirement is one of the reasons that OSHA has not issued more emergency temporary standards. Thus, instead of speeding up the issuance of permanent standards to supersede

emergency standards, the 6-month provision is deterring the issuance of emergency standards.

In a September 1973 report 1/ to the Senate Committee on Labor and Public Welfare, we (1) pointed out that the 6-month requirement could deter use of the emergency temporary standards provision and (2) recommended that the Committee consider asking the Congress to amend section 6(c)(3) of the act to allow more time to promulgate a permanent standard after issuance of an emergency temporary standard. The Department of Labor disagreed, stating that additional time was not needed and that extending the 6-month period may increase the use of the emergency standard procedure far beyond the intent of the act. In February 1977 an OSHA official said that this position had not changed.

Industry's ability to promptly comply with standards

The acting director of OSHA's standards staff said that he would not attempt to include requirements in an emergency temporary standard unless he had assurance that the affected industry was physically able to comply with such requirements within 6 months.

The only criteria in the act for issuing emergency temporary standards are whether (1) employees are exposed to grave danger and (2) the standard is needed to protect employees from that danger. In recognition of possible difficulty by industry in complying with standards, the act provides that OSHA, in citing employers for violations of standards, fix reasonable time periods for correction. Such correction periods may be extended if the employer shows a good faith effort to comply and cannot do so because of factors beyond his control.

The act provides also that an employer may obtain temporary or permanent permission to deviate from a standard. Temporary permission to deviate may be given if the employer (1) cannot promptly comply because of the unavailability of professional or technical staff, materials, or equipment or because construction or alteration of facilities cannot be completed in time and (2) is taking all available steps to safeguard his employees against the hazard covered by the

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1/"Slow Progress Likely in Development of Standards For Toxic Substances and Harmful Physical Agents Found In Workplaces," B-163375, Sept. 28, 1973.

standard. Permanent permission to deviate from a standard may be given if an employer demonstrates that his alternative means of protection are as safe and healthful as the protection provided by the standard.

We believe the above provisions are adequate for allowing employers reasonable time to comply with standards. Application of such provisions on a case-by-case basis would serve the interests of worker protection better than deciding not to issue a standard because of concern for industry's general ability to promptly comply.

NEED TO PROMPTLY ISSUE STANDARDS BASED ON BEST AVAILABLE DATA

Generally, OSHA's approach is to develop comprehensive standards that prescribe exposure limits and various other protective measures and work practices. For many of the substances being considered for standards development, NIOSH or OSHA officials determined that the data compiled by NIOSH did not adequately support all of the measures considered desirable for complete protection.

In such cases, NIOSH has recommended standards based on its view that workers should be protected promptly with whatever standards that can be supported by the data. But OSHA, instead of issuing standards containing the measures that were supported by the data, delayed issuing standards pending the development of more or better data. In our opinion, OSHA's approach is not responsive to the act's intent that standards be promptly issued based on the best available data and improved later as more or better data become available.

Intent of the act

The act does not contain specific requirements on what a health standard is to include. Section 6 states that:

--Whenever practicable, standards shall be expressed in terms of objective criteria and the performance desired.

--Standards shall prescribe the use of labels or other appropriate forms of warning as are needed to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms, appropriate emergency treatment, and proper conditions and precautions for safe use or exposure.

--Where appropriate, a standard shall prescribe suitable protective equipment and control or technological procedures to be used in connection with the hazard, and shall provide for monitoring or measuring employee exposure as may be necessary for protection.

--Where appropriate, a standard shall prescribe the type and frequency of medical examinations or other tests, which shall be made available to employees exposed to the hazard, to most effectively determine whether their health is adversely affected by such exposure.

Section 8 of the act provides that the Secretary of Labor shall issue regulations requiring employers to maintain accurate records of employee exposure to potentially toxic materials or harmful physical agents which are required to be monitored or measured by standards issued under section 6.

In addition to the provisions cited above, section 6 states that other considerations shall be (1) the latest available scientific data in the field, (2) the feasibility of the standards, and (3) experience gained under the act and other safety and health laws. As we stated in our August 1976 report to the Congress, 1/ it is clear that the Congress did not intend that any standard represent for all time the means by which to provide safe or healthful employment; the Congress recognized the need for standards to be constantly improved and replaced as new knowledge and techniques are developed.

The following cases demonstrate that OSHA's approach has not been responsive to the need to promptly issue standards based on available data.

MOCA and laboratory activities involving 13 other carcinogenic chemicals

MOCA is a trade name for a chemical (4,4'-Methylenebis (2-chloroaniline)) identified as a carcinogen along with 13 other chemicals. In April 1973 OSHA determined that

--exposure to any of those 14 chemicals posed a grave danger to workers,

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1/"Better Data on Severity And Causes Of Worker Safety and Health Problems Should Be Obtained From Workplaces," HRD-76-118, Aug. 12, 1976, pp. 34 and 35.

--workers were being exposed to the chemicals, and

--an emergency temporary standard was necessary to protect workers from the chemicals.

In May 1973 OSHA issued, as one package, emergency temporary standards to protect workers from the 14 chemicals. The standards were revised in July 1973 to provide more definitive controls for workplaces and work operations and to require more explicit warning signs and labels. As provided in the act, the emergency temporary standards also served as proposed permanent standards. In January 1974 after obtaining public comments and holding a public hearing, OSHA published final permanent standards on the 14 chemicals.

In August 1974 the U.S. Court of Appeals for the Third Circuit vacated that part of the standards on the use of one of the 14 chemicals--ethyleneimine--in laboratory activities. The Court held that substantial evidence supported the finding that ethyleneimine was carcinogenic in rats and mice, but it vacated the laboratory provisions because the notice of proposed standards did not advise that the agency planned to establish special provisions regarding the use of ethyleneimine in laboratories.

In December 1974 the same Court vacated the entire section of the carcinogens standards covering MOCA. Although the Court upheld the determination concerning MOCA's carcinogenicity, it vacated the MOCA section of the standards because the proposed standards were published before a standards advisory committee--formed by the Secretary of Labor to consider the standards--had submitted its report. The Court said that, because of this situation, parties were not given adequate time to submit comments or prepare for hearings after the advisory committee's work was completed.

In the December 1974 ruling, the Court also vacated the special provisions pertaining to laboratory usage of the other 12 chemicals. The basis for this ruling was the same as in the August 1974 ruling on ethyleneimine--interested parties were not given adequate advance notice of the special provisions for laboratories.

Based on the Court's reasons for vacating the MOCA standard and the laboratory provisions for the 13 other chemicals, it appeared to us that OSHA could have overcome the Court's objections by republishing the standards, giving parties appropriate time to comment, conducting hearings if requested, and issuing final standards.

In April 1976, about 16 months after the Court's December 1974 decision, we asked Labor why it was taking so long to reestablish final standards for MOCA and for laboratories using the 13 other carcinogens. By letter of July 15, 1976, Labor told us that:

--Reestablishment of the vacated standards was delayed primarily because they were given lower priority than other pending projects.

--The delay in completing action on the MOCA standard was related to OSHA's efforts to develop an exposure limit. (An exposure limit was not included in either the emergency temporary standard or the vacated final standard on MOCA; nor do the standards for the other 13 chemicals contain exposure limits.)

--OSHA would move as quickly as possible to publish a proposed amendment to the existing unvacated standards for the 13 chemicals to include laboratories within their scope, rather than republish the specific laboratory provisions in each standard.

--A revised draft on MOCA was being prepared and would be published pending completion of an economic feasibility/inflationary impact study, which was due in 4 months.

As of November 1, 1976, the acting director of OSHA's standards staff told us that OSHA (1) did not have a basis for setting an exposure limit for MOCA, (2) had not taken action to include laboratory activities in the standards for the other 13 chemicals, and (3) had not made significant efforts regarding these matters because the staff was working on other standards.

Because of OSHA's decision not to reestablish any part of the vacated MOCA standard until an exposure limit is developed, employers have not been required to provide various other protective measures that were included in the vacated standard. These measures, which would seem desirable regardless of whether there is an exposure limit, included requirements that employers:

--Establish "regulated areas" where MOCA is manufactured, processed, used, repackaged, released, handled, or stored, and control each area as specified for the type of activity involved. Such controls would include having employees wash their hands, arms, faces, and necks

upon leaving an area or upon completion of certain tasks; restricting areas to authorized personnel; prohibiting open vessel system operations; providing continuous local exhaust ventilation; having employees wear protective clothing, shoe covers, gloves, and respirators; placing clothing and equipment in special containers at point of exit for decontamination or disposal; having employees shower at the end of the day; and prohibiting drinking fountains in the area.

--Provide for safe maintenance, repair, or decontamination activities by requiring that employees (1) wear protective clothing, gloves, boots, and continuous-air supplied hoods, (2) be decontaminated before removing the protective garments and hood, and (3) be required to shower upon removal of the garments and hood.

--Establish and maintain a daily roster of employees entering regulated areas and retain the rosters or a summary thereof for 20 years.

--In cases of emergencies (unforeseen spills, leaks, or other conditions resulting in employee exposure), evacuate the affected area immediately; eliminate the condition that created the emergency and decontaminate the area before resuming normal operations; establish medical surveillance by a physician within 24 hours for employees in the area where the emergency occurred; require employees who contacted the chemical to shower immediately; and report the emergency to OSHA.

--Prohibit the storage or consumption of food, beverages, cosmetics, and tobacco products in regulated areas.

--Provide washing and showering facilities in accordance with certain specifications.

--Decontaminate the surfaces of equipment and materials.

--Post warning or instruction signs at entrances and exits of regulated areas, informing employees of procedures that must be followed upon entering or leaving a regulated area.

--Label containers to identify the chemical, and, when appropriate, warn workers that it is a "cancer-suspect agent."

--Provide training and indoctrination for each employee before authorizing entrance to a regulated area. Some of the minimum requirements would be that each such employee be educated on the nature of the hazard, the nature of the operations that can result in exposure, the medical surveillance program, decontamination practices, and emergency procedures.

--Report to OSHA a description and the location of each regulated area and the number of employees in each area.

--Provide, at no cost to the employees, medical examinations before employees are assigned to enter a regulated area and at least once a year thereafter.

--Maintain complete and accurate records of all medical examinations.

The above or similar practices were included in the emergency temporary standard as revised in July 1973. These practices have not been required since the permanent standard was vacated in December 1974. OSHA does not know the extent that employers are doing these things. As stated on p. 27, NIOSH recommended in October 1976 that OSHA issue an emergency temporary standard on MOCA.

Benzene

Benzene is used in several industries or processes, including coke and gas, printing and lithography, paint, rubber, dry cleaning, adhesives, petroleum, and coatings. It is also used extensively in chemical laboratories as a solvent and reactant. NIOSH estimates that 2 million workers have potential exposure to benzene.

The current OSHA standard on benzene--one of the nearly 400 adopted in 1971--requires that the amount of benzene in workroom air not exceed (1) 10 parts per million parts of air as a time-weighted average for an 8-hour period, (2) 25 parts per million except for a maximum period of 10 minutes, and (3) 50 parts per million at any time. The standard does not include any required work practices or other measures.

In July 1974, NIOSH sent OSHA a criteria document recommending that the standard be revised to limit employee exposure to (1) 10 parts per million determined as a time-weighted average for up to a 10-hour work day, 40-hour week and (2) 25 parts per million for any 10 minute period. The

document said that, although conclusive evidence was not available, the possibility that benzene can induce leukemia could not be dismissed. The recommended exposure limit was, according to NIOSH, a conservative limit and was justified because of the bone marrow and blood changes that occur in humans and animals exposed to benzene.

