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REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

The Consumer Product Safety Commission Needs To Issue Safety Standards Faster

The Consumer Product Safety Commission develops and issues safety standards to protect consumers from hazardous products. However, as of June 30, 1977, and since it began in May 1973, the Commission had issued only three safety standards under the Consumer Product Safety Act.

The Commission has not promptly issued standards, because of inadequate information about injuries from products, poor guidance to the Commission's staff and those who develop standards, and lack of a priority-setting mechanism.

HRD-78-3

DECEMBER 12, 1977

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

B-139310

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

This report shows that the Consumer Product Safety Commission has not promptly issued safety standards to protect consumers from hazardous products. The report discusses improvements the Commission should make to speed up the issuance of standards for protecting consumers.

Our review was prompted by congressional interest in Commission activities, specifically why the Commission has not promptly issued safety standards under the Consumer Product Safety Act. Our review was made 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).

Copies of this report are being sent to the Director, Office of Management and Budget, and the Chairman, Consumer Product Safety Commission.

Elmer B. Staats
Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

THE CONSUMER PRODUCT SAFETY COMMISSION NEEDS TO ISSUE SAFETY STANDARDS FASTER

D I G E S T

The Consumer Product Safety Commission issues standards to protect the public from injury associated with consumer products. The Consumer Product Safety Act contains several provisions designed to guide the development and issuance of standards.

How promptly is the Commission issuing standards to protect consumers from hazardous products? Is the Commission issuing safety standards within the time provided by the law?

The Commission was not developing and issuing safety standards within the proper time. The three standards which had been issued as of June 30, 1977, took an average of 834 days to develop and issue. This far exceeded the guidelines provided by law. (See p. 6.)

The law allows anyone to participate in developing safety standards. One provision lets people outside the Commission (offerors) prepare and submit proposed standards to the Commission. The Commission can pay some of the offeror's costs.

GAO's findings indicated that the Commission

--has not been providing its staff and offerors adequate guidance during the development of safety standards (see p. 9),

--was not promptly evaluating safety standards recommended by offerors (see p. 10),

--was not keeping enough information on product-related injuries to adequately support development of its standards (see p. 23), and

--was slow in establishing priorities for its standard development workload (see p. 31).

The Commission has made some changes to increase the usefulness of its data on injuries, but more needs to be done. (See pp. 22 and 25.)

The Commission should make the necessary changes to its injury information collection system, so the data within the system complements its standard development activities. This would help those who are developing standards to be more responsive to the hazards associated with the product. (See p. 25.)

The Commission should also establish procedures that (1) specify the duties and responsibilities of its staff which monitors the development of safety standards (see p. 13) and (2) identify criteria to be used during evaluation of standards recommended by offerors. (See p. 13.)

These procedures should help offerors to develop safety standards which are acceptable to the Commission and should enable the Commission to evaluate and issue the standards in less time.

The Commission provided extensive comments for GAO's consideration. (See app. I.) The Commission agreed with many of GAO's recommendations, and it has made many changes to improve its operations. The Commission said it will continue to evaluate regularly its regulatory development process to insure the maximum achievement of its mission.

Contents

ABBREVIATIONS

CPS Act	Consumer Product Safety Act
CPSC	Consumer Product Safety Commission
GAO	General Accounting Office
NEISS	National Electronic Injury Surveillance System

CHAPTER 1

INTRODUCTION

The Congress enacted the Consumer Product Safety Act, as amended (CPS Act) (15 U.S.C. 2051), to protect the public against unreasonable risk of death, personal injury, or serious or frequent illness associated with consumer products. The Consumer Product Safety Commission (CPSC) was given authority to develop and issue safety standards to protect the public from hazardous consumer products. However, as of June 30, 1977, and since it began operations in May 1973, the Commission had issued only three safety standards under the CPS Act. 1/

An estimated 20 million consumers are injured each year in using consumer products, of which 110,000 are permanently disabled and 30,000 are killed. More than an estimated 10,000 different consumer products are on the market, and more than 2.5 million manufacturers, importers, packagers, distributors, and retailers of these products are subject to the Commission's jurisdiction.

NATIONAL COMMISSION ON PRODUCT SAFETY

In November 1967 the Congress established the National Commission on Product Safety (Public Law 90-146) to investigate the Federal, State, and local governments' role in protecting consumers from hazardous products. The National Commission's June 1970 report formed the basis for the Congress to create the Consumer Product Safety Commission.

The Congress created the National Commission to "conduct a comprehensive study and investigation of the scope and adequacy of measures now employed to protect consumers against unreasonable risk of injuries which may be caused by hazardous household products." It was also directed to recommend any remedial legislation it deemed appropriate. The National Commission analyzed the three major consumer safety programs--automobile safety, flammable fabrics, and hazardous substances--and concluded that administration of these programs had been "marked by too much timidity and inordinate delay."

1/The Commission also administers four other laws: the Federal Hazardous Substances Act, as amended (15 U.S.C. 1261); the Flammable Fabrics Act, as amended (15 U.S.C. 1191); the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471); and the act of August 2, 1956 (Refrigerator Safety Act) (15 U.S.C. 1211).

The National Commission's report contained findings, conclusions, and recommendations to the President and the Congress, including a proposed law to protect the public from unreasonable risk of injury associated with consumer products.

CONSUMER PRODUCT SAFETY ACT

Based on the National Commission's final report, the Congress realized that existing Federal, State, and local laws and regulations were inadequate to protect consumers from product hazards. Several bills to protect consumers from hazardous products were introduced in the Congress after the National Commission's June 1970 report. After several alternative laws were considered, the CPS Act was passed in 1972. The act has four purposes:

1. Protecting the public from unreasonable risks of injury associated with consumer products.

2. Assisting consumers in evaluating the comparative safety of consumer products.

3. Developing uniform safety standards for consumer products and minimizing conflicting State and local government regulations.

4. Promoting research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

The CPS Act broadly defines consumer products as including products and their component parts which are sold to consumers, although certain items, such as tobacco products, are excluded because they are subject to other agencies' jurisdictions or are specifically exempt from the act.

IDENTIFYING HAZARDOUS PRODUCTS

The Consumer Product Safety Commission collects data, identifies and analyzes hazards, develops methods for dealing with hazards, and stores injury data to assist it in identifying products which pose unreasonable risks of injury to consumers. The National Electronic Injury Surveillance System (NEISS) is used to collect data on product-related injury cases which are treated in hospital emergency rooms. NEISS is a bilevel system consisting of both surveillance data and followup indepth injury investigations which are discussed below.

NEISS, which consists of 119 reporting hospitals, represents a statistical sample of product-related injuries that the Commission can project nationwide. These projections represent about 40 percent of all injuries which require medical treatment. Remaining injuries require treatment in physicians' offices, at home, or elsewhere.

The Commission uses NEISS and other information sources to determine the need for followup action, including developing safety standards or banning hazardous products, to address problems which are identified with products under its jurisdiction. To supplement NEISS, the Commission investigates selected injury cases indepth to determine the cause or causes of the injury and the product involved. These investigations, which are generally conducted by investigators in the Commission's 13 area (field) offices, provide the Commission detailed information for evaluating product hazards by identifying hazard patterns and uses of a product. Analyses of NEISS data, indepth investigations, and other data assist the Commission in determining if regulatory action is necessary to eliminate or reduce the risk of injury.

STANDARD DEVELOPMENT PROCEDURE

The Commission's Office of Standards Coordination and Appraisal was responsible for developing safety standards and rules. A Commission reorganization in May 1977 replaced this office with the Office of Program Management, which (1) recommends the development of standards, (2) considers the legal, technological, economic, and social effects of proposed standards, (3) coordinates standard development activities with other bureaus, offices, agencies, and organizations, and (4) reviews proposed and final standards.

The CPS Act provides that any interested person may petition the Commission to initiate development of a safety standard or to ban a product. 1/ To be considered, a petition must justify the need for, and briefly describe what a proposed safety standard or ban should contain. The Commission has 120 days to grant or deny petitions. If a petition is granted, the Commission initiates a proceeding to either

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1/As used herein, a petition is a written document which requests the Commission to issue, amend, or revoke (1) a safety standard or (2) a declaration that a product is banned (products can be banned from manufacture, importation, distribution, and sale if a safety standard will not protect the public from the hazards associated with them.)

develop a safety standard or ban the product as hazardous. (The Commission can also initiate rulemaking proceedings without a petition.) If the petition is denied or the Commission fails to act within 120 days, the petitioner may file suit in U.S. district court to compel the Commission to initiate the action.

The CPS Act contains a procedure (referred to herein as the "offeror process") that allows offerors (third parties, parties outside the Commission) to submit existing standards 1/ or offer to develop new standards that the Commission may issue as mandatory. This procedure was designed to encourage interested persons, including consumers, to be responsible for and/or participate in developing safety standards.

To initiate standard development, the Commission (1) identifies the product and the nature of the risk of injury associated with it, (2) states that a standard is necessary to eliminate or reduce that risk, (3) considers information on existing standards, and (4) includes an invitation for any person to submit a proposed standard for consideration. The Commission may contribute to the offeror's costs of developing a standard if it determines a more satisfactory standard might result. The law gives the Commission 330 days to issue a standard after it publishes a notice to proceed. (See p. 6.)

If the Commission accepts an offeror's proposal to develop a standard, the Commission cannot develop a proposed standard applicable to the same risk on its own unless (1) the sole offeror represented a manufacturer, distributor, or retailer of the product to be regulated by the standard or (2) it determines that the offeror is not making satisfactory progress. The CPS Act gives the Commission 210 days, beginning when it accepts the offer, to publish (1) a notice terminating the proceeding or (2) a proposed rule which either proposes a product safety standard or declares the item a banned hazardous consumer product.

Before issuing a standard, the Commission must determine (1) the degree and nature of the risk of injury the standard is designed to eliminate or reduce, (2) the approximate number of products involved, (3) the public's need for the product, (4) the probable effect the standard will have on the utility, cost, and availability of the product, and (5) the means of

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1/A standard issued or adopted by any Federal agency or by any other qualified agency, organization, or institution.

achieving the objective of the safety standard while minimizing adverse effects on competition and other commercial practices.

SCOPE OF REVIEW

Our review was conducted at Commission headquarters in Washington, D.C., and Bethesda, Maryland, to determine whether the Commission was promptly issuing safety standards under the Consumer Product Safety Act to protect the public from the unreasonable risk of injury associated with consumer products. Our review covered the six standards the Commission had issued or had under development at December 31, 1976, which were updated to June 30, 1977. The Commission subsequently started to develop a standard for miniature Christmas tree lights in March 1977.