In addition to the exposure limit, NIOSH recommended that, under certain conditions, employers be required to (1) provide medical examinations and biological monitoring of employees, (2) inform and educate employees of benzene hazards, (3) post warning signs at entrances to areas where exposure to benzene is likely to occur, (4) use exhaust ventilation and enclose work processes to control benzene concentrations, and (5) establish and maintain numerous work practices to help protect workers.

Shortly after receiving the criteria document, OSHA asked NIOSH to clarify whether or not benzene causes leukemia. In a November 1974 letter NIOSH told OSHA that (1) it could be postulated that bone marrow changes and blood dyscrasia would precede leukemia if induced by benzene, (2) if these changes were prevented, leukemia should not result, and (3) the standard recommended by NIOSH was designed to prevent such changes.

According to an OSHA official, OSHA's delay in issuing a standard on benzene was caused partly by OSHA's view that NIOSH had not (1) provided adequate evidence supporting the recommended exposure level and (2) addressed the issue of whether the standard should cover employees at gasoline stations because of the high levels of benzene in unleaded gasoline. In trying to resolve these questions, OSHA and NIOSH undertook efforts to obtain or develop more and better data.

The validity of many of the protective measures recommended by NIOSH would not be affected by the two issues discussed above. In view of the dangers involved with benzene, we believe that such protective measures as are supported by available evidence should be established as soon as possible.

In August 1976, NIOSH sent OSHA a revised recommendation for a standard on benzene. Instead of the previously recommended exposure levels of 10 parts per million as averaged for a 10-hour day and 25 parts per million for any 10-minute period, NIOSH recommended that the exposure limit be set at 1 part per million as determined by 2-hour samples taken at the rate of 1 liter of air per minute.

NIOSH's recommendation of the more stringent exposure limit was based on NIOSH's conclusion that recently accumulated evidence proved that benzene causes leukemia and produces progressive, malignant disease of the blood-forming organs.

As of October 31, 1976, OSHA had not issued either a proposed or final standard on benzene. OSHA had the NIOSH criteria document for 27 months. NIOSH's October 27, 1976, memorandum to OSHA (see p. 27) strongly recommended that OSHA publish an emergency temporary standard on benzene without delay.

Inorganic arsenic

Inorganic arsenic is a by-product of copper smelting. Inorganic arsenic compounds are used in several industries or industrial processes, including pesticides manufacturing, pigment production, glass manufacturing, textile printing, tanning, and taxidermy. NIOSH estimates that 1.5 million workers are exposed to inorganic arsenic.

The standards adopted by OSHA in 1971 included exposure limits of 0.5 milligrams per cubic meter for "arsenic and compounds" and 1.0 milligrams per cubic meter for calcium arsenate. The above limits are on time-weighted averages for an 8-hour period. The standards do not include any other protective measures or work practices.

In January 1974, NIOSH sent OSHA a criteria document recommending that exposure to inorganic arsenic (excluding lead arsenate and arsine) be limited to 0.05 milligrams per cubic meter. NIOSH said that (1) it was apparent that arsenic had been a factor in causing job-related lung cancer, but the evidence was not unequivocal and (2) although data were not available to validate any specific exposure limit, the recommended limit would, as a minimum, significantly reduce the incidence of arsenic-induced cancer.

In addition to the exposure limit, the NIOSH criteria document recommended that employers be required to:

--Establish medical surveillance of all employees exposed to inorganic arsenic.

--Put warning labels on arsenic containers and post warning signs at entrances to areas where there is exposure.

--Use engineering controls to maintain arsenic at or below the limit and require the use of respirators until the limit is complied with.

--Provide employees with protective clothing and require that clothing be changed daily and not taken home.

--Inform and educate employees on the hazard and conditions for safe use.

--Monitor and keep records of exposure levels.

In November 1974, NIOSH sent OSHA a revised recommendation: limit exposure to inorganic arsenic to a level at which none can be detected (OSHA determined that level to be 0.002 milligrams per cubic meter of air). This was based on NIOSH's conclusion that information obtained after the first recommendation offered stronger evidence that exposure to inorganic arsenic can cause cancer.

OSHA issued a proposed standard in January 1975 and held hearings in April 1975. The wood preservative industry contended that the supporting evidence for the proposed standard did not apply to that industry because it used a different arsenic compound than the industries where the research had been done to develop the evidence.

NIOSH officials said that there was no evidence that the arsenic compound used in the wood preservative industry was not carcinogenic, and available data did not show that the compound was so different from the others that it should be excluded from the standard.

However, OSHA did not accept NIOSH's judgment and continued to seek additional information. As of October 1976, OSHA had not finalized the arsenic standard and was still considering whether the standard should include the arsenic compound used in the wood preservative industry.

We believe the question on the applicability of the proposed standard to the wood industry does not justify delaying protection of employees in other industries where arsenic has been shown to cause cancer. Further, the possibility that the wood industry's arsenic compound causes cancer would, in our opinion, justify a standard to require, as a minimum, medical surveillance of exposed employees and monitoring of exposure levels in that industry.

Chloroform

Chloroform is used by many manufacturers for pharmaceutical purposes. NIOSH estimates that 80,000 workers are exposed to this chemical. The current OSHA standard on chloroform--adopted in 1971--requires that workplace air cannot contain more than 50 parts per million at any time. The standard does not require any other protection. The exposure limit was to prevent serious short-term effects on the liver.

In September 1974 NIOSH gave OSHA a criteria document recommending that the exposure limit be revised to 10 parts per million (time-weighted average for up to a 10-hour workday) and 50 parts per million for any 10 minute period. NIOSH also recommended requiring medical surveillance, warning labels and signs, employee information and education, various work practices, and monitoring and recording of exposure levels.

NIOSH's recommendations were based on findings that exposure to chloroform causes liver and kidney damage, depression of the central nervous system, cardiac irregularities, and other problems. The NIOSH criteria document said that more studies were needed to clarify the cancer question.

In June 1976 NIOSH told OSHA that new information showed that chloroform causes cancer of the liver and kidneys. NIOSH lowered its recommended exposure limit to 2 parts per million as determined by sampling 45 liters of air for up to 1 hour.

As of October 31, 1976, OSHA had not proposed a revised standard on chloroform. Part of the reason was that OSHA officials did not believe the initial NIOSH criteria document adequately addressed the questions of whether chloroform causes cancer or fetal malformations.

Although prompt action by OSHA on NIOSH's initial recommendations on chloroform would have resulted in establishing a standard less stringent than NIOSH's revised recommendation, such a standard would have been more effective than the present standard and could have been revised later. Also, workers would have been provided with required medical surveillance, warning signs and labels, information and education, and other protective measures.

Cotton dust

Exposure to cotton dust can cause a lung disease known as byssinosis. OSHA estimates that 800,000 workers are involved in cotton fiber processing.

OSHA's current standard--adopted in 1971--requires that exposure to cotton dust not exceed 1 milligram per cubic meter of air (8-hour time-weighted average). The standard does not include any other protective measures.

In September 1974 NIOSH sent OSHA a criteria document recommending the addition of various work practices to the cotton dust standard. NIOSH further recommended in December 1974 that exposure to cotton dust be limited to the lowest level feasible and that the limit not be more than 0.2 milligrams of lint-free cotton dust per cubic meter of air. NIOSH stated that (1) because of inconsistent data, it could not determine the exposure limit that would prevent all adverse effects, (2) lowering the exposure limit would decrease the occurrence of byssinosis, and (3) pending the acquisition of more information, available knowledge should be used to provide maximum worker protection.

In addition to a lower exposure limit, NIOSH's criteria document recommended that the cotton dust standard include requirements for (1) medical surveillance of exposed employees, (2) warning signs, (3) the use of engineering controls and respirators, (4) employee information and education programs, (5) monitoring and recording of exposure levels, and (6) various other protective work practices.

As of November 1976 OSHA had not issued a revised standard on cotton dust. One of the reasons for the delay was that OSHA did not believe that NIOSH's criteria document was adequate, mainly because it addressed only part of the textile industry. The NIOSH criteria manager said that the criteria document was based on the best information available at the time, and the recommendations would have reduced cotton dust exposure for most of the textile industry.

OSHA did not attempt to issue a revised standard based on the available information but made a comprehensive study of the entire cotton industry from November 1974 through January 1976. In December 1976 OSHA published a proposed standard covering the entire industry except harvesting, that would limit exposure to cotton dust to the same level as recommended by NIOSH in December 1974.

CONCLUSION

OSHA has made limited use of its authority to (1) issue emergency temporary standards to protect employees from grave dangers and (2) promptly provide needed protection that can be supported by available evidence. The gravity of the dangers posed by toxic substances dictates that OSHA use its authority more aggressively. Millions of workers are exposed to substances that can cause cancer and other serious or irreversible diseases.

OSHA needs to establish criteria on the conditions under which emergency temporary standards should be issued. The criteria should define grave danger and the evidence needed to support a determination that a grave danger exists. The definition should make it clear that direct evidence of fatalities attributable to the workplace is not necessary.

OSHA's announced intent to issue emergency temporary standards on confirmed carcinogens would, if carried out, be a significant step toward establishing the needed criteria. Additional criteria are needed for substances which, although noncarcinogenic, pose grave dangers to workers.

The criteria for issuing emergency temporary standards should apply both to toxic substances not covered by standards and toxic substances covered by inadequate standards. The question of industry's general ability to comply with a standard within 6 months should not deter efforts to protect workers from a grave danger.

Reluctance to issue emergency temporary standards has been influenced by the position that such action should not be taken unless a permanent standard can be issued in 6 months to supersede the temporary standard. Although the act requires that a permanent standard be issued within 6 months after a temporary standard, it does not say whether the temporary standard expires if this requirement is not met. OSHA's interpretation that the standard expires after 6 months is not consistent with the basic intent of protecting workers from grave danger.

Regardless of whether evidence is adequate to support emergency action, OSHA should promptly issue standards based on available evidence, even if the standards cannot include all protective measures that would be desirable if more or better data were available. The act provides that any standard may be revoked or modified as additional evidence is obtained.

RECOMMENDATIONS TO THE SECRETARY OF LABOR

The Secretary should require OSHA to take the following actions to implement section 6(c) of the act:

--Define grave danger to include exposure of workers to a toxic substance or harmful agent which has resulted or can result in incurable, irreversible, or fatal harm to health.

--Issue emergency temporary standards in all cases where they are needed to protect employees from grave danger, including any such dangers posed by toxic substances or harmful agents covered by inadequate standards.

--Require that emergency temporary standards remain in effect until superseded by a permanent standard.

The Secretary should also require OSHA to promptly issue emergency temporary or permanent standards on toxic substances to require needed protection that can be supported by available evidence and to revise and add to such standards as more and better evidence becomes available.

CHAPTER 6

POLICY AND CRITERIA NEEDED FOR IDENTIFYING CARCINOGENS

The question of whether a substance can cause cancer is critical to standard-setting. Generally, standards should be more stringent for carcinogens than for non-carcinogens.

Neither NIOSH nor OSHA has established a policy or guidelines on the evidence needed to classify a substance as a carcinogen for regulatory purposes. NIOSH has not required that all information on carcinogenicity be included in its criteria documents. The lack of such requirements, policies, and guidance has contributed to delays in issuing standards.

CADMIUM

Cadmium is a metal used in electroplating, and NIOSH has estimated that about 100,000 workers are exposed to it. NIOSH took about 50 months to develop its criteria document on cadmium. A major cause for this delay was deciding whether cadmium should be considered carcinogenic.

The criteria document--initially prepared by a contractor in 1973--was directed to noncarcinogenic effects of cadmium. The contractor's draft recommended an exposure limit of 0.01 milligrams per cubic meter of air (time-weighted average for an 8-hour period).