We reviewed the National Commission on Product Safety's final report and related hearings and the legislative history of the Consumer Product Safety Act as well as the Consumer Product Safety Commission's draft report on the offeror process. We also reviewed Commission policies and procedures for developing and issuing safety standards under that law as well as examining its collection and analysis of injury data and development of standards. We interviewed Commission officials and representatives of the offerors developing recommended standards for the Commission.

CHAPTER 2

NEED FOR MORE TIMELY DEVELOPMENT OF SAFETY STANDARDS

The Consumer Product Safety Commission has not been promptly developing and issuing safety standards. During its first 4 years of operation, the Commission issued standards under the Consumer Product Safety Act for only three products--swimming pool slides, architectural glass, and matchbooks. As seen on the chart on page 7, the Commission neither issued the three standards within the law's 330-day guidelines, nor were three of the four other standards, under development at June 30, 1977, meeting these guidelines. (See app. III.)

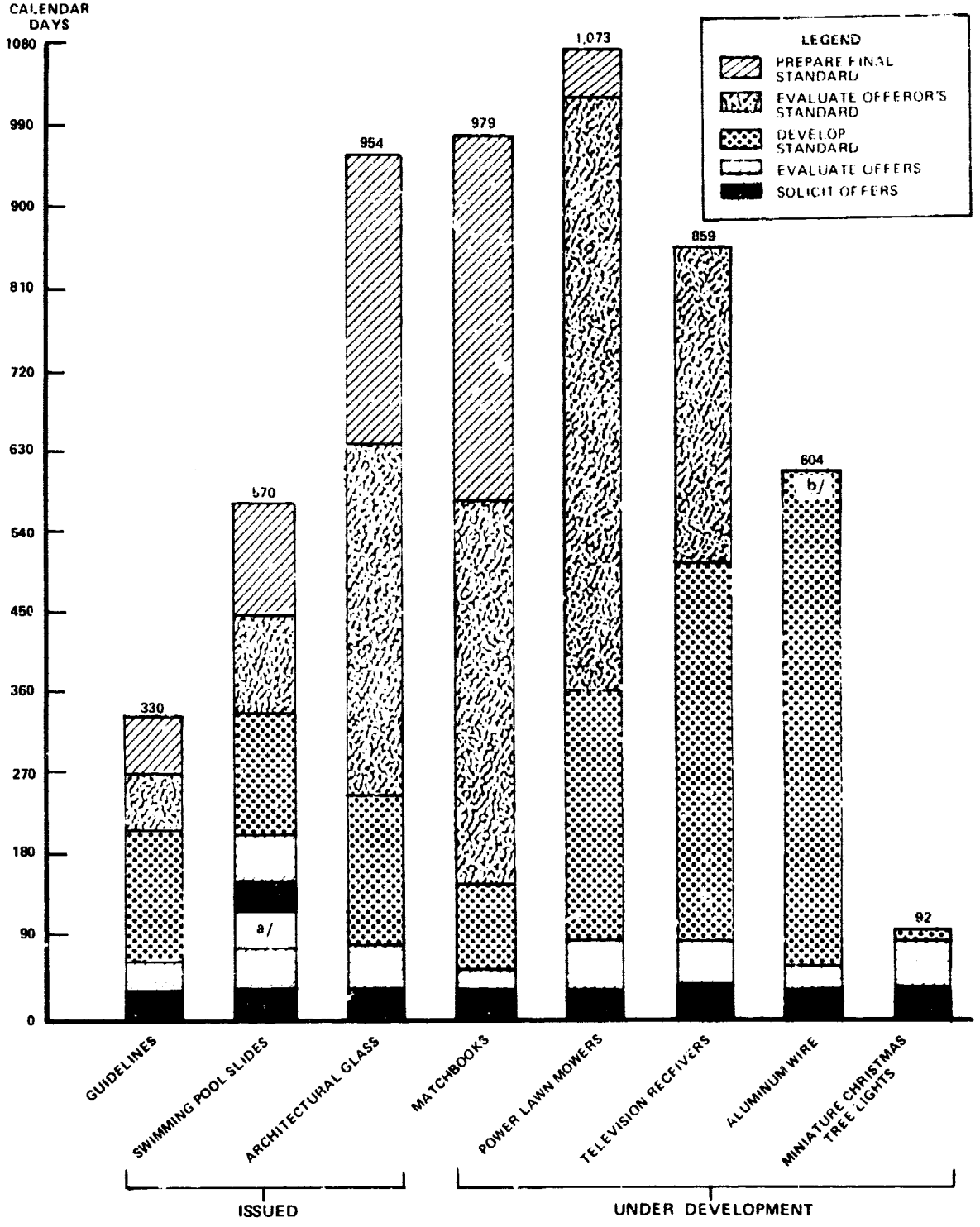
Both the Congress and the National Commission on Product Safety were concerned about product safety because existing legislation and Federal agencies either lacked authority to address hazards associated with such products or took too much time to develop safety standards for the public protection. The CPS Act gave the Commission the means to develop safety standards to protect consumers from hazardous products.

The CPS Act specifies the number of days in which the Commission is to develop and issue safety standards--330 days after it issues a notice to proceed. This includes a 150-day development period which starts when the Commission accepts an offer to develop a standard and ends when the offeror submits its recommended standard to the Commission. The Commission can extend this time period for good cause. (See app. II.)

The three standards the Commission has issued to date averaged 834 days to develop and issue, far more than the 330 days the Congress specified in the Consumer Product Safety Act. Also, up to December 30, 1976, the Commission was developing standards to protect consumers from the unreasonable risk of injury associated with three other products--television receivers, aluminum wire, 1/ and power lawnmowers. None of these standards had been issued as of June 30, 1977, although they had been under development for an average of 845 days.

1/In March 1977 a U.S. district court ruled that the Commission did not have jurisdiction over aluminum wire. The Commission is appealing. Furthermore, in May 1977 the Commission suspended its standard development activity.

DAYS STANDARDS UNDER DEVELOPMENT
AS OF JUNE 30, 1977



a/ Initial offer rejected; solicited offers a second time.
b/ Development activity stopped on May 5, 1977.

The Commission estimated that during calendar year 1976, about 8 million injuries treated in hospital emergency rooms were associated with consumer products. The three products for which the Commission has issued safety standards accounted for 75,500 of these injuries, less than 1 percent of emergency room treated injuries.

Of the thousands of consumer products available to the public and under the jurisdiction of the five laws the Commission administers, the Commission had identified and was working on about 180 projects in January 1977. These projects include such products as televisions, bicycles, tents, extension cords, public playground equipment, smoke detectors, Christmas tree lights, as well as administrative rules and petitions. However, the Commission used no priority criteria in selecting these projects, and no procedure exists for specifying how they will be completed.

From its inception in May 1973 through the end of fiscal year 1977, the Congress will have provided the Commission about $157 million. Of this, $25 million related to identifying hazards and another $38 million for determining how to address a specific hazard which means determining the regulatory alternative to take and developing the necessary safety standards. These costs represented about 40 percent of the Commission's total funding. The Commission's cost-accounting system does not account for costs identified with a specific product. Therefore, the Commission does not know and was unable to tell us how much it has spent to work on a specific product hazard or develop a standard.

In each instance in which the Commission initiated a standard development proceeding, it determined at that time that the hazards associated with the products may present an unreasonable risk of injury. The Commission found that the hazards were such that existing voluntary standards were inadequate to protect consumers and that mandatory safety standards were needed to reduce or eliminate the unreasonable risks of injury.

Many factors have contributed to the Commission's lack of timely development of safety standards. For instance, the need for better data--both before and during the standard development process--has been a significant factor in why standards have not been developed faster. (See ch. 3.) Other factors that contributed to the Commission's untimely standard development relate to how the Commission monitors the development of standards by offerors (see p. 9) and how it evaluates standards recommended by offerors (see p. 10).

The Commission was also slow to establish workload priorities, and this contributed to the Commission not working on the most hazardous products. (See ch. 4.)

INADEQUATE COMMISSION GUIDANCE DURING STANDARD DEVELOPMENT

Commission practice had been to allow offerors to develop proposed safety standards without any influence by the Commission. CPSC staff members were nonparticipating observers in offerors' standard development activities. They maintained a hands-off attitude and did not influence or otherwise interfere with an offeror's work. Commission monitors advised the Commission of offerors' progress and problems but in some instances did not act to redirect or guide offerors if problems were identified.

Commission agreements with offerors name a Commission monitor to coordinate and maintain liaison between the offeror and the Commission. Commission representatives inspect offeror facilities and standard development activities to determine if satisfactory progress is being made. Offerors also submit monthly progress reports summarizing progress made, work underway, significant problems, and work remaining.

Commission regulations state that if an offeror is not making satisfactory progress toward completing a safety standard, the offeror is to be given an opportunity to demonstrate its willingness and ability to complete the standard, or the Commission may terminate the agreement. Although the agreement states the offeror's requirements and identifies the Commission monitor, the Commission has not defined the monitor's functions and has followed a policy of not interfering with the offeror.

The Commission's hands-off policy resulted in inadequate guidance and direction to offerors. Offerors have requested technical and procedural guidance and assistance from monitors, and although the staff had considerable knowledge of the hazards being addressed, it did not always share this information with offerors because of the Commission's policy.

For example, the offeror who was developing the power lawnmower standard asked the monitor the amount of technical rationale and support which would be needed to justify the safety provisions included in the standard in order for the standard to address the hazards the Commission had identified. The monitor did not give the offeror such guidance because of the Commission's policy. The offeror's recommended standard

contained several safety provisions which the Commission said were without adequate technical rationale. Approximately half of the provisions were eliminated because they were too stringent or the Commission and the offeror were not able to justify including them in the standard. Many of these provisions would not have been included in the recommended standard if the Commission had adequately monitored the offeror's progress. Inclusion of these provisions contributed to a delay in issuing the standard because the Commission required more time than it had initially planned due to an attempt to develop the needed justification and to evaluate the offeror's recommended standard.

Even though the law requires the Commission to determine if satisfactory progress is being made by the offeror who is developing the safety standards, CPSC has not always exercised its responsibility. For instance, no corrective action was taken until after the offeror submitted its recommended power mower standard to the Commission. While it was evaluating the recommended standard, the Commission requested that the offeror give a more detailed justification of certain provisions in the recommended standard. These issues were not resolved until after the standard was submitted to the Commission for evaluation. This contributed to the delay in issuing the final standard.