NIOSH completed the cadmium document in August 1976 and sent it to OSHA. The document does not say that cadmium should be treated as a carcinogen. It recommends an exposure limit of 0.04 milligrams per cubic meter, which is designed to prevent acute or short-term effects. This decision was reached in spite of the fact that NIOSH epidemiologists had reported in January 1976 that cadmium causes prostate cancer and possibly lung cancer. The epidemiologists' conclusion was based on a study of workers exposed to cadmium and arsenic.

In March 1976 a NIOSH headquarters official noted that the workers studied by the NIOSH epidemiologists had also been exposed to arsenic, and inquired:

"With the known ability of arsenic to cause lung cancer, is it appropriate to draw inferences about carcinogenicity of cadmium, at least for the lung, from this paper?"

A NIOSH epidemiologist replied:

"With these study results and the repeatability of our study with those * * * concerning prostatic carcinoma I think it is safe to conclude that cadmium is a carcinogen, most specifically of the prostate and that our study and others do suggest an increased risk of respiratory cancer * * *.

"I would make the point that cadmium is a human carcinogen and that whether it is specific for one or more organ systems is of little relevance in developing a criteria for recommending a safe exposure level to a carcinogen. The criteria must be determined based on the fact that the agent is carcinogenic, not the number of sites affected."

The criteria manager said that he drew his conclusion from all the evidence available, not just one study. He said that some relevant animal studies were negative, indicating cadmium was not a prostate carcinogen, and that other epidemiological studies were contradictory with regard to lung cancer.

In an April 19, 1976, letter commenting on a draft of the criteria document, a NIOSH epidemiologist stated:

"Having now read the document I am appalled at the inability of the criteria manager to understand and interpret the epidemiologic studies; thus leading to the complete disregard of the carcinogenicity of cadmium. This is documented by the complete misrepresentation of the NIOSH epidemiological study of which I was senior author as well as the apparent inability of the manager to correlate the results of this study to that of other human studies as well as animal studies showing the carcinogenicity of cadmium * * *."

The NIOSH project manager told us that (1) the conclusion that cadmium should not be regulated as a carcinogen was based on subjective judgment and (2) there was no NIOSH policy or guidelines on the evidence needed to support a conclusion that a substance should be regulated as a carcinogen.

In its April 1977 letter (app. II), HEW stated:

> "In this case as in all others, including nickel and benzene, NIOSH protects the right of individuals to disagree with Institute decisions and policy. The cadmium write up in the GAO report presents the essence of such a scientific disagreement; however, it is important to note that the Institute's position is expressed in the criteria document and is based on a thorough evaluation of all available evidence pertaining to the carcinogenic potential of cadmium. The Institute's decision was that cadmium should not be controlled as a suspect human carcinogen due to the lack of sufficient evidence indicating same. Not everyone agrees with this position."

We have not concluded that cadmium should or should not be treated as a carcinogen. We believe that HEW's comments further demonstrate the need for a policy and guidelines on this issue.

BERYLLIUM

NIOSH sent OSHA a criteria document on beryllium in June 1972, recommending exposure limits of 2 micrograms per cubic meter of air (determined as a time-weighted average for an 8-hour workday) and 25 micrograms per cubic meter for any 30-minute period. These limits were to prevent "acute and chronic beryllium disease." The document indicated that there was insufficient evidence to consider beryllium as a human carcinogen.

In 1975 OSHA asked NIOSH to review the evidence of beryllium's potential to cause cancer. In September 1975 NIOSH stated that there was compelling evidence that beryllium caused cancer in animals, but only "suggestive" evidence that it caused cancer in humans.

In December 1975, NIOSH concluded that it posed a cancer risk to humans.

In support of this conclusion, NIOSH cited 28 scientific studies of beryllium's carcinogenicity. Although 25 of these studies were done before NIOSH completed the criteria document in June 1972, only 9 were cited in the original criteria document. According to a NIOSH official, some items found in these studies but not included in the criteria document's discussion of cancer were:

--Two studies showing that beryllium caused cancer in monkeys.

--A study showing that rabbits developed cancer after inhaling beryllium.

A NIOSH epidemiologist told us that criteria for classifying substances as carcinogens were needed so that available evidence could be properly evaluated. He said that the evidence of beryllium's potential to cause cancer was "overwhelming" compared to the evidence for some of the 14 cancer-causing chemicals covered by OSHA's standards issued in 1974. OSHA's determination that these chemicals should be considered carcinogenic in humans was upheld in Federal court (see p. 34).

OSHA's actions on the beryllium document were slowed by the need to more fully consider the cancer issue and redirect the proposed standard. As of November 1976 OSHA had not issued a final standard on beryllium but had published a proposed standard that would limit exposure to half the level recommended in the June 1972 NIOSH criteria document. The preamble to the proposed standard states that beryllium should be treated as a carcinogen.

INORGANIC LEAD

NIOSH's January 1973 criteria document on inorganic lead recommended an exposure limit of 0.15 milligrams per cubic meter of air, as determined by a time-weighted average for an 8-hour workday. This limit was to prevent "acute and chronic plumbism" (lead poisoning). Subsequently, OSHA and NIOSH reviewed scientific evidence not available or relied on in preparing the criteria document.

Based on this review, NIOSH told OSHA in August 1975, that the exposure limit should be somewhere between 0.15 and 0.05 milligrams per cubic meter.

OSHA published a proposed standard on inorganic lead in October 1975, including an exposure limit of 0.10 milligrams per cubic meter. The OSHA project officer said that the proposed standard did not address cancer because his knowledge of the subject was limited.

The NIOSH criteria document had two references to carcinogenicity of inorganic lead: a 1963 study of battery workers and a 1971 study of exposed rats. OSHA's literature search identified several scientific studies--done before the criteria document was prepared--of lead's potential to cause cancer. Neither OSHA nor NIOSH has decided whether the literature supports treating inorganic lead as a carcinogen. In November 1976, the OSHA project officer told us that OSHA would have to decide on this question before issuing a standard.

In its April 1977 letter, HEW said that the data on carcinogenicity of lead was evaluated, referenced in the criteria document, and considered during the development of the standard. Subsequently, NIOSH officials told us that (1) it would be impossible to determine whether or not the carcinogenicity data identified by OSHA were obtained and evaluated during development of the criteria document and (2) such data were not discussed or referenced in the criteria document.

BENZENE AND CHLOROFORM

As stated on page 28, an OSHA official told us that, in his opinion, the evidence of the potential for benzene and chloroform to cause cancer was not strong enough to support emergency temporary standards. A NIOSH official said that the evidence for these two chemicals was at least as strong as that for the 14 carcinogens on which OSHA issued emergency standards. NIOSH has strongly recommended an emergency standard for benzene.

In support of its August 1976 conclusion that benzene causes cancer (leukemia), NIOSH cited 46 scientific studies. Of those, 25 were published before NIOSH completed its original criteria document in July 1974. The original document cited only two of those studies.

HEW told us that (1) the 23 additional studies on benzene were "case reports" and not epidemiological studies, (2) scientific opinion on the merits of case studies has changed, and (3) NIOSH may presently place greater emphasis on case studies than it did in the past.

POLICIES AND CRITERIA FOR IDENTIFYING CARCINOGENS SHOULD BE COORDINATED

As of November 1976, NIOSH and OSHA were considering the need for policies and criteria for deciding whether to regulate a substance as a carcinogen. Such policies and criteria should be (1) at least as stringent as the tacit policy and criteria used in previous decisions which were upheld in Federal court and (2) coordinated with HEW's National Cancer Institute. Also, because of their common goals, OSHA and NIOSH policies and criteria should be the same.

Policy and criteria used in previous decisions

The two most common types of evidence of a substance's carcinogenicity are derived from:

--Epidemiological studies, which include comparing the cancer rate among exposed workers to the cancer rate among unexposed people in the same geographic area.

--Animal studies, which measure a substance's ability to produce cancer in test animals.

A basic problem in epidemiological studies is that they do not provide 100 percent proof that cancer is caused directly or solely by exposure to a specific substance. With animal studies there is a problem deciding whether a substance has the same effect on humans as it does on animals.

In an April 1970 report to the Surgeon General, the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens stated that:

> "Any substance which is shown conclusively to cause tumors in animals should be considered carcinogenic and therefore a potential cancer hazard for man * * * [and] no level of exposure

to a chemical carcinogen should be considered toxicologically insignificant for man. For carcinogenic agents 'a safe level for man' cannot be established by application of our present knowledge."

OSHA's decision to regulate 14 chemicals as carcinogens in January 1974 (see p. 34) relied heavily on data obtained from NIOSH. For two of the chemicals--3,3-dichlorobenzidine and ethyleneimine--NIOSH said that the case for carcinogenicity was based on (1) evidence that they had caused cancer in three species and two species of animals, respectively and (2) the absence of evidence that they did not cause cancer in humans. The preamble section of the OSHA standards on the 14 chemicals stated:

"We think it improper to afford less protection to workers when exposed to substances found to be carcinogenic only in experimental animals. Once the carcinogenicity of a substance has been demonstrated in animal experiments, the practical regulatory alternatives are to consider them either non-carcinogenic or carcinogenic to humans, until evidence to the contrary is produced. The first alternative would logically require, not relaxed controls on exposure, but exclusion from regulation. The other alternative logically leads to the treatment of a substance as if it was known to be carcinogenic in man.

"We agree with the Director of NIOSH and the report of the Ad Hoc Committee * * * to the Surgeon General * * * that the second alternative is the responsible and correct one * * *."

In upholding OSHA's decision to consider ethyleneimine as a carcinogen, the U.S. Court of Appeals for the Third Circuit stated in August 1974 that:

"* * * Lastly, we hold that there does exist substantial evidence in the record as a whole to support the * * * findings that * * * [ethyleneimine] is carcinogenic in rats and mice and in the absence of evidence of carcinogenicity in humans, the Secretary [of Labor] properly weighed the only available alternative actions."

Similarly, in upholding OSHA's decision on 3,3-dichlorobenzidine, that same court stated in December 1974 that:

> "The contentions made here with respect to 3-3-Dichlorobenzidine * * * by employers who use it are similar to those raised in connection with * * * [ethyleneimine]--that is, the data derived from tests revealing carcinogenicity in animals were not properly extrapolated to human susceptibility. Nothing in the record permits a differentiation here from our earlier decision on * * * [ethyleneimine], and we do not make one. While the scientific data varies, of course, the same legal principle applies and, accordingly, the petitioners' contention must fail."

Need to coordinate with National Cancer Institute

In a June 1976 report to the Congress, 1/ we pointed out that Federal agencies, including NIOSH and OSHA, may have problems in applying the results of carcinogenicity tests to people because (1) the National Cancer Institute had only recently developed minimum test guidelines for determining a chemical's carcinogenicity and other agencies had not officially adopted them and (2) there are no scientific principles to help Federal agencies apply animal test results to humans.

We recommended in the report that the National Cancer Institute set a Federal policy that addresses the scientific issues which have hampered public protection from carcinogens, including the test guidelines that should be followed, the way test results should be evaluated, and the setting of acceptable levels of risk.

NIOSH and OSHA should have common policy and criteria

In March 1975 NIOSH drafted a policy and criteria for classifying substances as carcinogens, but as of October 1976 had not finalized them.

1/"Federal Efforts to Protect the Public from Cancer-Causing Chemicals Are Not Very Effective," MWD-76-59, June 16, 1976.

A NIOSH official said that the delay was caused by the need to consider NIOSH's relationship to OSHA and the National Cancer Institute, and the fact that OSHA had not established a policy and criteria.