OFFERORS' RECOMMENDED STANDARDS HAVE NOT HAD TIMELY EVALUATIONS

The Commission evaluates offerors' recommended standards to determine if a mandatory standard is needed, if the recommended standard will reduce the unreasonable risk of injury associated with the product, and if the technical provisions are technically sound and legally enforceable. Several problems have contributed to the Commission taking considerably more time to evaluate recommended standards than planned.

Because of problems identified with recommended safety standards during this "evaluation" stage, the Commission has had to obtain additional data and perform more studies and analyses and has required offerors to provide additional documentation, before issuing final standards. This has contributed to delays in issuing safety standards, and in some cases, has resulted in eliminating provisions which offerors have included in their recommended standards.

For example, because the offeror had inadequate data to demonstrate the hazards of swimming pool slides, it was unable to determine whether the cause of injury was the slide, its installation, and/or maintenance. Therefore, the offeror's recommended standard contained some safety requirements that were supported by technical judgments instead of injury or laboratory data which demonstrated that the standard addressed individual hazards. The Commission needed technical rationale to support certain provisions of the standard. As a result, CPSC staff had to perform an additional study while evaluating the recommended standard. Consequently, instead of taking 60 days to evaluate, the recommended swimming pool slide standard evaluation took 108 days and delayed the final standard.

In another example, during its evaluation of the match book standard, the Commission said the offeror had not provided adequate written justification of some individual safety requirements, such as the proposed burn time requirement which would extinguish a match within 15 seconds after igniting. The Commission said the offeror had not shown how effectively the "burn time/burn distance" requirement would reduce match-related injuries to children. The offeror provided additional technical rationale to the Commission.

However, providing this information took up 6 months of the time the Commission needed to evaluate the recommended standard.

Commission staff said that many of the delays during the evaluation of offerors' recommended standards were due to the lack of clear Commission policies and procedures on how to evaluate an offeror's recommended standard. The staff believes that formal procedures would assist the Commission in the more timely evaluation and issuance of safety standards.

CONCLUSION

The time for developing and evaluating recommended safety standards has far exceeded the guidelines in the Consumer Product Safety Act. The Consumer Product Safety Commission's practice of not permitting its staff to actively participate in offerors' development of safety standards has contributed to the lack of timely development of standards. We believe that the Commission's staff should provide technical guidance and assistance to offerors and that the Commission should specify the scope of responsibility its staff is to exercise during the development of safety standards by offerors.

Also, the Commission has failed to promptly complete evaluations of safety standards which have been recommended by offerors. CPSC attributes this to a need for more and better injury data, although other factors have contributed to the delays. The Commission needs to provide offerors the data for developing safety standards and needs to establish procedures that specify the criteria for evaluating recommended standards. Such criteria will assist Commission staff in reviewing and evaluating safety standards which have been developed by offerors. Such procedures would also assist offerors because they would know the Commission's criteria for evaluating standards which they are developing.

COMMISSION COMMENTS AND OUR EVALUATION

In its comments on a draft of this report, the Consumer Product Safety Commission said the time guidelines in the Consumer Product Safety Act are unrealistically short and that the time frames require case-by-case determinations, depending on the complexity of the standard. CPSC also said that it has changed the offeror process in the current standard development proceeding for miniature Christmas tree lights. Although this proceeding started after completion of our fieldwork, we recognize that the Commission has handled this standard proceeding differently than those we reviewed and that the Commission's monitor is more actively participating in the offeror's development of this standard.

However, the Commission has not established a policy or procedures which specify the duties and responsibilities its monitors are to perform.

The Commission formed an agreement with the offeror which was developing the miniature Christmas tree light standard. This agreement provided that a Commission monitor would be responsible for establishing and maintaining liaison with the offeror during the development period. However, the agreement does not specify the monitor's functions.

The Commission also said that at the start of a standard development proceeding, it provides the offeror with all available information regarding the product and hazard involved, including injury data, information on existing standards, and promising approaches to standard development. The Commission pointed out that a rigid step-by-step approach to evaluating offeror-recommended standards is inappropriate.

However, as discussed herein, Commission performance to date has shown that CPSC evaluation of offeror-recommended standards has not been timely, which has been partially attributed to insufficient data being available to offerors. We believe the Commission needs to give offerors additional injury data and more insight into what criteria it uses so that standards' evaluation times can be reduced.

RECOMMENDATIONS TO THE COMMISSION

We recommended that the Commission establish a policy and procedures specifying the duties and responsibilities of the Commission which monitors staff development of safety standards by offerors. Also, the Commission should promptly provide offerors necessary data for developing safety standards, and it should establish procedures to specify criteria to be used during evaluation of such standards.

CHAPTER 3

THE COMMISSION NEEDS BETTER DATA ON PRODUCT-RELATED INJURIES

The Commission has not been obtaining the data needed to identify injuries caused by consumer products and to evaluate the hazards associated with these products to determine the unreasonable risk of injury associated with them. The Commission did not have adequate procedures or data systems to assist in determining the cause of product-related injuries or to determine which hazardous products required regulatory action.

The Consumer Product Safety Act directs the Commission to (1) maintain an injury information clearinghouse and (2) conduct continuing studies and investigations of deaths, injuries, diseases, other health impairments, and economic losses resulting from accidents involving consumer products. The Commission's objective is to establish a detailed and reliable information base to provide the scope, magnitude, and causal patterns of product-related injuries to support CPSC's standards' development activities as well as other Commission functions. The Commission's Bureau of Epidemiology has been responsible for collecting data on the frequency, severity, and distribution of product-related injuries and for determining the cause of these injuries. With the Commission's reorganization, the newly created Directorate for Hazard Identification and Analysis is responsible for these functions.

This data base consists of NEISS surveillance data, in-depth injury investigations, and supplemental information on injuries not receiving hospital emergency room treatment. The Commission uses these different data sources to assist in identifying product hazard patterns and in analyzing hazards to determine if regulatory action is necessary to eliminate or reduce the risk of injury.

During fiscal year 1976 the cost of the Commission's data collection system was about $6 million. In that year the system accumulated much data on product-related injuries and deaths, for example, types of products involved, number of product-related injuries, and statistics on victims' ages. During fiscal year 1976, 119 sample hospital emergency rooms reported about 412,000 injuries involving consumer products. The Commission collected and reviewed approximately 45,000 death certificates and performed about 4,400 indepth

investigations of reported product-related incidents to analyze further the nature of the injuries.

We found that the Commission's injury data collection system was not adequately identifying product use and the extent of product involvement in injuries. Also, the Commission was not adequately evaluating injury data to determine how a product was involved in an injury.

Commission studies of its data collection and analysis activities have identified problems and weaknesses in these activities, and some changes have been made. However, additional improvements are needed to enable the Commission to better identify those hazardous products requiring regulatory action.

INADEQUATE DESIGN AND IMPLEMENTATION OF THE NATIONAL ELECTRONIC INJURY SURVEILLANCE SYSTEM

The Commission's National Electronic Injury Surveillance System provides a statistical basis for identifying hazardous products and also provides data for further injury investigations by identifying the types of products involved in injuries, quantifying the frequency of injuries related to specific products, and arranging the injury data by the age of injury victims to reflect injuries to children. However, this system does not identify (1) how a product was being used or (2) the cause of the incident resulting in the reported injury.

Although the Commission uses this system for identifying product involvement in an injury-related incident and what caused the incident, NEISS had several weaknesses that limited its effectiveness.

Limitations due to system design

NEISS reports on product-related injuries which are treated in 119 hospital emergency rooms. Although emergency room cases identify the more severe injuries requiring medical treatment, they are not representative of all product-related injuries. Most injuries are treated in physicians' offices, at home, in other hospital units, or elsewhere and are not reported.

For instance, product-related fatalities are generally underrepresented in NEISS because they are not treated in emergency rooms, unless the victim dies during emergency

treatment. Burn injuries are underreported because many persons suffering severe burns are taken to a burn center and not necessarily to an emergency room. Also, product-related illnesses and other health impairments are not reported, such as loss of sight or hearing, because they may occur over a long period and may not be treated in an emergency room.

Commission studies have identified problems with the system's design and have recommended improvements. Although the Commission has moved to obtain better data on all product-related incidents, as of June 1977, these problems still existed.

Shortcomings in selecting hospitals

NEISS gathers product-related injury data from statistically selected hospital emergency rooms which are located throughout the country. Hospitals were selected based on geographic location and number of cases treated in their emergency rooms. From this data, statistically based estimates of product-related injuries treated in emergency rooms are made. However, the statistical credibility of the system needs improvement, and several problems exist in the method used for selecting hospitals and the design of the system.

Hospitals included in the system were statistically selected to represent a cross section of geographic areas and emergency room use. However, the sampling plan used to select these hospitals failed to recognize that not all hospitals would be willing to participate in this system or that some might subsequently drop out, thereby reducing the representativeness of the data. Approximately 60 percent of participating hospitals were selected from the original sample plan. The other 40 percent were replacements. Also, some participating hospitals subsequently dropped out, further reducing the proportion of the original sample and also reducing the representativeness of the data collected.

A study of NEISS concluded that the Commission had incorrectly estimated national product-related injuries and cautioned the Commission that reaching decisions based on erroneous data was certainly undesirable and should be corrected.

The Commission staff recommended that the system be redesigned to provide a reasonable rationale for selecting alternative hospitals and for periodically updating sample hospitals. Although the Commission plans to redesign the sample to retain its statistical validity, as of June 1977, the same shortcomings existed.

Problems in using the hazard index

The "age-adjusted-frequency-severity index" (referred to herein as the hazard index) ranks consumer products 1/ by considering the frequency and severity of injuries treated in emergency rooms and the age of the person injured. The index has several uses, including identifying products involving serious injuries or deaths and injuries occurring to children.

The major purpose of the hazard index is to rank the data received to provide the Commission clues for identifying potential problem areas that may need followup investigation. The index is not the sole criteria for determining which projects the Commission will undertake. However, it does provide a basis for identifying unreasonable risks of injury associated with consumer products.

The hazard index consists of a severity weighted factor and an age weighted factor. The severity factor quantifies the severity of an accident with the frequency at which it is reported and is used to surface those emergency room cases involving serious injuries or death. A geometrically determined weight is assigned to injuries to account for the severity of an injury based on the injury diagnosis, body part affected, and hospitalization (if any) required. The severity factor is assigned to the injury based on information available at the time it is treated in the hospital's emergency room.