An OSHA official told us in September 1976 that some thought was being given to establishing a policy and criteria, but nothing had been drafted. He said this was a spare-time project with no planned completion date. As of December 1976, OSHA had not expressed its position on NIOSH's draft of a policy and criteria.

In January 1977 OSHA announced that it intended to propose regulations setting forth criteria for determining whether and how substances will be identified and regulated as carcinogens. OSHA said its intent was to speed up standards completion on carcinogens by providing for:

--Classifying substances as (1) confirmed carcinogens if positive evidence is found in either humans, two animal species, or, under certain conditions, one animal species, (2) suspect carcinogens if the evidence of carcinogenicity in humans or in one or more animal species is found to be only "suggestive" as opposed to confirming, or (3) neither confirmed nor suspected carcinogens if evidence is inadequate to classify them in either of those two categories.

--Issuing, immediately following classification, emergency temporary standards on confirmed carcinogens and proposed permanent standards on suspect carcinogens.

--Advising NIOSH, the National Cancer Institute, and the Environmental Protection Agency of the substances classified as neither confirmed nor suspected carcinogens, and requesting any additional information which could have a bearing on such a classification.

--Setting exposure limits for carcinogens as low as feasible or at zero in certain cases.

--Including in standards certain provisions common to health standards, such as rules on monitoring and measuring exposure, medical surveillance, personal protective measures, recordkeeping requirements, personal hygiene, sanitation and housekeeping measures, and employee training.

An OSHA official told us in February 1977 that OSHA had not set a timetable for finalizing the regulation and it would be at least 6 or 7 months before the final regulation would be issued. He said also that OSHA would obtain the views of NIOSH and the National Cancer Institute before finalizing the regulation.

CONCLUSION

Health standards development has been delayed by the lack of policies and guidelines to help NIOSH and OSHA personnel develop and review evidence and decide whether a substance should be regulated as a carcinogen.

Because NIOSH's recommended standards must be accepted by OSHA, their policy and criteria for classifying substances as carcinogens should be essentially the same. It should be at least as stringent as those used in previous decisions upheld by the Federal court. Also, the policy and criteria should be coordinated with the National Cancer Institute.

OSHA's announced intent to issue a regulation describing the criteria for determining whether and how to identify and regulate substances as carcinogens is in line with our views on what needs to be done. Because OSHA plans to follow the rulemaking process, it will take at least 6 months to establish the criteria. Considering the importance of this matter, OSHA and NIOSH should immediately apply the criteria.

RECOMMENDATIONS TO THE SECRETARIES OF LABOR AND HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretaries direct NIOSH and OSHA to establish and use, in consultation with the National Cancer Institute, a common policy and guidelines for developing and and reviewing evidence and deciding whether a substance should be regulated as a carcinogen. We recommend that the policy and guidelines be at least as stringent, in terms of protecting workers, as those applied to substances in the past and upheld by Federal court.

HEW COMMENTS AND OUR EVALUATION

HEW said that our recommendation was not consistent with the following statement in our June 16, 1976, report (see p. 52):

"The Director of the National Cancer Institute is responsible for directing Federal efforts and should, with the cooperation of other involved Federal agencies, develop a uniform Federal policy for identifying and regulating cancer-causing chemicals."

Our recommendations are not inconsistent. Our June 1976 recommendation recognized the need for close cooperation among affected Federal agencies. If a uniform policy were established as recommended, each Federal agency would still need to adopt a policy consistent with the overall policy and establish guidelines for its implementation. Further, the absence of an overall Federal policy does not relieve Federal agencies of their responsibilities to establish policies for their programs.

CHAPTER 7

LIMITED TEAMWORK HAMPERS STANDARDS DEVELOPMENT

Chapters 3, 5, and 6 discuss the need for NIOSH and OSHA to work together to establish common programs, policies, and criteria for setting priorities for standards, issuing emergency temporary standards, using available evidence to promptly establish standards, and deciding whether a substance should be regulated as a carcinogen.

The two agencies also need to improve coordination and cooperation on a project-by-project basis by (1) providing for earlier and closer involvement of OSHA in NIOSH's projects and (2) OSHA placing more reliance on the scientific data compiled, reviewed, and summarized by NIOSH for OSHA consideration in establishing standards.

LIMITED OSHA INVOLVEMENT IN NIOSH PROJECTS

Generally, OSHA does not get involved in NIOSH projects until NIOSH or a contractor 1/ has completed an initial draft of a criteria document; at that time OSHA personnel meet with NIOSH personnel and consultants to review and discuss the draft. A NIOSH official told us that OSHA is always invited to attend two formal reviews of each document, but OSHA does not always attend. A senior OSHA project officer stated that, during such reviews, little emphasis is placed on the recommendations section of the document, and important literature is not made available to the participants. The OSHA project director said also that participants do not get feedback on their contributions to the document.

1/About 75 percent of NIOSH's criteria documents are prepared by contractors. Their work generally includes a worldwide literature search for medical, biological, engineering, chemical, and trade information; they evaluate it and prepare an initial draft of a criteria document. Relevant literature and a draft criteria document are submitted to NIOSH for review and analysis.

HEW told us that most of the emphasis in NIOSH's review sessions is placed on the recommendations in the criteria documents and, since October 1976, copies of critical literature have been made available to participants.

By the time an initial draft is prepared, NIOSH has (1) decided that a standard is necessary and should be given top priority and (2) completed a literature search and compiled and summarized the scientific evidence that NIOSH or the contractor considered necessary to support the standard.

In June 1976 NIOSH contracted for literature reviews and summaries to update 15 criteria documents that had been sent to OSHA at least 2 years earlier. OSHA was not involved in this decision. Seven of the 15 documents under the contract were not being worked on by OSHA because it considered them to be low priority at the time; an OSHA official told us that updated information was needed on several active projects not included in the contract.

According to OSHA project managers, many problems arose after NIOSH sent other completed criteria documents to OSHA. For example:

--After getting the criteria document on benzene, OSHA had problems with (1) NIOSH's position on the leukemia issue, (2) the evidence supporting the recommended exposure limit, and (3) NIOSH's decision not to consider the need for the standard to cover gasoline station employees. (See p. 38.)

--OSHA had problems with whether the criteria document on chloroform adequately addressed the potential of chloroform to cause cancer or fetal malformations. (See p. 39.)

--OSHA officials believed that NIOSH's criteria document on cotton dust did not adequately consider the results of a study in the textile industry.

--An OSHA project officer believed that the criteria document on inorganic lead did not adequately identify the work processes that should be regulated.

--OSHA officials said that NIOSH did not adequately support its assertion that sufficient technology

exists to permit compliance with the recommended standards on hexavalent chromium.

--An OSHA project officer said that NIOSH did not critically analyze a study used as major support for the recommended standard on inorganic mercury; he believed the study was deficient for several reasons.

LIMITED RELIANCE ON NIOSH

To develop criteria and support for a standard, NIOSH, either directly or through a contractor, tries to identify and review all available literature on such matters as (1) the biologic effects of exposure to a substance and the number of workers exposed, (2) the bases for previous voluntary and mandatory standards on the substance, and (3) methods of sampling for the substance. The data considered to be relevant is summarized in the NIOSH criteria document.

In developing health standards, including those preceded by a NIOSH criteria document, OSHA personnel have usually done their own literature searches and reviews to obtain scientific criteria and support.

To help identify relevant literature, NIOSH maintains a computerized data bank containing information from thousands of scientific articles on a great many substances. Although OSHA has a remote terminal for access to NIOSH's data, OSHA maintains its own computerized data bank for such information. OSHA considered this necessary because it believed NIOSH to be about 2 years behind in updating its data.

OSHA officials told us that OSHA does its own literature searches and reviews mainly because (1) OSHA is the agency responsible for setting final standards, (2) OSHA must be in a position to defend its standards at public hearings and any ensuing court proceedings, and (3) the scientific evidence is critical in defending standards.

During discussions with us, OSHA officials criticized the evidence used by NIOSH in many of the completed criteria documents. For the most part, OSHA did not give NIOSH feedback on these problems and independently acted to resolve them.

CONCLUSION

Faster issuance of health standards will require closer coordination between OSHA and NIOSH. In addition to the need to work together to establish common programs, policies, and criteria (as discussed in chapters 3, 5, and 6,) the two agencies need to improve cooperation and coordination on individual standards development projects.

OSHA involvement in NIOSH decisions to start work on given hazards would increase the likelihood that OSHA will promptly act on NIOSH's subsequent recommendations.

Earlier OSHA involvement in NIOSH projects would also enable NIOSH to better consider OSHA's needs when deciding on such matters as the direction and scope of literature searches, the issues to be addressed, the protective measures to be included in the standard, and the evidence to be included in the criteria document to support the standard. This could eliminate or reduce OSHA's problems with NIOSH criteria documents.

Although a major reason for NIOSH's existence is to develop, compile, and analyze scientific data to be used as criteria and support for OSHA standards, OSHA has not placed enough reliance on NIOSH for doing so. This results in time-consuming duplication of much of the NIOSH effort and does not promote a sense of responsibility and commitment in NIOSH to provide sound, defensible criteria. OSHA's independent action to resolve problems with NIOSH's criteria documents relieves NIOSH from its basic responsibility to provide well-supported recommendations and does not give NIOSH a basis for improving future work.

RECOMMENDATIONS TO THE SECRETARIES OF LABOR AND HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretaries direct OSHA and NIOSH to establish and implement an agreement under which:

--OSHA will rely upon NIOSH to provide the scientific information needed to support health standards. This should include NIOSH defending its evidence at public hearings and court proceedings.

--OSHA will not duplicate literature searches and reviews on substances covered by NIOSH literature searches and reviews.

--OSHA will provide its views to NIOSH before NIOSH starts a project to develop recommended new or revised health standards or to update previous recommendations, and OSHA will inform NIOSH when it disagrees on the priority that should be given to the project.

--For each project, NIOSH will obtain OSHA's views on the direction and scope of the literature search, the issues to be addressed, the protective measures to be considered, and the evidence to be sought for support.

--OSHA will participate in NIOSH meetings to review and discuss draft criteria documents.

--OSHA will provide feedback to NIOSH on problems that may arise concerning the validity of, and scientific evidence for, NIOSH's recommended standards and work with NIOSH in resolving such problems.

HEW COMMENTS AND OUR EVALUATION

HEW stated that teamwork is important but, to some extent, NIOSH and OSHA should work independently. HEW stated that NIOSH had attempted to cooperate with OSHA. HEW stated also that OSHA's early involvement with NIOSH in the special standards completion project did not increase the likelihood that OSHA would promptly act on NIOSH's recommendations. We understand HEW's concern but still believe that closer teamwork is one of many improvements that should be made.

CHAPTER 8

INFLATIONARY IMPACT EVALUATIONS

DELAY STANDARDS COMPLETION

The 1970 act does not require an evaluation of a proposed standard's inflationary impact. Such evaluations, however, are required by Executive Order 11821, which became effective November 27, 1974.

The evaluation of inflationary impact pursuant to the Executive order has caused considerable delays in OSHA's completion of health standards.

We did not evaluate the quality of inflationary impact evaluations or identify specific ways for reducing the time required for such evaluations. The long periods of time taken in the past indicate that OSHA may be able to reduce the time for future evaluations. OSHA had not evaluated past cases to determine whether or not the time taken could be reduced.

EXECUTIVE ORDER AND IMPLEMENTING DIRECTIVES

Executive Order 11821 requires that major proposals for legislation and regulations by any executive branch agency be accompanied by a statement which certifies that the inflationary impact of the proposal has been evaluated. The Executive order states that:

--The evaluation must be in accordance with criteria and procedures pursuant to the Executive order.