A Commission study found that assigning a severity factor at this time may not be accurate because adequate information is not always available to make the diagnosis. For example, certain types of emergency room cases, such as poisonings, are considered more severe and given a higher severity ranking because they often result in hospitalization, if only for observation. However, a case requiring further treatment related to an injury would be assigned a lower severity ranking because it was treated and released in an emergency room, and subsequent treatment (generally not performed in an emergency room) would not be included in the data reported to the Commission.

1/The hazard index ranks products by their product "category"--a family of related products. Some products have their own category; other products are combined into one category. As used with the hazard index herein, the term "product" includes product category.

The Commission's age factor weights children's product-related injuries treated in emergency rooms by multiplying them by 2.5 to give special consideration to potential product hazards for this age group. For this purpose, the Commission defines children as those 14 years old or younger. The 2.5 factor is used because about 2-1/2 times as many persons in the United States are over 14 years old as are 14 or younger. The factor is used to relatively compare the total number of accidents involving persons 14 or younger to total accidents to persons over 14.

Again, a Commission study noted that certain products may not be accurately reflected in the hazard index because the Commission's use of an age-weighted factor could lead to erroneous identifying and ranking of hazardous products. For example, many injuries to children are superficial. As a precaution, parents take their children to a hospital for treatment. However, adults generally would not seek treatment for themselves for such injuries. Thus, more injuries are reported for children, and products related to these types of injuries have higher hazard index rankings.

FURTHER INDEPTH INVESTIGATION OF PRODUCT-RELATED INJURIES NEEDED

Commission policy is to identify and evaluate causes of product hazards. Indepth injury investigations, consisting of comprehensive reviews of accident sequence and injury, provide the specific details required to evaluate fully the product's involvement. Commission Directive 9010.24, "In-Depth Investigations," contains the procedures for conducting investigations, including a requirement that they be completed and reported to headquarters within 30 days. Investigations consist of contact with the injured (if possible) and others who were present at the accident location when the injury occurred. Investigators are to identify and evaluate the product, determine whether other agencies have information about it, and prepare an accident investigation report.

The Commission performs indepth investigations on selected injury cases to determine the cause of the injury and how a product was involved. These investigations give the Commission indepth information to better evaluate product hazards by identifying injury patterns and design characteristics related to product usage. They assist the Commission in determining if regulatory action may be necessary to eliminate or reduce the risk of injury associated with a product.

The objective of indepth investigations is to supplement the basic injury data and provide additional information to evaluate product hazards, identify injury patterns, and determine product usage. They are designed to identify those factors that cause product-related accidents and are essential because they help to identify the nature and extent of the hazard and provide insight into regulatory action needed. Also, these investigations can be effective in verifying the accuracy of the basic surveillance data.

Indepth investigations are either centrally assigned by headquarters or self-initiated in area offices. Headquarters-assigned cases are generally computer selected from NEISS data using a predetermined priority--such as excessive accidents involving a product or current Commission project. Area offices select cases when local interest in a product hazard may exist or an unusual or unique incident is reported.

Investigations could be more useful and effective to the Commission if problems related to (1) how injury cases are selected for indepth investigation, (2) the investigators' ability to complete them, and (3) the adequacy and completeness of the investigation conducted, could be improved.

Injury cases being investigated may not be representative

Injury cases for indepth investigation were usually not selected on a statistically valid basis because their selection was primarily influenced by resources available to perform investigations. Therefore, the Commission cannot make statistical projections about accidents associated with specific products. Also, through fiscal year 1976, Commission area offices substituted self-initiated cases for those assigned by headquarters (headquarters was attempting to assign cases statistically) and this further reduced the statistical validity of the investigations. For example, in fiscal year 1975 about 63 percent of the 9,945 cases assigned were related to the NEISS data base, whereas in fiscal year 1976 over 98 percent of the 9,914 cases assigned were from the NEISS data base.

A Commission study concluded that since Commission regulatory actions depend on these investigations to identify the cause of the reported injury and the product's involvement, these cases should be selected randomly from the NEISS data base. The Commission staff believes that randomly selecting cases would be more representative. However, such selection is generally not being done. With the exception of about

15 special studies, consisting of less than 20 percent of all completed indepth investigations, the Commission has not been randomly selecting cases for indepth investigation.

Assigned indepth investigations not being completed

During the 12-month period ended June 30, 1976, about 34 percent of assigned indepth investigations were prematurely terminated--that is, they were not conducted or they were not completed. The Commission estimates that 80 percent of assigned cases should be completed for the sample to be representative and useful. Some investigations were not made on injuries reported from several locations outside major population centers or from selected locations inside central city ghettos. For instance, some investigations were not conducted in central city ghetto areas because investigators (1) would not enter that area of the city (for example, because of fear for their safety) or (2) could not locate the accident victims because they gave fictitious names, phone numbers, and addresses when treated for injuries. Also, in some instances, some investigations were not being made because travel funds were not available.

At times investigators were performing abbreviated investigations (generally over the telephone) in which insufficient data was obtained to make a complete and fair assessment of the injury and to determine the cause of the injury and the product's involvement in it. For instance, during one period in fiscal year 1976, "abbreviated" investigations were conducted on injury cases reported at 21 NEISS hospital emergency rooms.

Another reason investigators were unable to complete indepth investigations was that injured persons would not give permission to be interviewed by investigators. The Commission does not have authority to require injured persons to be interviewed about their injuries. Some people were unwilling to participate because they did not want to get involved, felt that interviews were an invasion of their privacy, or were embarrassed because the accident was their own fault.

The Commission cannot require people to talk to investigators. However, it has attempted to increase investigators' awareness of the need to explain to accident victims why they are making the investigation and whom they represent. To help conduct indepth investigations in many of the central city ghetto areas, the Commission planned to contract with special groups to perform investigations in these areas.

Injury investigations not adequate for regulatory development

The Commission's available injury data and the method by which the data is analyzed are inadequate for determining the unreasonable risk of injury and the appropriate regulatory action. A Commission study concluded that the Commission needs to (1) determine how a product is being used and who is using it when it is involved in an injury, (2) improve the quality of its indepth investigations, (3) train its investigators to perform better investigations, and (4) improve the evaluation of its injury investigations.

The Commission's collection and analysis of product-related injury data have been directed toward the mechanical factors associated with such injuries. For instance, Commission engineering evaluations identify and evaluate problems associated with product design and defect (mechanical factors). However, it has directed little attention toward determining how human factors--the way people use products--are involved in product-related injuries. Also, the frequency and severity of injuries are important statistics and are used to identify product hazard patterns. However, without adequate product exposure data (for example, number of products sold, number of consumers using products, and the life of the product) and data on how people actually use products, it is difficult for the Commission to identify adequately the unreasonable risk of injury.

A Commission study concluded that data on a user's exposure to a product must supplement data on the frequency and severity of injuries to identify meaningfully the unreasonable risks of injury.

Commission indepth investigations were inadequate partially because Commission procedures for reviewing their accuracy were also inadequate. Although the Commission evaluated selected investigations, it does not have a continuous program for monitoring indepth investigations and providing feedback to investigators. About 15 to 20 percent of the investigations were being evaluated, and a Commission official believes that approximately 50 percent of the reports should be evaluated to more effectively monitor investigations. Commission representatives attribute the lesser number reviewed to limited Commission resources.

A Commission study concluded that indepth injury investigations were inadequate because (1) investigators examine a variety of products and product-related injuries

and are inefficient because they do not specialize in particular products or injuries, and (2) Commission training is inadequate for preparing investigators to make the required investigations. Although the Commission staff recommended that the Commission upgrade its investigators by providing more training and establishing a career ladder for them, this had not been done through June 1977.

Attempts to obtain supplemental injury information not successful

The Commission recognized that NEISS could not be its sole injury data gathering system and has used several other sources for identifying and obtaining supplemental injury data. This information is needed and could be used to better estimate the scope and magnitude of product-related injuries and to provide for further collaboration of data collected through NEISS and indepth investigations. However, as of June 1977, the Commission had not implemented the additional data systems needed to complement its existing data base.

The Commission has initiated several projects to obtain additional injury information. One project was unsuccessful, and some projects gave the Commission limited additional injury data. Others were being tested as of June 1977.

One such attempt to obtain additional information was a physicians' office survey intended to obtain product-related injury data on patients treated in doctors' offices. The Commission believed that data obtained through such a survey would complement its existing injury data base. The survey was initiated by sending questionnaires to doctors inquiring about the treatment of patients with product-related injuries. However, only 7 of 43 doctors included in a pretest of the questionnaire responded to the questionnaire--a response rate the Commission considered unsatisfactory. A second attempt to obtain this information was made several months later, but its results were also unsatisfactory, and the Commission terminated the survey.

In April 1974 the Commission attempted to obtain more information on the scope and problems associated with fire-related injuries. Over 33,000 households were surveyed and asked to report on fires which had occurred during a 12-month period. In those households reporting a fire, additional information was obtained on where injuries may have been treated, the part of the body injured, where and how the incident occurred, and whether a product was involved in the accident and/or injury.

This survey provided the Commission information on the persons involved, the ignition source, items ignited, location, time, and the circumstances involved in approximately 2,500 fires. However, information collected was inadequate for the Commission to determine the cause of the fires. Although the survey results dealt with a product's involvement in the fire, it was insufficient to determine whether a person or product caused the fire.

Another ongoing Commission project is a review of death certificates to obtain information on deaths caused by consumer products. Agreements have been reached with most States to allow the Commission to obtain death certificates. As with much of the data the Commission has available, death certificates provide information on deaths involving a consumer product. The certificates do not help the Commission determine if the product caused the death or how it was involved in the incident.

With few exceptions the Commission is unable to perform more indepth investigations on reported deaths because it must maintain the confidentiality of the death certificates. Therefore, even with this information on product-related deaths, it is unable to determine if the product was the cause of death, how the product was being used, and whether other factors are necessary to make a meaningful hazard analysis.

NEED FOR BETTER INFORMATION ON THE CAUSE OF INJURIES

Recognizing that the Commission does not need a large volume of injury data to justify a safety standard, it does need sufficient evidence about the cause of injuries or potential injuries to develop an appropriate safety standard. This can be illustrated by the problems experienced by the offeror as part of the development of the swimming pool slide standard. In this case, the offeror had to perform additional injury studies and analyses to determine the cause of injuries associated with swimming pool slides.

When the Commission initiated the proceeding to develop a standard for swimming pool slides, it estimated that approximately 42,000 injuries occurred annually which were associated with swimming pools and required emergency room treatment. However, it did not indicate how many injuries were associated with slides. It had performed two indepth injury investigations in which the injuries were associated with slides and knew of approximately 14 other injury cases

concerning the major hazard it identified--paraplegic and quadriplegic injuries.

Because limited data was available on swimming pool slide injuries, the offeror was unable to determine whether the user, the slide, the installation, and/or the maintenance of the slide caused the injuries. Also, the offeror's project manager said the Commission did not provide any information concerning the human behavior aspects associated with swimming pool slides nor could it correlate the information concerning swimming pools to the problems inferred with slides. Therefore, the offeror performed additional studies to identify the hazards and the causes of the injuries associated with swimming pool slides before it could develop a recommended standard.

The Commission's efforts to develop a safety standard for architectural glazing materials is another case in which adequate injury data was not available. In June 1973 the Commission was petitioned to issue a standard concerning injuries associated with glass doors, storm doors, and shower bath panels. The petition followed National Commission on Product Safety findings that various glass doors, storm doors, and shower bath panels presented an unreasonable hazard to the health and safety of consumers. The National Commission attributed the major problem to common annealed glass (for example, regular polished plate glass) in these products.

The Commission granted the petition in November 1973 and in May 1974 published a notice for developing a standard for architectural glazing materials, including glass windows. It included windows because of the many injuries associated with them. The offeror told the Commission that the risk of injury associated with windows was not demonstrated by the injury data available, and that addressing windows would take an additional 5 months because the injury data associated with window hazards was incomplete.

In October 1974 the Commission extended the offeror's standard development period for 3 months. One reason for this extension was to allow the offeror to determine the cause of injury to develop energy levels and test procedures for windows. The offeror did not develop a safety requirement for windows, and the Commission (which decided to further study the need for a standard for windows) did not include windows in the safety standard issued January 6, 1977.

The offeror said that a reasonable mandatory safety standard could have been issued to protect consumers from the hazards attributed to glass doors, storm doors, and shower bath panels 3 years earlier if the Commission had limited its standard development activities to the issues identified in the petition.

CONCLUSIONS

The Commission's product injury data base, including its surveillance and indepth investigation activities, does not adequately support its hazard identification and hazard analysis needs. The Commission needs injury information that it can use to determine the causes of a product-related injury, the product's involvement in the incident, and the user's (people) involvement in the incident.

The Commission's NEISS, indepth injury investigations, and supplementary injury information have not adequately provided this type of information. An improved injury information data base is important to the Commission to assist in identifying and analyzing hazards to allow the Commission to develop necessary safety standards to eliminate or reduce the unreasonable risk of injury associated with consumer products.

RECOMMENDATIONS TO THE COMMISSION

We recommend that the Commission improve its injury information data collection activities by:

--Determining that the emergency room hospitals, included in the injury surveillance system, are representative of hospitals with emergency rooms.

--Adjusting the hazard index factors to insure their accuracy and representativeness of injury severity and frequency.

--Assigning injury indepth investigation cases on a random basis to maintain the system's validity.

--Monitoring assigned indepth investigation cases more closely to verify that they are being completed.

--Training investigators to provide the product-related injury data necessary to identify and analyze product hazards.

--Continuing to search for ways to obtain additional information on the types of injuries not included in the Commission's product-related injury surveillance system.

COMMISSION COMMENTS

The Commission said that it either has taken or plans to take the action we recommend. It said that it had completed a redesign of the NEISS system in April 1977 and that in August 1977 it approved and funded the redesigned system for implementation during fiscal year 1978.

The Commission outlined the actions it had taken or plans to take

--to improve the representativeness of hospitals included in the NEISS system,

--to assign indepth investigations on a random-sampling basis,

--to improve the monitoring and assessment of injury investigations, and

--to review and update its investigators' training.

The Commission said that NEISS would remain as its primary source of injury information, although CPSC recognizes the need for other information and special surveys. The Commission also said it will continue with its death certificate and coroner's reporting systems to obtain additional information, but it has no plans to develop any other ongoing data collection activities. Instead, as data needs arise which cannot be met by NEISS or other available sources of data, ad hoc surveys will be considered.

The Commission said that the problems we identified with its use of the hazard index are judgmental and reflect current policy. For instance, the Commission prefers that hazards to children be more visible because children are less able to identify and gauge product hazards. Also, because the hazard index is a management tool for identifying potential hazards which require further study, the Commission prefers to illuminate and possibly overestimate these types of hazards rather than overlook them. The Commission did acknowledge the need to refine its data and said that it undertook a study in fiscal year 1977 to look for other measures of severity designed to complement the hazard index.

CHAPTER 4

THE COMMISSION WAS SLOW TO ESTABLISH WORKLOAD PRIORITIES

Commission policy is to deal first with those products presenting the greatest risk of injury to consumers. However, the Commission has not always followed this policy. The Commission had many projects in process at the same time and continued to start new projects without finishing those already in process. The Commission's limited resources were spread over many projects, and few were being completed.

RECOGNIZING THE NEED FOR PRIORITIES

The National Commission on Product Safety, in reporting that consumers must be protected from unreasonable risks of injury, recognized that some method was needed to identify and direct resources to the most hazardous products. The National Commission recommended that its proposed product safety commission annually establish priorities for regulatory activities. The CPS Act did not contain such a provision. However, the legislative history shows that the conference committee believed that the Commission should have taken about 3 years to properly order its priorities.

Although the CPS Act does not include the National Commission's recommendation for establishing priorities, the Consumer Product Safety Commission established a priority policy in November 1973 which included the National Commission's recommendation: "The Commission will deal first with those products which pose the greatest risk of injury to the public. The Commission will set (and will periodically reevaluate) its priorities, taking into consideration the number of injuries associated with a particular product, the severity of those injuries, the consumer's likelihood of exposure to that product, and other factors which the Commission considers important."

In July 1976 the Commission further refined this policy by formally identifying the criteria to be used in determining product priority areas. These include

--frequency and severity of injuries,

--cause of injuries,

--chronic illnesses and possibility of future injuries,

--cost and benefit of Commission action,

--unforeseen nature of the risk,

--vulnerability of the population,

--probability of exposure to the hazard, and

--additional criteria that may warrant Commission attention.

This policy also stated that the Commission's operating plan would be as specific as possible regarding products, groups of products, or generic hazards to be addressed.

Because the Commission did not have a priority listing of projects for standard development before July 1975, no assurance existed that the Commission was working on the more hazardous products. This can be illustrated by comparing those products the Commission said may present an unreasonable risk of injury with their ranking on the hazard index.

Although the hazard index was not established as a priority list, it is a source for identifying products which contain hazards. The index also attaches "values" to those products based on the frequency and severity of injuries (treated in emergency rooms) associated with them, and the age of the injured. The index also ranks the products based on their value--the products with the highest frequency and severity are assigned a lower number and are ranked highest on the hazard index. The Commission's fiscal year 1976 hazard index ranked 375 products under its jurisdiction.

The Commission determined that 11 products may present an unreasonable risk of injury. In comparing the 11 products to the hazard index ranking, we found that 9 were listed on the hazard index at the time the Commission said these products might present an unreasonable risk of injury, and 2 were not. Of the 9 products (see table below) only 1--architectural glass--was ranked within the top 10 on the hazard index.

Product	Hazard index ranking (note a)	Estimated NEISS injuries (note b)
Architectural glass	10	64,619
Christmas lights (note c)	144	734
Extension cords (note c)	85	2,303
Gas-fired space heaters (note c)	15	3,113
Matches	29	9,151
Power lawnmowers	11	61,239
Swimming pool slides (note c)	16	1,734
Television sets	64	17,237
Tents (note c)	178	2,676

a/Ranking at time Commission said the product may present an unreasonable risk of injury. (See app. III.)

b/For the 12 months ended Dec. 31, 1976.

c/These products were not ranked separately. They were included in a more general product category, the ranking for which is shown. For example, gas-fired space heaters are included in the space heaters and heating stoves product category.

The other two products the Commission said may present an unreasonable risk of injury--aluminum wire and refuse bins--were not ranked on the hazard index because the emergency room injuries reporting system did not collect data on them.

In determining that these 11 products may contain an unreasonable risk of injury, the Commission did not say whether the hazards contained in these products presented a greater risk of injury to the public than hazards contained in other products in its data system. Nor did the Commission, in making these decisions, say how these products were selected in line with its priority policy.

Petitions used to establish priorities

Four of the six standards the Commission was developing or had issued through June 30, 1977, were started because the Commission granted a petition stating that

the hazard may present an unreasonable risk of injury (the other two standards were started because the Commission's analyses showed them to be hazardous). As the Commission interpreted the CPS Act, it was to develop standards (or take other action) for those products for which it granted a petition. This interpretation was the basis for establishing priorities in its standard development work.

Although the Commission believed it was to give priority to products which were started after it granted a petition, it did not in all cases operate that way. For instance, as of June 30, 1977, the Commission had not started to develop safety standards for two products (tents and extension cords) after granting petitions in which it agreed that these products may present an unreasonable risk of injury. The petitions were granted over 3 years ago.

The Commission recognized that developing safety standards in response to petitions was not the most effective means of protecting consumers from the most hazardous products. During the Commission's January 1976 House oversight hearings, the former Commission Chairman said that if the Commission would develop standards in response to 10 petitions granted under the CPS Act, approximately 155,000 annual injuries could be prevented. He said that if the Commission was in a position--which he felt it was not because petitions were to be addressed first--to select and work on the 10 product categories with the highest rate of injury, approximately 1.2 million annual injuries might be addressed. The former Chairman recognized that the public interest was probably not being served when the Commission used its limited resources on lower priority, petition-generated projects.

During the Commission's Senate appropriation hearings in 1976, the former Chairman reiterated the Commission's interpretation of the act which directs the Commission's priorities to petitions. The Chairmen of the cognizant Senate appropriation subcommittee and the House Subcommittee on Consumer Protection and Finance both said the Commission can and should consider priorities when deciding to grant or deny petitions. The chairman of the House subcommittee believed the Commission had the authority and responsibility to set priorities and to deny or grant petitions based on those priorities. He said:

> "* * * There is nothing in the language of the bill or in the legislative history which

would indicate that the Commission is precluded from setting priorities and basing denials on the frequency and severity of injury. A responsible administrator would be expected to do precisely this."