--The Director of the Office of Management and Budget (OMB) is, to the extent permitted by law, to develop criteria for identifying major legislative proposals, regulations, and rules which may have a significant impact on inflation and to prescribe procedures for their evaluation.

--In developing criteria for identifying legislative proposals, regulations, and rules subject to the Executive order, the Director of OMB must consider, among other things, the following categories of significant impact:

(a) cost impact on consumers, businesses, markets, or Federal, State, or local government;

(b) effect on productivity of wage earners, businesses, or governments at any level; (c) effect on competition; and (d) effect on supplies of important products or services.

--Each Federal department and agency must, to the extent permitted by law, cooperate with the Director of OMB and furnish him with such information as he may request, and comply with the procedures pursuant to the Executive order.

OMB issued Circular No. A-107 on January 28, 1975, which states that agency heads are responsible for developing criteria for determining which proposed legislation, regulations, or rules are major and therefore require evaluation and certification. In addition to effects on costs, productivity, competition, and important product and service supplies as specified in the Executive order, the Circular states that agencies' criteria are to consider effects on employment and on energy supply and demand. The Circular states also that each agency shall develop procedures for evaluating proposals, including where applicable:

--An analysis of the principal cost or other inflationary effects of the action and, where practical, an analysis of secondary cost and price effects. These analyses should have as much quantitative precision as necessary and should focus on a time period sufficient to determine economic and inflationary impacts.

--A comparison of the benefits to be derived from the proposed action with the estimated costs and inflationary impacts, quantified to the extent practicable.

--A review of alternatives to the proposed actions that were considered, their probable costs, benefits, risks, and inflationary impacts compared with those of the proposed action.

The OMB Circular states that agencies should use existing resources and personnel in complying with the requirements.

The Secretary of Labor issued an order November 15, 1975, setting forth the criteria for identifying "major" proposed legislation, rules, or regulations requiring inflationary impact analysis and certification. The criteria, which apply to each new proposed OSHA standard, 1/ provide that an inflationary impact statement must be prepared if any of the following economic effects will prevail:

--An expected net increase in costs to consumers, businesses, or Federal, State, or local governments exceeding, on a national basis, $100 million for any year or $180 million in a 2-year period or, for any one industry or level of government, $50 million for any year or $75 million in a 2-year period.

--Negative effects on productivity that may arise through (1) reducing or restricting industry capacity or capital investment, (2) increasing labor staff-hours per unit of output, (3) increasing barriers to substitution of processed or raw material supplies, and (4) reducing or restricting adaptation of new technologies, equipment processes, or skills.

--An expected increase, in any 1 year, in demand for or decrease in supply of petroleum or other forms of energy of 25,000 barrels per day or its equivalent.

--An expected decrease of 3 percent or more in the total national supply of critical materials.

--An expected decrease of more than 0.2 percent in the national demand for labor, or 10,000 workers at the industry, State, or local government level.

--A substantial limitation on market entry, a substantial increase in market concentration, or an increase in the potential for a monopoly in a line of commerce. (This applies only to markets where commerce exceeds $100 million a year.)

1/Inflationary impact statements by order of the Secretary of Labor are not required for emergency temporary standards, but are required for the permanent standard that follows the emergency standard.

An OSHA headquarters official told us that elaborate studies are required to support inflationary impact statements or certifications that such statements are not required. All inflationary impact evaluations completed or in process as of September 30, 1976, were contracted out.

TIME TAKEN TO COMPLETE EVALUATIONS

As of September 30, 1976, OSHA had completed four inflationary impact statements or certifications that impact had been evaluated for proposed health standards. At that time, 19 other impact evaluations were in process on health standards being developed. (These do not include evaluations related to proposed standards under the "standards completion project." (See p. 65.) The time spent on the evaluations is shown below.

	Months to complete
Completed evaluations:	
Coke-oven emissions	9
Cotton dust	10
Inorganic arsenic	17
Noise	11

	Months in process as of September 30, 1976
Evaluations in process:	
Abrasive blasting	6
Ammonia	10
Asbestos	10
Benzene	11
Beryllium	10
Carbon monoxide	15
Hexavalent chromium	7
Inorganic lead	10
Inorganic mercury	10
Laboratory provisions for 13 carcinogens	2
Methyl chloroform	5
MOCA	6
Noise and cotton dust (combined impact)	7
Perchloroethylene	5
Sulphur dioxide	10
Sulphuric acid	10
Toluene	10
Toluene diisocyanate/ Methylene di-(4-phenylisocyanate)	10
Trichloroethylene	10

Evaluations of inflationary impact are the principal reason OSHA has not issued any final standards under the standards completion program. As discussed on page 12, OSHA had NIOSH's recommendations for 132 revised standards from 7 months to more than 18 months as of September 30, 1976. By that time OSHA had completed inflationary impact evaluations for six of the recommended standards. The evaluations took 10 months to complete. Evaluations had been in process for 11 other recommended standards for 10 months.

Evaluations had not been started for any of the remaining recommended standards in the standards completion program, partly because OSHA believed that some of the substances did not warrant standards. OSHA had not identified the substances that did not warrant standards.

An OSHA headquarters official told us that OSHA did not have formal criteria for determining when an inflationary impact evaluation is acceptable. He said that the review process accounts for about one-third of the time taken to complete evaluations.

CONCLUSION

Inflationary impact evaluations are delaying OSHA's completion of health standards. It may be possible to reduce the time taken for such evaluations. OSHA has not studied past cases to see whether future evaluations can be done more quickly. Also, OSHA's indecision about which of the substances in the standards completion program do or do not warrant standards could delay evaluations for many of the substances.

RECOMMENDATIONS TO THE SECRETARY OF LABOR

We recommend that the Secretary direct OSHA to:

--Review and formally report to the Secretary on why inflationary impact evaluations have taken so long and whether steps can be taken to complete such evaluations in less time.

--Decide which substances in the standards completion program do not warrant standards and expedite the completion of any required inflationary impact evaluations on the remaining substances.

CHAPTER 9

NIOSH PLANS TO DIRECT MORE RESEARCH TO SPECIFIC NEEDS FOR STANDARDS

During its first 5 years under the 1970 act, NIOSH did not insure that its laboratory and field research was, to the extent practicable, directed to developing data needed for recommending standards.

NIOSH headquarters officials recognize this problem and plan to improve control of the program to see that research efforts are needed and will be used for recommending standards to OSHA.

USE OF PAST RESEARCH RESULTS

During fiscal years 1972 through 1975, NIOSH funded about 260 research projects at an estimated cost of $43 million. These projects, many of which were in process for several years, resulted in a variety of technical reports and journal articles. According to NIOSH officials, such reports and articles either have been used in criteria documents, will be used in future criteria documents, or were not intended for use in criteria documents.

We selected a number of projects and asked NIOSH research officials in Cincinnati how the results were used. These officials did not have records to readily show the use made of their research results. Although maintaining that a substantial portion of completed research has been or will be used in criteria documents, NIOSH headquarters officials did not have records to readily show the use made of past research results.

As an indication that research could be directed more to specific needs for criteria documents, NIOSH and OSHA officials identified specific needs for research on many substances after NIOSH had completed criteria documents. For example:

--After NIOSH completed the criteria document on benzene, OSHA and NIOSH recognized the need to obtain or develop information on whether gasoline-station employees should be covered by the recommended standard. (See p. 38.) Also, the criteria document

stated that, because of the shortage of exposure-effect data, there was a great need for detailed, comprehensive epidemiological studies of benzene.

--The NIOSH criteria document on chloroform stated that more studies were needed to find out whether chloroform causes cancer. (See p. 39.)

--After NIOSH completed the criteria document on coke-oven emissions, a NIOSH headquarters official told us that important additional research was needed, including research on cancer and non-malignant respiratory disease.

Individual NIOSH researchers have initiated projects of their own choosing, without having to relate the projects to specific research needed for criteria documents. In some cases, NIOSH researchers began work on a substance before NIOSH decided that it would develop a criteria document on the substance and before a thorough literature search was completed.

NIOSH documents usually cover eight technical areas, which may require work in five different NIOSH research branches. Some NIOSH researchers started projects to develop information in one technical area without assuring that information needed for the other areas was already available or would be developed simultaneously by other researchers.

We also noted significant differences between research projects and NIOSH's priority list of toxic substances. We reviewed 36 projects that were related to 67 substances. The NIOSH priority list in effect at the time contained 471 substances ranked in priority order. Only 4 of the 67 substances were in the top 10 on the priority list, 19 were ranked 100th or lower on the list, and 20 substances were not on the priority list.

Chapter 3 discusses NIOSH's priority list. The differences discussed above indicate that in addition to improving its priority system, NIOSH should see that priorities are followed.

NIOSH RECOGNIZES NEED TO IMPROVE RESEARCH DIRECTION

We discussed with NIOSH officials the feasibility of requiring researchers to propose projects on a substance

only after NIOSH has decided to develop or update a criteria document on the substance, made a thorough search of existing literature, and decided that additional research is needed to support or later update the criteria document. NIOSH headquarters officials said that they generally agreed with this approach and would implement changes along these lines.

Beginning in fiscal year 1977, NIOSH plans to do complete literature searches on all substances on which it plans to issue criteria documents in fiscal year 1978 and later. According to a NIOSH headquarters official, research projects will then be based on the need for specific information not available in the existing literature on substances for which criteria documents are to be developed.

In December 1976, a NIOSH headquarters official told us that literature searches had been done for criteria documents to be developed in fiscal year 1978. He said that specific research needs were identified by those literature searches and that research projects would be programed to fill those needs. He could not, however, provide us with a listing of the criteria documents, the identified research needs, or the research projects that were to be initiated to fill those needs. HEW told us that at least six fiscal year 1977 research projects were related to criteria documents planned for fiscal year 1978 and at least 12 fiscal year 1977 projects were related to criteria documents planned for fiscal year 1979.

CONCLUSION

The actions proposed by NIOSH should, if implemented, provide better assurance that research efforts are

--to the extent practicable, directed at developing data needed for recommending and supporting standards for OSHA,

--in line with NIOSH priorities, and

--coordinated among the various research branches.

High-level attention is needed to insure that those planned actions are implemented on a short- and long-term basis. Records of research results and the use made of such results would be useful toward this end.

RECOMMENDATIONS TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretary of HEW see that NIOSH implements its plan to improve control of its research efforts by requiring NIOSH to take the following steps before starting research projects.

--Identify those substances or hazards on which NIOSH has decided to develop or update criteria and recommendations for standards, and state whether they are in line with NIOSH priorities.

--Conduct complete literature searches on those substances to identify specific needs for research.

--Require that each research project be directed at filling a specific need identified by such literature searches, or an explanation be made as to what other specific need the project will fill.

--Require that research needed in two or more NIOSH research branches be coordinated so that, to the extent practicable, all such research can be done simultaneously.

We recommend also that the Secretary of HEW require NIOSH to maintain records to readily show the results of research and the use made of such results.

HEW COMMENTS

HEW said that there had been some problems in changing the orientation of the Bureau of Occupational Safety and Health to NIOSH's responsibility for developing recommended standards under the 1970 act. HEW said that significant improvements had been made over the last 18 months.

HEW said that NIOSH, through its project planning system, has always required that each research project either be directed to fill a specific need identified by a literature search or an explanation be made as to what other specific need a project is to fill. A NIOSH headquarters official told us that although NIOSH had such requirements in the past, specific research needs often were not adequately identified because literature searches and project planning were left largely to individual researchers. He said that

under NIOSH's new system, headquarters officials would help identify research needs by conducting literature searches and require that research projects fill those needs.