In March 1976 the chairman of the Senate appropriation subcommittee requested the Commission to reassess its position on establishing priorities and to list the 50 product hazards most deserving of Commission attention and regulation. However, it was not until June 1977, about 15 months after it was requested, that the Commission established its first priorities and provided copies to the appropriate congressional committees.

COMMISSION GUIDANCE NEEDED TO ESTABLISH PRIORITIES

In an effort to implement the Commission's 1973 priority policy and to establish work priorities, in June 1974 Commission staff presented the Commissioners a regulatory priority document that was based in part on the hazard index, prior Commission decisions to develop standards, and ongoing Commission projects. The document, generally agreed to by Commission bureaus and offices, identified time schedules, priority listings, and manpower requirements for what the staff considered priority projects. It identified over 100 projects for developing regulations and responding to petitions under the laws the Commission administers.

The Commissioners rejected the priority document plan because they wanted to make decisions on priority setting and resource allocations. However, no substitute priority plan was prepared. Because it had not received an alternative priority worklist, the Commission staff generally planned to follow its June 1974 priority document. However, the staff could not follow it because the Commissioners directed the staff to work case-by-case on projects.

In July 1975 the Commission established lists of activities as its basis for priority setting and included them in its fiscal year 1977 budget request. These lists consisted of four separate sections identifying selected activities in various stages of regulatory development--data analysis, alternative remedial strategy, specific regulatory action, and enforcement. These were the first published lists identifying the Commission's working priorities. However, the Commission never used them to make decisions.

The Commissioners continued to make decisions on priority setting and resource allocation. The staff used the lists to allocate resources until the Commissioners' November 1975 decision to make miniature Christmas tree lights a high priority project for regulatory development. The list had not included this project, and the staff was directed to make it high priority. The Commissioners neither provided the staff their rationale for making tree lights a high priority project nor guidance to the staff for reassigning priorities to other ongoing work.

To give the staff some workload direction, in July 1975 the Acting Executive Director asked the staff to identify 10 products for standard development priorities. The factors used to identify product candidates included the anticipated long-and-short-term reduction in the frequency of injuries, the product's position on the hazard index, the number of death certificates on file associated with the product, and the average severity of injuries associated with the product. The staff identified and recommended 10 products for priority standard development activity in fiscal year 1976.

In September 1975, before standard development activity was initiated on these products, the former Chairman directed the staff to establish a priority list for developing standards. A Commission official said that such a priority list was necessary because some bureaus and offices had established their own priorities which resulted in research being done on numerous projects. He said the Commission needed to identify priorities since such research was inadequate to effectively use the Commission's limited resources.

The former Chairman did not guide the staff in developing this priority list. Therefore, in responding to the Chairman's request, the staff established priorities based on

--previous Commission decisions on regulatory development,

--projects initiated by predecessor agencies,

--ongoing and completed work on various products, and

--Commission analyses of injury reduction potential and ranking on the hazard index.

The staff developed a priority list of about 100 projects that consisted of developing standards, evaluating

petitions, and amending existing standards and included it in the fiscal year 1976 operating plan. The list identified fiscal year 1976 and 1977 milestones and possible product categories for attention in fiscal year 1978. It also withdrew certain regulatory development projects, for items such as pacifiers and tricycles, from continued development work. The staff reasoned that some projects had to be withdrawn so the Commission could devote its limited resources to fewer high priority projects instead of attempting to address numerous projects.

The list was neither approved by the Commissioners nor used for deciding which projects to initiate. For example, the staff was directed to give pacifiers a top priority for regulatory action after it had recommended that the pacifier project be withdrawn. Although the Food and Drug Administration initially proposed a regulation for pacifiers in 1972, the Commission had not devoted many resources to the project until early 1976. This resulted from the death of a 5-month old child which was attributed to a pacifier in February 1976. The Commissioners then decided to go ahead with the regulation, and it was issued in June 1977.

In June 1976 the newly appointed Chairman asked the staff to review the Commission's mechanism for priority setting. The staff was directed to summarize available data on specific product categories to assist the Commissioners in identifying priority areas. In August 1976 the staff analyzed approximately 100 product categories and rated each product's hazard potential as high/medium or low. It listed 30 product categories for priority consideration.

The Commissioners deleted some products from the staff's recommendations and added others. They identified about 35 product categories which were included in the Commission's fiscal year 1978 budget request and fiscal year 1977 operating plan. However, the Commissioners did not give their staff any feedback on how they selected the priorities.

In June 1977 the Commission finally issued its priority ranking of products. During its mid-year review, the Commission reviewed the progress of ongoing projects and assessed the future projects to determine which should have priority. After completing this review, the Commission gave priority to 46 projects: twenty-nine were considered high priority--to be worked on as soon as possible and 17 were considered medium priority--to be addressed as soon as possible after the high priority projects. The Commission

did not assign priorities to its other ongoing work. It will, however, continue to collect and analyze injury data, review consumer complaints, accept petitions, and use its authority to deal with substantial hazards discovered in the marketplace.

CONCLUSIONS

The Commission did not promptly establish work priorities. Some of the Commission's standard development activity was directed to petition-generated projects and not necessarily to the most hazardous products.

The Commission established a priority list of projects subsequent to the completion of our fieldwork. If it effectively implements its priority policy and follows projects identified for priority attention, the bulk of the Commission's work in developing safety standards should be directed to the most hazardous products.

APPENDIX I

U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

September 23, 1977

Mr. Gregory J. Ahart
Director, Human Resources Division
General Accounting Office
441 G Street, NW.
Washington, D.C. 20548

Dear Mr. Ahart:

Enclosed is the Consumer Product Safety Commission response to the draft General Accounting Office report to Congress entitled "The Consumer Product Safety Commission Needs to Speed-Up Issuing Safety Standards." We have also enclosed copies of two Commission staff reports which are mentioned in both the GAO draft report and the Commission response.

We appreciate the opportunity to comment on the draft report. Please let me know if you need any further information.

Sincerely,

S. John Byington
Chairman

Enclosures (3)

APPENDIX I

CONSUMER PRODUCT SAFETY COMMISSION

RESPONSE TO DRAFT GAO REPORT

ENTITLED

"CONSUMER PRODUCT SAFETY COMMISSION NEEDS TO SPEED-UP

ISSUING SAFETY STANDARDS"

SEPTEMBER 23, 1977

Introduction

Before commenting on criticisms mentioned in the GAO report, it should be noted that the Consumer Product Safety Commission has taken a number of actions during FY'77 to improve regulatory development activities.

Specifically, the CPSC completed its own evaluation of the offeror process in November 1976. Moreover, a comprehensive CPSC evaluation of the National Electronic Injury Surveillance System (NEISS) was completed in May 1975 and is in several stages of implementation. While the GAO critique closely parallels numerous Commission findings and recommendations from these reports, it largely disregards the operational revisions which have been initiated or completed by management in both processes. This response will attempt to update GAO's information.

The Commission changed the program structure and organization of the budget and planning process from a process-oriented structure to a hazard category or product/project specific program structure. Whereas the former program structure addressed internal CPSC activities (Hazard Identification, Hazard Strategy Analysis, Regulatory Development, Information and Education, Compliance and Enforcement, and Administration), the new structure addresses specific hazards (Fire and Thermal Burn Hazards, Electric Shock Hazards, Acute and Chronic Chemical and Environmental Hazards, and Mechanical Hazards). This new structure will allow the Commission to measure directly its progress in accomplishing the purposes of the Commission, as set forth in Section 2(b) of the Consumer Product Safety Act. These programs, which use the product/project specific hazard approach, were the basis of the Commission's priority setting and Zero Base Budgeting exercises.

Additionally, this past spring the Commission conducted a comprehensive review of regulatory development activities. From this review, the Commissioners were able to establish a priority ranking of activities underway in 1977 and forthcoming in 1978.

The reorganization and the establishment of clear-cut priorities are expected to aid regulatory development efforts.

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The GAO report criticizes the agency for alleged delays in the implementation of the standards development process under Section 7 of the CPSA. This process (known generally as the offeror process) is unique to the Consumer Product Safety Commission. We believe it would provide a useful framework to understanding the GAO comments and the agency's replies if we provide a short background discussion concerning rulemaking.

Most regulatory agencies follow one of two types of procedures under the Administrative Procedure Act in establishing rules or standards. These procedures are formal and informal rulemaking.

Formal rulemaking is a process in which an agency proposal is heard by a hearing examiner or administrative law judge and a record is assembled on the proposal. The parties participating in the process do so in writing or in formal hearings conducted much like a trial. Proponents and critics of the rule or standard present their views, evidence is submitted, and there is cross examination of parties. The hearing examiner or administrative law judge then produces a decision or recommendation for the appointing authority and that authority ratifies, modifies, or rejects that decision. The matter is then open to challenge in the courts based upon the review of the record assembled. The test used in the courts for review of the rule or standard is whether the portions of the regulation attacked are supported by substantial evidence in the supporting record taken as a whole.

The informal rulemaking process allows an agency, through whatever internal process statutorily or internally prescribed, to arrive at a proposed rule. This rule is then published in the FEDERAL REGISTER for public comment. Oral comments may or may not be allowed. The agency evaluates the comments and reaches a decision, which is published in the FEDERAL REGISTER. The rule is then open to challenge in court. The test used in courts for review of these rules is usually whether the proponent agency acted arbitrarily or capriciously in promulgating the rule on the basis of the information available to the agency.

When Congress debated the type of rulemaking process to be followed under the Consumer Product Safety Act, there was criticism of formal rulemaking because it takes very long. Some rules have taken as long as 8 to 10 years to complete. This was considered to be too long for a public health and safety action. On the other hand, informal rulemaking was criticized because this rulemaking was alleged to have produced very few changes by agencies after the initial proposed rule. The time and effort taken to develop the proposal usually shaped the final rule despite public comments. In an effort to strike a compromise between these two types of rulemaking and to create an open agency with adequate public participation, Congress created the offeror process contained in Section 7. This process allows, as will be discussed in more detail later, greater public participation than informal rulemaking in that the initial proposal is shaped by the public participants. However, it does not take as long as formal rulemaking because trial type techniques are not used.

APPENDIX I

In attempting to ensure timely rulemaking, Congress also provided time frames within which actions should take place. Recognizing that the complexity and subject matter of each rule are different, provisions for extending these time frames were also incorporated into the Act. What GAO has done in its report is to ignore the time other regulatory agencies take to issue complex health and safety rules. Further, it has treated the Congressional guidelines as definitive. In fact, this new process was untried and the Congressional time frames must be looked upon as targets. Therefore, a failure to meet the goal is not to be condemned until the scope, breadth and reach of the proposed rule and the complexity of the subject matter are examined. Also, the state of the technology required to meet the rule is many times a factor to be considered in looking at the time it takes to promulgate a rule. Finally, the offeror process might require a longer time than the shorter process of informal rulemaking because public participation should be maintained. It believes such participation is valuable and needed.

It is also appropriate to mention at the outset that prior to the GAO report, the Commission had made many of the changes recommended in the report. In fact, most of these were made after consideration of Commission staff evaluations of the offeror process completed in November 1976, and the National Electronic Injury Surveillance System (NEISS) completed in May, 1975. Copies of these Commission studies are being sent to GAO with this response to the GAO report.

Standards Development (Chapter 2)

The GAO concludes in Chapter 2 that the time the Commission has taken to develop standards exceeds guidelines specified in the CPSA. The GAO attributes this to a Commission policy of not permitting its staff to actively participate in the offerors' development of standards and failing to give offerors guidance during the standard development process.

The offeror process is a new and unique, statutorily required procedure for developing standards. It provides the opportunity for broad based participation of non-government parties - both consumer and industry representatives. The implementation of the offeror process was a learning experience for all involved.

At first, the Commission attempted to implement the offeror process by maintaining a hands-off policy requiring only that the offeror follow a development plan approved by the Commission. The reason for a hands-off approach was the Commission's belief that direct participation might stifle creativity and innovation on the part of non-government participants and that the quality of the resulting standard might be diminished. Under the hands-off policy, the Commission monitor's duties included providing available, off-the-shelf information requested by the offeror and attending meetings of the offeror to insure that the meetings were open to the public, that there was consumer participation and that the offeror was following the agreed development plan. However, in those first proceedings the monitor was not permitted to redirect offeror

efforts throughout the development period as an active participant in the proceeding.

Experience has led the Commission to believe that active participation of a Commission monitor will not stifle the creativity and innovation of an offeror, but rather, that specific direction and assistance from the Commission staff can assist the offeror in developing a complete and adequate recommended standard. Therefore, the Commission has decided to experiment with broadening the scope of the monitor's responsibility. In the most recent standard development proceeding - for miniature Christmas tree lights - the Commission staff now participates actively in the standard development process and provides extensive guidance and assistance to the offeror. In the miniature Christmas tree light proceeding, prior to publishing a Notice of Proceeding which solicited offers to develop the recommended standard, the Commission prepared and made available to potential offerors a packet of informational materials. This packet included technical, epidemiological and economic information representing the full extent of current Commission knowledge on miniature Christmas tree lights. The packet also contained detailed Commission recommendations concerning promising approaches which could be used by the offeror to develop the standard. The Commission staff also met with potential offerors to answer questions they had about the proceeding and about submitting offers.

After selecting the National Consumers League as the offeror, the Commission provided a team of Commission technical experts to make presentations to the offeror's committees, to provide guidance and to comment as appropriate during the proceedings, and to provide needed laboratory services. Additionally, the Commission, after perceiving the need for technically trained and experienced FEDERAL REGISTER notice writer, is contracting with a qualified person to draft the recommended standard for the offeror. This should assure that the offeror-prepared standard will be submitted to the Commission in the proper FEDERAL REGISTER format.

Although the Commission's new procedure appears to be successful in the miniature Christmas tree light proceeding, the Commission will not be able to fully assess the results until after the standard development is completed. The Commission will use the experience it has gained in this proceeding in formulating the plan for the next standard development it undertakes under the CPSA.

The Commission's original hands-off policy may have contributed to delay in the development of standards by offerors. However, even if the staff had actively participated and guided the offeror, the Commission believes that the timeframes in the CPSA could not have been met. The Commission believes that in most instances the timeframes specified in the CPSA for offeror development appear to be unrealistic.

Each standard development is unique in its complexity and need for specific test provisions and design specifications. In the offeror process, consumer and industry participants must assimilate extensive

technical information and must become accustomed to working together to produce a recommended standard. Although the timeframes specified in the CPSA are used as guidelines, the Commission believes that, if the offeror is to be afforded the opportunity to perform responsibly, the actual development time must reflect the complexity of the subject matter.

The need for additional time to develop standards is demonstrated by the fact that, with the exception of the matchbook proceeding, each offeror has requested an extension of the development time. Further, it has been pointed out by the American Society for Testing and Materials, the matchbook offeror, that in order to meet the statutory timeframes, the offeror did not have certain desirable technical work performed.

The GAO report fails to make clear that the Commission is permitted under the CPSA to extend the development time for good cause. Further, the report fails to make clear the fact that the Commission has published in the FEDERAL REGISTER the reasons for each time extension. To date the Commission has not received a single written comment stating that there were insufficient reasons for granting the time extensions requested by the offerors.

As stated above, the Commission believes that the timeframes specified in the CPSA for developing standards are unrealistically short, and that these times must be determined on a case by case basis, depending on the complexity of the standard.

For example, in three outstanding offeror proceedings concerning power lawn mowers, television receivers and aluminum wiring, the Commission has granted time extensions. The power lawn mower proceeding time was extended 6 months at the offeror's (Consumers Union) request because of the complexity of the subject and the need to allow additional time for post-development review. In addition, it appears that the time may be further extended to allow full analysis of the many technical comments the Commission received. The television receivers proceeding was extended at the offeror's (Underwriter's Laboratories) request by 250 days as announced in the FEDERAL REGISTER on November 4, 1975, due to "...the increasing need for extensive testing and evaluation, the late availability of large amounts of subpoenaed data, the time necessary to analyze these data, and the increasing complexity of the standard...." It was later extended again to allow full analysis of the recommended standard and injury data, as described below. The aluminum wiring proceeding is unique for the reason that the Commission development efforts are in abeyance until the courts determine Commission jurisdiction over this product. In summary, the GAO report criticizes the Commission for the time extensions but fails to address the merits of the Commission's reasons cited in allowing additional development time.

GAO also concludes in Chapter 2 that the Commission has not promptly completed evaluations of safety standards recommended by offerors. GAO attributed this to the need for more and better injury data, the need for procedures that specify the criteria to be used in evaluating recommended standards, and other factors.

In most of the standard development proceedings completed to date, the staff evaluations were based on injury information available to the Commission off-the-shelf and no new injury data were collected. Only in the case of the television receiver standard did the Commission direct the staff to collect and analyze recent injury data in order to determine whether an unreasonable risk still exists in view of apparent recent upgrading of voluntary standards.

It is not feasible to develop rigid step-by-step criteria for evaluating recommended standards because each proceeding presents its own unique technical issues and problems. General guidelines, however, are contained in the Act and in the Commission's procedures for developing consumer product safety standards. In essence, the Commission must determine whether each provision of a standard addresses the hazards set out in the Notice of Proceeding, and whether that provision would be effective in eliminating or reducing the injuries associated with the hazards. The work the offeror submits to the Commission is viewed as a recommendation. The Commission, in publishing a proposed standard in the FEDERAL REGISTER, assumes full responsibility for its technical and legal content. Thus, the Commission analyzes all provisions in the recommended standard to assure that the provisions are technically sound and legally enforceable.

[See GAO note, p. 59.]

The GAO report suggest that the Commission inadvertantly failed to specify the causality of injuries concerned with swimming pool slides and that this contributed to extending the time for Commission evaluation of the recommended standard. The Commission did provide the offeror with about ten accident reports involving swimming pool slide injuries - all of them extremely serious. It was the Commission's specific intent to let the offeror determine the causality of the accidents during the standard development process. Some of these determinations involved expert judgment by specialists in biomechanics and human factors, as well as by orthopedic surgeons and engineers who were members of the offeror's development committees. As discussed earlier, the Commission believed at that time that the expertise and creativity of offerors might be inhibited by active Commission direction. Therefore, it was consistent with the policy at that time to have the offeror determine causality.

The time consumed by CPSC staff in evaluating the recommended swimming pool slide standard was used to verify test procedures and to examine closely some of the complex mathematical models developed by the offeror in support of certain test parameters. These were Commission evaluation activities which are necessary as a result of the Commission's legal responsibilities to ensure that mandatory requirements are needed, reasonable, and defensible in lawsuits.

GAO also criticized the Commission for not exercising its responsibility to determine if unsatisfactory progress is being made in a standard development proceeding. However, on at least two occasions, the Commission

has exercised its responsibility to ensure that satisfactory progress is being made by the offeror in developing a recommended standard.

During the television receiver standard development, the offeror (Underwriter's Laboratories, UL) was required to appear in a public meeting before the entire Commission following a report by the monitor that the standard development was proceeding toward an unsatisfactory end. Specifically, the offeror had attempted to rely heavily on voluntary compliance with existing UL standards rather than having the standard under development stand on its own. During the meeting with the Commission, this apparent conflict with the CPSA and Commission guidelines was resolved, and the offeror was directed to proceed with the development of the standard.

In another case, following a request by Consumer Union (CU) to extend the development period for the power mower standard, the Commission met with CU's Executive Director, and granted an extension for good cause only after CU had demonstrated that it was making satisfactory progress in the development of the power mower standard.

Additionally, even during the period of the hands-off policy, monitors frequently made the offerors aware of situations when committee actions appeared to take a direction which had not been delineated in the agreement between the offeror and the Commission. This helped keep the offeror process on course and helped the satisfactory progress of the proceeding. In addition, contrary to the statement on page 13 of the GAO report, the Commission staff shared with the offerors all information the Commission had regarding the product involved in the standard development, including information on the hazards being addressed.

Recommendation

The GAO report recommends that the Commission establish procedures specifying the duties and responsibilities of its staff monitoring the development of safety standards by offerors. In the proceeding discussion the Commission has shown that prior to this report the Commission redefined and expand the scope of the duties and responsibilities of monitors. These changes have been made as a result of the experience gained in implementing the offeror process.

The GAO report also recommends that the Commission establish procedures that specify the criteria to be used during the evaluation of offerors' recommended safety standards. The Commission has pointed out that a rigid step-by-step approach to evaluation is inappropriate. However, at the beginning of each standard development proceeding, the Commission does provide the offeror with as much information as it has regarding the product and hazard involved, including injury data and information about existing standards and promising approaches the offeror may take. The Commission also makes clear that in issuing a final standard it is bound by the requirements of the CPSA. Thus, the offeror has guidance as to the criteria the Commission will use in evaluating the recommended standard submitted.