HEW said that the need for coordinating research among the various NIOSH branches is presently being addressed by a NIOSH coordinating committee.

HEW also pointed out that some NIOSH research was important even though it may not be directly related to future recommendations for standards. As examples, it cited research directed at developing improved ventilation systems and better information and education methods.

CHAPTER 10

NEED TO JOINTLY ASSESS PROGRESS AND CONSIDER ALTERNATIVES FOR PROTECTING WORKERS

As discussed in the preceding chapters, OSHA and NIOSH should take several actions to speed up the issuance of health standards. Such actions, however, may not be adequate to provide prompt protection against many of the toxic substances.

OSHA and NIOSH have not made a thorough assessment of the total needs for health standards, how long it will take to produce them with current funding levels, and whether increased funds could be used effectively to increase their production. We believe that an assessment is needed to enable the agencies and the Congress to adequately consider such alternatives as increasing funds for health standards development and/or putting more emphasis on informing and educating employers and workers about toxic substances.

FUNDS FOR STANDARDS DEVELOPMENT

NIOSH officials have stated that, at current funding and personnel levels, NIOSH can produce no more than 26 criteria documents a year. A Labor official said that OSHA can issue no more than 12 to 18 standards a year. If OSHA could issue 26 standards a year, it could still take well over 100 years to cover existing toxic chemicals. Further, it is possible that new substances warranting standards are being introduced faster than standards can be completed.

As shown on page 5, OSHA allocated about $32 million to standards development during fiscal years 1972 through 1977. This represents only about 6 percent of OSHA's total funds for that period. A substantial portion of the funds allocated to standards development was devoted to safety standards. The bulk of the funds for activities other than standards development has gone for compliance and enforcement activities. About 90 percent of the compliance and enforcement effort has been concerned with safety hazards.

Although NIOSH's funding levels seem low in view of the magnitude and importance of its mission, NIOSH has not determined the extent that more funds could be effectively used to increase standards development. Also, increases in NIOSH's rate of production would make little sense unless OSHA could issue standards at a comparable rate.

FUNDING FOR INFORMATION AND EDUCATION ACTIVITIES

Section 21 of the act requires that the Secretary of Labor (1) provide for establishing and supervising programs for educating and training employers and workers in the recognition, avoidance, and prevention of unsafe or unhealthy working conditions and (2) consult with and advise employers, workers, and their representatives on effective means of preventing occupational injuries and illnesses.

During fiscal year 1976 OSHA spent about $3.6 million on education and training, which represented only about 3 percent of the total OSHA funds for that year. We could not readily ascertain how much of the funds were used to inform and educate employers and workers on toxic substances.

Section 21 of the act requires that NIOSH conduct (1) education programs to provide an adequate supply of qualified personnel to carry out the purposes of the act and (2) informational programs on the importance and proper use of adequate safety and health equipment. Section 20 requires that NIOSH, upon written requests by any employers or authorized representatives of employees, evaluate toxic substance hazards at workplaces and report the findings to the employers and employees as soon as possible.

During fiscal year 1976, NIOSH spent about $7 million on information and education activities and hazard evaluations. This represented about 17 percent of total NIOSH funds for that year.

CONCLUSION

Although several steps can and should be taken to speed up the issuance of health standards, such actions by themselves may not be enough to promptly provide needed protection against hundreds of toxic substances.

In view of the situation, OSHA and NIOSH should jointly make a thorough evaluation of whether and to what extent additional funds could be effectively used to speed up health standards completion and increase information, education, and training activities related to toxic substances. If additional funds can be used effectively for these activities, consideration should be given to allocating a greater portion of the agencies' budgets for this purpose.

RECOMMENDATIONS TO THE SECRETARIES OF LABOR AND HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretaries direct OSHA and NIOSH to:

--Estimate, based on the best available data, the total needs for health standards and how long it will take to develop them within existing funding levels.

--Determine whether and to what extent additional funds can be used effectively to speed up standards development and increase efforts to inform, educate, and train employers and employees on toxic substances.

We recommend that, if additional funds can be used effectively, the Secretary of Labor direct OSHA to allocate a greater portion of its funds to health standards development and health information, education, and training activities.

We recommend that the Secretary of Health, Education, and Welfare direct that NIOSH decisions on how much of its effort should go towards standards development, as opposed to its other worker protection activities, be based in part on OSHA's ability to promptly act on NIOSH's recommended standards.

HEW COMMENTS AND OUR EVALUATION

HEW said that NIOSH had made studies of whether increased staff and funds could be used effectively and had received increased resources to speed up the standards development process. In support of this statement, NIOSH officials gave us a copy of a 1972 internal memorandum stating that (1) it was difficult to obtain consensus regarding the number of criteria documents that NIOSH should produce annually and (2) the Department of Labor would agree that NIOSH should produce 40 to 60 criteria documents a year. A NIOSH official said that, to his knowledge, there was no supporting data or analysis in NIOSH files for this estimate.

HEW stated also that NIOSH has recognized the size of the standards development job and has taken steps to finish the job somewhat quicker than we projected. HEW said that, by 1981, NIOSH will have recommended standards to OSHA for some 5,000 substances, including 1,800 pesticides and more than 3,000 other substances. NIOSH officials said that more than 4,800 substances and physical agents would be covered in 96 criteria documents, of which 24 would deal with single chemical compounds and 72 would deal with groups of compounds,

physical hazards, and processes or industries. HEW said that many of the substances that are introduced each year will be covered by an existing standard or criteria document because many of the planned criteria documents will cover large classes of chemical compounds and industrial processes. HEW believed that we should also acknowledge the beneficial impact of the Toxic Substances Control Act (Public Law 94-469, October 11, 1976) on this problem.

Our projection was based on the past rate of issuance of standards by OSHA and not on NIOSH's completion of recommended standards. NIOSH's future rate of progress will mean little unless OSHA develops the capability to issue standards at a comparable rate.

NIOSH officials told us that as a result of the Toxic Substances Control Act, new information will become available for use in standards development and the number of hazardous chemicals introduced each year will be reduced.

APPENDIX I

U.S. DEPARTMENT OF LABOR
OFFICE OF THE ASSISTANT SECRETARY
WASHINGTON

APR 12 1977

Mr. Gregory J. Ahart
Director
Human Resources Division
U. S. General Accounting Office
Washington, D. C. 20548

Dear Mr. Ahart:

Thank you for providing us with the opportunity to comment on the draft report entitled, "Delays in Setting Workplace Standards for Cancer-causing and Other Dangerous Substances."

We are refraining from presenting you with a response to this draft report for the following reasons:

-- Appointment of a new Assistant Secretary for Occupational Safety and Health, who has not had an opportunity to give the report the degree of attention it merits.

-- Serious issues which must be considered in fashioning strategy for dealing with workplace health problems.

When the final report is issued, we will address the recommendations contained in the report.

Sincerely,

FRED G. CLARK
Assistant Secretary for
Administration and Management

APPENDIX II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

APR 12 1977

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Delays in Setting Workplace Standards for Cancer-Causing and Other Dangerous Substances." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Thomas D. Morris
Inspector General

Enclosure

GAO note: The enclosure referred to in this letter included GAO's draft report digest as revised by HEW to reflect its view. This digest was omitted because of its length and the fact that GAO's final report digest was revised.

Backup to "Digest" Revisions

1. NIOSH has responsibilities other than only research and the provision of recommended standards to DOL.

2. Sentence is potentially misleading in that HEW neither sets nor enforces standards under the Occupational Safety and Health Act. Also, with all the criteria documents issued to date and the recommendations contained in the Standards Completion Program, NIOSH has developed recommendations for more than one thousand chemicals.

3. Not all the 387 are single substances; some are groups of substances. Therefore there are many more than 387 single chemicals involved.

4. The 22 months figure represents the average time required to complete a criteria document using the entire five year period. This "average" is very misleading in that it does not show the significant progress that has been made in reducing the amount of time NIOSH takes to complete a criteria document.

   The following table graphically shows improvement in document completion rate.

Calendar Year	Document Completion (excludes revisions)
72	5
73	7
74	9
75	7
76	29

The backlog of older documents has been reduced. Currently 28 documents are in some phase of development. Only 4 of these were started prior to January, 1976. The current criteria documentation contract called for completion of 13 documents during 1976. All were completed by the end of the year. Average Development time, including literature searches was 14½ months.

NIOSH is currently preparing documents by contract under a 37-week schedule, preceded by a 14-week period for literature searches. In-house documents are prepared under

a 42-week schedule preceded by a 26-week literature search-review period.

5. There is no single cutoff date used consistently in the report. As such, the rewording has been proposed to indicate the actual situation. If there is to be a cutoff date, it should be consistent. [See GAO note below.]

6. The GAO statement of the priorities problem completely overlooks the significant, positive efforts made by NIOSH to obtain reliable priority setting data. It should be noted that in addition to its other efforts in this area, NIOSH has encouraged the advice, suggestions, and recommendations from all persons involved or interested in occupational safety and health. Requests for information on proposed priorities have been published in the Federal Register (January 5, 1976; April 27, 1976; and December 23, 1976) as well as providing copies of the announcements to other interested persons, organizations and agencies.

   Additionally, it needs to be pointed out that OSHA has many times been asked by NIOSH to assist in the development of priorities (memorandum from NIOSH to OSHA on July 23, 1972; February 15, 1973; March 21, 1973; August 20, 1975; September 11, 1975; September 17, 1975). NIOSH has had little or no response or recommendations from OSHA.

7. Since its creation, NIOSH has had an operational progress reporting system for projects, including criteria document projects. That project progress reporting system was supplemented in FY73 with a "program progress" reporting system. These program progress reports also contained information on criteria document status and any problems encountered. These systems have been improved each year to the point where they are now felt to be highly effective in both the monitoring of progress and lack thereof and the provision of a stimulus for greater effort.

   Four "critical" milestones are identified for each document. They are: document preparation begun, completion of first draft, completion of final draft, and transmission to DOL. Quarterly progress reports are prepared that show completed milestones and a rescheduling of uncompleted milestones with a reason for delay. In addition a more detailed tracking system is maintained that identifies more than 40 events, with dates, in the development of each document. This system is a working tool to help assure that the four

GAO note: The rewording referred to in this comment was to recognize that NIOSH, as of January 1977, had sent OSHA its recommendations for all 387 substances or groups of substances in the standards completion project.

APPENDIX II

"critical" milestones are met and to distribute information to NIOSH staff that are involved in various reviews or meetings. It is updated monthly.

In order to assure better historical records of criteria documents, a special file for each criteria document will be developed for the retention of key information.

8. First of all, GAO in its June 16, 1976, report to Congress entitled, "Federal Efforts to Protect the Public from Cancer-Causing Chemicals are not Very Effective," stated,

> "The Director of the National Cancer Institute is responsible for directing Federal efforts and should, with the cooperation of other involved Federal agencies, develop a uniform policy for identifying and regulating cancer-causing chemicals."

GAO should be consistent in its recommendations.

Beyond this point, NIOSH believes the present GAO statement to be misleading. From the very beginning of the criteria document effort, NIOSH has attempted to collect and evaluate all data relevant to establishing a recommended occupational standard for any substance. Of primary importance has been any data relating to carcinogenicity. Although earlier criteria documents did not contain a separate and highly visible subsection of Chapter III in which the data pertaining to carcinogenicity was sumarized, as they now do, all available carcinogenicity data was evaluated and, when deemed relevant, included in the document. The decision as to whether or not to classify any particular substance as a carcinogen was made under conditions prevailing at that time but was, in all cases, based on a thorough evaluation of available data, including that relating to the development of cancer in experimental animals and humans. As in the case of a great many things, conditions change. In the present context, the data base often changed in that new data were published following completion of the criteria document. In addition, scientific opinion regarding the merit of certain experimental techniques and the usefullness of case histories changed.

In essence, although NIOSH may presently place greater emphasis on certain types of studies (e.g., case histories) than previously, it has never been NIOSH policy to do other than gather and fully evaluate all data ralating to carcinogenicity during the development of criteria

documents. Due to the constantly expanding data base and the need to periodically review and update NIOSH recommendations, several criteria documents have been revised in the area of cancer. Benzene, beryllium, and chloroform, though not originally labeled as suspect human carcinogens by NIOSH are presently considered to have human carcinogenic potential. In all three of these documents, data relating to carcinogenicity was presented; however, the data was considered inconclusive and not sufficient for labeling these compounds as suspect human carcinogens. The reassessment of all toxicological data, initiated by the publication of new data pertaining to cancer, resulted in the NIOSH decision to revise the recommended standards and label them as suspect human carcinogens.

9. The report only involves standards development and as such should restrict the lack of team work statement to the health standards development area. NIOSH and OSHA have worked and continue to work cooperatively and effectively in a number of areas, including maintenance and calibration of industrial hygiene equipment, analytical services, safety research, etc.

   The proposed NIOSH rewording to the GAO statement also attempts to indicate that to some extent NIOSH and OSHA need to work independently. NIOSH must perform objective research which depends upon cooperation with management and labor. OSHA must promulgate and enforce the standards and is almost always in an adversarial position.

10. There has been some problem in changing the orientation of the Bureau of Occupational Safety and Health (NIOSH's predecessor organization) to the orientation required for NIOSH to meet its standards recommendations responsibilities under the Act. The GAO statement should acknowledge that there has been significant improvement in this area. In planning its FY77 program, NIOSH decided how much of its research program should be directed at filling gaps in previously issued standards recommendations, at filling gaps in future specific standards recommendations, at providing information generally useful to future standards recommendations, and at providing useful needed occupational safety and health information not directly related to standards development. Each FY77 research project was put into one of those four categories, and the research budget was allocated with the NIOSH targets for those areas in mind.

The GAO report fails to recognize the need for research not directly related to providing data for recommending standards to DOL. Research directed at developing improved ventillation systems, better methods of provision of occupational safety and health information to those that need it, etc. are important parts of the NIOSH research program even though they may not relate directly to future standards recommendations.

[See GAO note on p. 94.]

11. It should be noted that NIOSH has recognized the size of the standards development job and has taken steps to finish the task somewhat quicker than the decades GAO projects. By 1981, if OSHA acts on all NIOSH criteria documents, standards will be in effect for some 5,000 substances (1,800 pesticides plus 3,000+ other substances). Many of the substances that are introduced each year will be covered by an existing standard or criteria document because many of

the criteria documents planned cover large classes of compounds. GAO should also acknowledge the beneficial impact of the Toxic Substances Control Act on this problem.

Also, NIOSH has initiated efforts to develop recommended standards for processes, which may involve a number of chemicals. NIOSH's control technology program will also have a major impact on the occupational health problem existing today. Control of exposure to one substance in the workplace often means that exposure to other substances is also controlled.

12. Any such estimate would have to be based on what we know today. It must be recognized that new occupational safety and health problems will be emerging over the years. Also, it is naive to talk in terms of completing research. With new information, there will always be research to pursue in the field of occupational safety and health.

13. This recommendation needs clarification. If the Standards Completion Program is meant, then this recommendation should only be addressed to the Secretary of Labor.

[See GAO note on p. 94.]

Part 2

Chapter by Chapter Comments

Chapter 1 - Introduction

Mention should be made of the NIOSH testing and certification program for industrial hygiene and personal protective equipment.

In the section on NIOSH, it is stated that NIOSH cannot set standards. The statement should indicate that NIOSH cannot set standards under the Occupational Safety and Health Act. NIOSH does have some standard setting authority under the Federal Coal Mine Health and Safety Act.

[See GAO note on p. 94.]

The NIOSH budget table should be made consistent in format to the OSHA budget table.

[See GAO note on p. 94.]

Chapter 2 - Faster Standards Development Needed to Protect Workers

It is stated at the beginning of this chapter that standards have been established for only 15 substances since the act was passed. It is then stated, "Thus, the bleak occupational health conditions which the Congress sought to improve still exist, and may be getting worse." This conclusion cannot necessarily be drawn from that one fact. Both OSHA and NIOSH have other programs that have helped ameliorate occupational health problems. The NIOSH technical assistance and manpower development programs should be mentioned in this regard.

The report then goes on to say, "If the Congress' occupational health objective is to be reached in the foreseeable future by establishing and enforcing standards, OSHA and NIOSH must significantly increase their development of standards." The facts in the chapter do not support including NIOSH in this statement.

It is implied in the introduction to the chapter that OSHA and NIOSH are unaware of the magnitude of the standards development task and it is stated that they have made no study of whether increased manpower and funds could be used effectively to increase their production. Recognizing the need for quicker worker protection, NIOSH and OSHA initiated the Standards Completion Program to supplement the environmental limits of the approximately 400 "start-up" OSHA health standards. Additionally, NIOSH has begun developing recommendations for standards for industrial processes which should expedite the protection of American workers from exposure to hazardous substances

and agents. Regarding increased manpower and funds, NIOSH has made these studies and has received increased resources to speed up the standards development process.

The report makes mention of some of the health horrors of asbestos, coke ovens, and arsenic. It should be pointed out in the report that criteria documents have been developed for all three.

[See GAO note on p. 94.]

In the section on criteria documents, it is stated that it took NIOSH an average of 22 months to complete a criteria document. The 22 months figure represents the average time required to complete a criteria document using the entire five year period. This "average" is very misleading in that it does not show the significant progress that has been made in reducing the amount of time NIOSH takes to complete a criteria document.

The following table graphically shows improvement in document completion rate:

Calendar Year	Document Completion (excludes revisions)
72	5
73	7
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76	29

The backlog of older documents has been reduced. Currently 28 documents are in some phase of development. Only 4 of these were started prior to January, 1976. The current criteria documentation contract called for completion of 13 documents during 1976. All were completed by the end of the year. Average development time, including literature searches was 14½ months.

NIOSH is currently preparing documents by contract under a 37-week schedule, preceded by a 14-week period for literature searches. In-house documents are prepared under a 42-week schedule preceded by a 26-week literature search-review period.

[See GAO note on p. 94.]

[See GAO note on p. 94.]

The report states that reliable data were not available on the number of employees exposed to the substances covered by the criteria documents. It should be mentioned that the NIOSH National Occupational Hazard Survey data is now available and that data can provide better estimates of the numbers of workers exposed to a multitude of substances.

In discussing the hazardous nature of the substances addressed in the Standards Completion Program, the report states that NIOSH officials consider them to be "serious hazards." As that phrase has a specific meaning to OSHA, it would be more proper to state that NIOSH has sufficient concern for the hazardous nature of the substances to warrant development of a complete occupational health standard as defined in the Act.

NIOSH takes exception with the conclusions section of the chapter. The facts presented in the chapter do not support the conclusions drawn for NIOSH. Separate conclusions should be written for OSHA and NIOSH.

Chapter 3 - Need for Joint Effort to Obtain Data and Set Priorities

The report describes the NIOSH National Occupational Hazard Survey and some of the problems with the data. It should be mentioned that there are no other similar data available and that it does represent about half the workforce. It certainly is useful data.

The report's statement of the priorities problem completely overlooks the significant, positive efforts made by NIOSH to obtain reliable priority setting data. In addition to National Occupational Hazard Survey data, NIOSH has used data from its Registry of Toxic Effects of Chemical Substances (and associated subfiles) as well as collaborated and exchanged information with the World Health Organization. NIOSH also encourages the advice, suggestions, and recommendations from all persons involved or interested in occupational safety and health. Requests for information on proposed priorities have been published in the Federal Register (January 5, 1976; April 27, 1976; and December 23, 1976) as well as providing copies of the announcements to other interested persons, organizations and agencies.

The NIOSH priority setting system considers the following criteria:

1. there is no present OSHA standard,
2. it is listed as a suspected carcinogen, mutagen or teratogen
3. a new or reduced environmental limit has been recommended by a professional society,

4. the number of workers exposed, and
5. the severity rating.

This should be stated in the report.

Additionally, it needs to be pointed out that OSHA has many times been asked by NIOSH to assist in the development of priorities (memorandum from NIOSH to OSHA on July 23, 1972; February 15, 1973; March 21, 1973; August 20, 1975; September 11, 1975). NIOSH has had little or no response or recommendations from OSHA.

[See GAO note on p. 94.]

The report states that OSHA "shelved" the NIOSH criteria document on hot environments because they felt it to be of low priority. The document was returned to NIOSH because OSHA felt it to not be complete. Within two weeks NIOSH sent the document back to OSHA and the accompanying letter urged "the promulgation of a heat stress standard without further delay." The letter went on to further state that there seldom is enough research information to completely satisfy everyone in the development of standards but that there was then more than enough information on which a work practices type of heat stress standard could be set.

In the discussion of process and industry standards, it should be added that NIOSH also addresses groups of substances. The criteria document on the coal gasification industry is listed in that section. Other industry and process criteria documents being developed include the cement industry, foundries, printing, slaughtering and rendering, welding, and roofing. The report states that OSHA did not participate in NIOSH's decision to recommend industry or industrial process standards or in the selection of industries or processes to be addressed. It should be stated that NIOSH did invite OSHA to comment on these decisions.

In the conclusions section, it is stated "the success of NIOSH's efforts depends directly upon OSHA's acceptance and use of recommended standards." NIOSH's recommended standards have a usefulness in voluntary compliance aside from OSHA's use of them. Also, the conclusions should be made specific to OSHA and NIOSH, taking into account the positive actions taken by NIOSH.

Chapter 4 - Timely Completion of Standards not Emphasized - Poor Records and Loose Accountability

The report states that NIOSH could not provide GAO with the starting dates for work on 46 criteria documents. NIOSH could not provide GAO

with t he exact starting date for these documents, but did provide information on the starting dates for contracts and other information on which an estimated starting date was developed.

The report states that during 1976 NIOSH established a system that provides for setting 42 milestone target dates for each criteria document.

[See GAO note on p. 94.]

The system does require progress reporting and justifications for not meeting planned milestone dates and problems are documented in writing.

This detailed tracking system is in addition to the overall NIOSH progress reporting systems. Since its creation, NIOSH has had an operational progress reporting system for projects, including criteria document projects. That project progress reporting system was supplemented beginning in FY73 with a "program progress" reporting system. These program progress reports also contained information on criteria document status and any problems encountered. These systems have been improved each year to the point where they are now felt to be highly effective in both the monitoring of progress and lack thereof and the provision of a stimulus for greater effort.

Four "critical" milestones are identified for each document. They are: document preparation begun, completion of first draft, completion of final draft, and transmission to DOL. Quarterly progress reports are prepared that show completed milestones and a rescheduling of uncompleted milestones with a reason for delay. The system referred to in the GAO report is a working tool to help assure that the four "critical" milestones are met and to distribute information to staff that are involved in various reviews or meetings.

In addition to the NIOSH tracking of criteria documents, for several years they were tracked by the Secretary of HEW through the Department's Operational Planning System.

[See GAO note on p. 94.]

Chapter 5 - OSHA's Approach to Issuing Standards Ignores Need for Quick Action

In the section dealing with cotton dust, questions are raised as to the adequacy of the NIOSH criteria document. The reason the adequacy of the cotton dust criteria document was questioned by OSHA was principally because there is very little information on parts of the

industry. Nevertheless, there is adequate data to show the need for a standard in all processes where raw cotton is processed. It could be pointed out that despite the delay on the part of OSHA, the recommendations in their standards were nearly identical to those proposed by NIOSH.

Chapter 6 - Policy and Criteria Needed for Identifying Carcinogens

[See GAO note on p. 94.]

This is not correct. From the very beginning of the criteria document effort, NIOSH has attempted to collect and evaluate all data relevant to establishing a recommended occupational standard for any substance. Of primary importance has been any data relating to carcinogenicity. Although earlier criteria documents did not contain a separate and highly visible subsection of Chapter III in which the data pertaining to carcinogenicity was sumarized, as they now do, all available carcinogenicity data was evaluated and, when deemed relevant, included in the document.

With regard to the section on the cadmium criteria document, it needs to be stated that the final recommendation, which concludes that the data on carcinogenicity is inconclusive with regard to human exposure, is that of the Institute and not the "subjective" judgement of one or a few p ersons. In this case as in all others, including nickel and benzene, NIOSH protects the right of individuals to disagree with Institute decisions and policy. The cadmium write up in the GAO report presents the essence of such a scientific disagreement; however, it is important to note that the Institute's position is expressed in the criteria document and is based on a thorough evaluation of all available evidence pertaining to the carcinogenic potential of cadmium. The Institute's decision was that cadmium should not be controlled as a suspect human carcinogen due to the lack of sufficient evidence indicating same. Not everyone agrees with this position.

With regard to the section on inorganic lead, the Institute did not consider lead itself to be a suspect human carcinogen in 1973. Some lead salts such as lead chromate and lead arsenate have been classified as carcinogens by the Institute. Other hexavalent chromium compounds and arsenic itself are demonstrated carcinogens. The data on carcinogenicity of lead itself was evaluated, referenced in the criteria document, and considered during the development of the standard. The Institute found the data to be inconclusive and has not labeled other inorganic lead compounds as a suspect human carcinogen. However, in the present Bunker Hill study NIOSH is attempting to resolve a residual question concerning exposure to other inorganic lead compounds.

In discussion of the benzene criteria document, it is mentioned that only 2 of 25 studies indicating benzene cancer causing ability were referenced in the original NIOSH benzene criteria document. It should be pointed out that these other studies were case reports and not epidemiological studies.

The report concludes that there is a need for a policy on deciding whether a substance should be regulated as a carcinogen and that carcinogenicity be fully addressed at the outset of any efforts to develop criteria on toxic substances. The decision as to whether or not to classify any particular substance as a carcinogen has been made under conditions prevailing at the time, but was, in all cases, based on a thorough evaluation of available data, including that relating to the development of cancer in experimental animals and humans. As in the case of a great many things, conditions change. In the present context, the data base often changed in that new data were published following completion of the criteria document. In addition, scientific opinion regarding the merit of certain experimental techniques and the usefullness of case histories changed.

In essence, although NIOSH may presently place greater emphasis on certain types of studies (e.g., case histories) than previously, it has never been NIOSH policy to do other than gather and fully evaluate all data relating to carcinogenicity during the development of criteria documents. Due to the constantly expanding data base and the need to periodically review and update NIOSH recommendations, several criteria documents have been revised in the area of cancer. Benzene, beryllium, and chloroform, though not originally labeled as suspect human carcinogens by NIOSH are presently considered to have human carcinogenic potential. In all three of these documents, data relating to carcinogenicity was presented; however, the data was considered inconclusive and not sufficient for labeling these compounds as suspect human carcinogens. The reassessment of all toxicological data, initiated by the publication of new data pertaining to cancer, resulted in the NIOSH decision to revise the recommended standards and label them as suspect human carcinogens.

The r eport recommends that OSHA and NIOSH establish and use, in consultation with the National Cancer Institute, a common policy and guidelines for developing and reviewing evidence and deciding whether a substance should be regulated as a carcinogen. This is inconsistent with statements made in the GAO report to Congress of June 16, 1976 entitled, "Federal Efforts to Protect the Public from Cancer-Causing Chemicals are not Very Effective." That report stated,

> "The Director of the National Cancer Institute is responsible for directing Federal efforts and should, with the cooperation of other involved Federal agencies, develop a uniform policy for identifying and regulating cancer-causing chemicals."

Chapter 7 - Limited Teamwork Hampers Standards Completion

"Completion" in the chapter title should be replaced with "development" to avoid confusion with the Standards Completion Program. Also, the term "project" should be replaced with "criteria document" in the discussion to also avoid confusion.

The report states that a senior OSHA project officer stated that during criteria document reviews little emphasis is placed on the recommendations section of the document and that important literature is not made available to the participants. Most of the emphasis in the NIOSH review sessions is placed on the recommendations section of the document. Additionally, since October 1976, copies of critical literature have been made available to participants in the external review process.

Contrary to the tone of the report regarding providing OSHA with assistance once they are sent a criteria document, several years ago NIOSH advised OSHA of its availablility for assistance and to answer questions. To date there has only been one such request. It was involved with the emergency egress criteria document.

The statement attributed to OSHA regarding hexavalent chromium needs clarification.

The report only involves health standards development and as such the lack of teamwork discussion only applies to the health standards development area. NIOSH and OSHA have worked and continue to work cooperatively and effectively in a number of areas, including maintenance and calibration of industrial hygiene equipment, analytical services, safety research, etc. This should be mentioned in the report.

It is recognized that teamwork is important but to some extent, NIOSH and OSHA need to work independently. NIOSH must perform objective research which depends upon cooperation with management and labor. OSHA must promulgate and enforce the standards and is almost always in an adversary position.

The chapter's conclusions do not acknowledge NIOSH attempts to cooperate with OSHA. They also do not recognize the experience of the Standards Completion Program when it states that earlier OSHA involvement in NIOSH decision to start work on given hazards would increase the likelihood that OSHA will promptly act on NIOSH's subsequent recommendations. This is what was done in the Standards Completion Program, but without the predicted GAO outcome.

The recommendation regarding literature searches should be revised. NIOSH should not jointly with OSHA decide on the direction and scope of the literature search for a particular criteria document, but rather after consultation with OSHA, NIOSH should decide. This is in conformance with Section 20(a)(1) of the act.

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Chapter 9 - NIOSH Research Should be Directed More to Specific Needs for Standards

[See GAO note on p. 94.]

The report states that NIOSH permitted individual researchers to initiate projects of their own choosing, without having to relate the projects to specific NIOSH plans for developing criteria documents. While this is kept to a minimum, NIOSH recognizes the need for some independent research in its research program. There has been some problem in changing the orientation of the Bureau of Occupational Safety and Health (NIOSH's predecessor organization) to the orientation required for NIOSH to meet its standards recommendations responsibilities under the act. The report should acknowledge that

there has been significant improvement in this area. In planning its FY77 program, NIOSH decided how much of its research program should be directed at filling gaps in previously issued standards recommendation, at filling gaps in future specific standards recommendations, at providing information generally useful to future standards recommendations, and at providing useful needed occupational safety and health information not directly related to standards development. Each FY77 research project was put into one of those four categories, and the research budget was allocated with the NIOSH targets for those areas in mind.

The report fails to recognize the need for research not directly related to providing data for recommending standards to DOL. Research directed at developing improved ventilation systems, better respiratory protective devices, etc. are important parts of the NIOSH research program even though they may not relate directly to future standards recommendation.

The report states that only one criteria doucment planned for fiscal year 1978 could be tied-in with the research program. That statement fails to recognize the longer lead time required for research but additionally, quick analysis indicates that six FY77 research projects will support FY78 criteria documents and at least 12 of these FY77 projects will support FY79 criteria documents.

The third recommendation states that it be required that each research project be either directed to fill a specific need identified by a literature search, or an explanation be made as to what other specific need the project is to fill. NIOSH has always required that this be done through its project planning system.

The fourth recommendation dealing with coordination of research within NIOSH is also presently being adequately addressed by the NIOSH Program Coordinating Committee for Research.

Chapter 10 - Need to Assess Progress and Consider Alternatives for Protecting Workers

Again in this chapter the issue of making a thorough assessment of the total needs for health standards is raised. This was addressed previously. Additionally, it should be noted that NIOSH has recognized the size of the standards development job and has taken steps to finish the task somewhat quicker than the decades GAO projects. By 1981 if OSHA acts on all NIOSH recommendations, standards will be in effect for some 5,000 substances (1,800 pesticides plus 3,000+ other substances). Many of the substances that are introduced each year will be covered by an existing standard or criteria document because many of the criteria documents planned cover large classes of compounds. GAO should also acknowledge the beneficial impact of the Toxic Substances Control Act on this problem

APPENDIX II

Also, NIOSH has initiated efforts to develop recommended standards for processes, which may involve a number of chemicals. NIOSH's control technology program will also have a major impact on the occupational health problem existing today. Control of exposure to one substance in the workplace often means that exposure to other substances is also controlled.

Any estimate of total needs for health standards would have to be based on what we know today. It must be recognized that new occupational safety and health problems will be emerging over the years.

The second recommendation deals with determining whether and to what extent additional funds can be used effectively to speed up standards completion and increase efforts to inform, educate, and train employers and employees on toxic substances. This recommendation needs clarification. If the Standards Completion Program is meant, then this recommendation should only be addressed to the Secretary of Labor.

[See GAO note below.]

GAO note: Deleted comments refer to material contained in draft report but omitted from final report.

GAO REPORTS DEALING WITH THE SAME OR SIMILAR SUBJECTS

1. Report to the Senate Committee on Labor and Public Welfare: "Slow Progress Likely in Development of Standards for Toxic Substances and Harmful Physical Agents Found in Workplaces," (B-163375, Sept. 28, 1973).

2. Report to various members of the House of Representatives: "Answers to Questions on the Issuance of an Emergency Temporary Standard for Certain Chemicals Considered to be Carcinogens," (B-179768, Jan. 6, 1975).

3. Report to the Congress: "Federal Efforts to Protect the Public from Cancer-Causing Chemicals Are Not Very Effective," (MWD-76-59, June 16, 1976).

4. Report to the Congress: "Better Data on Severity and Causes of Worker Safety and Health Problems Should Be Obtained from Workplaces," (HRD-76-188, Aug. 12, 1976).

PRINCIPAL OFFICIALS RESPONSIBLE FOR ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
DEPARTMENT OF LABOR		
SECRETARY OF LABOR:		
F. Ray Marshall	Jan. 1977	Present
W. J. Usery, Jr.	Feb. 1976	Jan. 1977
John T. Dunlop	Mar. 1975	Jan. 1976
Peter J. Brennan	Feb. 1973	Mar. 1975
James D. Hodgson	July 1970	Feb. 1973
ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH:		
Eula Bingham	Mar. 1977	Present
Vacant	Jan. 1977	Mar. 1977
Morton Corn	Dec. 1975	Jan. 1977
Vacant	July 1975	Dec. 1975
John H. Stender	Apr. 1973	July 1975
Vacant	Jan. 1973	Apr. 1973
George C. Guenther	Apr. 1971	Jan. 1973
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE		
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:		
Joseph A. Califano, Jr.	Jan. 1977	Present
F. David Mathews	Aug. 1975	Jan. 1977
Casper P. Weinberger	Feb. 1973	July 1975
Elliot L. Richardson	June 1970	Jan. 1973
DIRECTOR OF CENTER FOR DISEASE CONTROL:		
David J. Sencer, M.D.	Feb. 1966	Present
DIRECTOR OF NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH:		
John F. Finklea, M.D.	Apr. 1975	Present
Edward J. Baier (acting)	Sept. 1974	Apr. 1975
Marcus Key, M.D.	June 1971	Aug. 1974

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