Injury Data (Chapter 3)

In Chapter 3 of the report, the GAO makes six recommendations to the Commission. These recommendations are based on two conclusions. First, that the Commission's product injury data base does not adequately support its hazard identification and hazard analysis needs. Second, that the lack of definition of the term "unreasonable risk of injury" has contributed to delays in identifying product hazards and developing safety standards to protect consumers from hazardous products. The first conclusion is addressed in the Commission's responses to the six recommendations, which follow.

[See GAO note, p. 59.]

[See GAO note, p. 59.]

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[See GAO note, p. 59.]

As discussed in the following responses to the six GAO recommendations, long before the GAO report was written the Commission had taken steps to extensively revise its injury information system. A major stage of the revision will begin early in FY78. However, the discussion of the injury information system should be viewed in the context of the Commission's responsibilities under the Consumer Product Safety Act and the other acts the Commission administers.

In deciding whether a product presents an unreasonable risk of injury and whether regulatory action is needed, the Commission of course looks at the probability that the risk will result in harm. The Commission is interested in determining the types of injuries and severity of injuries which may have been associated with the product. It seeks the most complete information reasonably available and thus has developed its unique injury information gathering system.

The legislative history of the CPSA makes it clear that in issuing a consumer product safety standard the Commission does not need proof of actual injuries related to a product before it may issue a safety standard. S. Rep. No. 749, 92nd Cong., 2d Sess. 27 (1972). Moreover, it would be inconsistent with the purpose of the Commission to protect the public against unreasonable risks of injury to read into the Act a qualification that there must be actual injuries in order to issue a standard.

The Commission may issue a standard based on such factors as its analyses of a product for injury potential, its own investigations and judgments, risk-based analyses, or other engineering data. If the Commission were limited to issuing a standard only if it has proof of actual injuries, it would never be able to issue a standard for a product for which there is no injury data even though the product clearly presents an unreasonable injury hazard.

The courts have stated that the Commission's findings as to the nature and degree of risk of injury associated with a consumer product may be based on facts available to it from which it draws reasonable inferences. They have made it clear that a "body count" of actual injuries is not necessary to support regulatory action involving remedial health and safety statutes such as the CPSA.

The statement of Arnold Elkind, Chairman of the National Commission on Product Safety, quoted in the 1969 Senate Report on the Federal Hazardous Substances Act which also provides for the issuance of regulations where there is an unreasonable risk of injury, is relevant to the issuance of standards under the CPSA as well:

> When your intelligence tells you that something will create an injury and that is seems conceptually clear that an injury will occur, it is primitive to wait until a number of people have lost their lives, or sacrificed their limbs, before we attempt to prevent those accidents. S. Rep. No. 91-237, 91st Cong., 1st Sess. 2-3 (1969).

The following are the Commission's specific comments on the six recommendations in Chapter 3 of the GAO report.

Recommendation 1: "Ensuring that the emergency room hospitals included in the injury surveillance system are representative of hospitals with emergency rooms."

Discussion:

The Commission has taken the following steps to ensure that the emergency room hospitals included in the injury surveillance system remain representative of hospitals with emergency room visits. As mentioned previously, these steps were initiated long before the GAO report, and were based, in part, on a Commission staff evaluation of the National Electronic Injury Surveillance System.

A contract to redesign the Commission's National Electronic Injury Surveillance System (NEISS) sample was completed in April 1977. In the first week in August 1977, the Commission approved and funded the NEISS redesign. Implementation of the NEISS redesign is due to start on October 1, 1977. Hospitals in the NEISS redesign are statistically selected to represent a cross section of all hospital emergency room visits in the U.S. and its territories. Considerable effort will be spent, with involvement of top level CPSC personnel, to ensure maximum participation and retention of the primary hospitals selected for the sample. In addition, a reasonable rationale for selecting alternative hospitals and for periodically updating sample hospitals has been provided in the redesign plan. The Commission believes that with the implementation of the NEISS redesign, many of the shortcomings identified by GAO in the section of its report entitled Shortcomings with Selecting of Hospitals will be minimized.

Reservations expressed by GAO under the section entitled Limitations Due to System Design should be tempered by the knowledge that the Commission has always recognized that product-related injuries reported through NEISS do not purport to be representative of other than those injuries that are treated in hospital emergency rooms. Efforts expended by the Commission to complement the NEISS are covered in the Discussion under Recommendation 6.

The Commission has also conducted studies to determine the extent to which product-related injuries are not captured in the emergency room. Such studies relate to specific injuries such as burns and poisonings that may bypass the emergency room or to general product-related injury categories not adequately identified in the emergency room.

The Commission is currently considering whether to capture all product-related injuries that bypass the emergency room but are treated in other hospital units. It is to be noted that if hospitals in the NEISS redesign sample are staffed with personnel primarily devoted to NEISS activities, the potential exists to perform ad hoc special surveys to capture additional data, including product-related illnesses and other health impairments, such as loss of sight or hearing.

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[See GAO note, p. 59.]

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Recommendation 2: Adjusting the hazard index factors to ensure their accuracy and representativeness of injury severity and frequency.

Discussion:

As more experience with the data is accumulated and improvements in the data collection and analysis are intitiated, the hazard index is adjusted accordingly.

The discussion under the section of the report Problems Using the Hazard Index expressed concern with the inadequacy of certain diagnoses made in the emergency room and the inflation of injuries to children. Both of these matters are judgmental and reflect current Commission policy.

For example, injuries to children are inflated in the Hazard Index, in keeping with the Commission's policy to give special consideration and protection to children because children generally are less able to identify and gauge hazards resulting from the use of specific products. Therefore, it is preferable that those hazards be visible to the Commission rather than be understated.

Within the Hazard Index a very high value is placed on poisonings which require in-patient hospitalization. It is also true that many of these hospitalizations to young children are only for observation for which it is later determined that no or negligible ingestion actually occurred. However, since the index attempts to reflect life-threatening situations in addition to the severity of injury, this type of measure should continue.

It should be noted that the Commission uses the Hazard Index primarily as a management tool to identify potential hazards which require further study. It is, therefore, preferable that these types of hazards be illuminated (though possibly overestimated) rather than be overlooked.

However, the Commission acknowledges the need to constantly refine the data. To this end, it awarded in FY77 a contract to undertake a study to provide other measures of severity designed to complement the Hazard Index. To ensure the accuracy and representativeness of injury frequency, the Commission has been engaged in the past in performing quality control visits at the hospitals to minimize biases resulting from under-reporting or misreporting product-related injury data. With the implementation of the NEISS redesign this commitment of resources and personnel will be increased to further reduce reporting biases in the hospitals and will be directed in particular to the staffing and training of personnel primarily devoted to CPSC activities in the hospitals selected for the new NEISS sample.

Recommendation 3: Assigning injury in-depth investigation cases on a random basis to maintain the system's representativeness.

Discussion:

The NEISS gathers product-related data from statistically selected hospital emergency rooms located throughout the nation. From these data, statistically based estimates of product-related injuries treated in emergency rooms are made. Through random selection of NEISS cases, follow-up investigations can be made that will allow inference to the universe of hospital treated emergency room cases.

Two actions have been completed recently by the Commission to provide for specific categories of product-related cases selected for follow-up investigation to be a representative subsample of NEISS.

Consumer products that have been identified through the NEISS and by other means as presenting an injury hazard have been reviewed and ranked by the Commissioners into high, medium, and low priority categories relating to the urgency for corrective action. Commensurate with resource availability, the selected product specific categories and developmental projects provide guidance to the staff for work accomplishments in FY78.

Having established those products receiving priority attention and the adequacy of injury data for each, plans have been developed for conducting follow-up investigation on products for which the data are inadequate. Whenever representativeness of the data is desirable, a random selection process will be employed. This will allow the Commission to develop, on an ad hoc basis, base-line data, make statistically valid projections about accidents associated with specific products, and evaluate the effectiveness of regulatory action.

As a result of the Commission's recent reorganization, there is a more direct relationship between the NEISS cases that are selected for investigative follow-up, the type and extent of the investigative follow-up, and the criteria used in selecting cases. This is being controlled by 8 program managers for specific product categories and staff assigned to support each of the 8 managers.

These teams identify the extent of the in-depth investigation and the manner of investigative follow-up. By determining program priorities and using an appropriate mix of on-site investigations and telephone and other similar approaches, dependent upon the need for data and their planned use, the Commission's injury data needs will be met in FY78.

Therefore, cases for investigative follow-up are specific to the needs of the Commission in specific product categories; are

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randomly selected when this approach best serves the Commission's needs; and when cases are randomly selected, follow-up will not be influenced by resource availability.

The Commission has devoted considerable resources to updating its computerized systems relating to assigning and tracking investigation assignments. In early June 1977, changes to the computer programs were completed to allow the Commission to begin to make assignments based upon a random sampling plan and track these assignments and provide status and appropriate management reports. Prior to this date, random selection of injury incidents had to be handled through a costly manual system. At this time, however, additional resources are still being devoted to make the system fully operational and error free. As the need arises for modifications to computer programs the Commission will devote the necessary resources to assure program efficiency is maintained.

Recommendation 4: Monitoring assigned in-depth investigation cases more closely to verify they are being completed.

Discussion:

A number of steps have been planned and will be in effect in FY78 which will provide for improved management of investigation reports, improve the quality of the reports, provide for an improved consumer response rate and provide for the verification of data validity.

The modified computer program as discussed in the Commission response to Recommendation 3 above will allow for improved management of case assignments. First, only cases of priority will be assigned for follow-up, and where representativeness is desirable, cases will be assigned on a random basis. The type of follow-up will be determined by Headquarters and in many instances data collection formats will be developed specific to the needs of the products receiving review. In this manner the need for essential information, including human factors and behavioral information, will be identified, and the format for its collection provided. Following case assignments, the system will allow for monitoring of the status of the reports from the time of assignment to their completion, receipt in Headquarters and acceptance or rejection of the report.

Insufficiency of support personnel continues to be a constraint in many areas of Commission operations, including prompt follow-up on case assignments and their receipt and processing in Headquarters. This is being corrected to the extent possible by taking steps to assure that the Commission's authorized personnel ceiling is maintained. This will allow the Commission to reach its full complement of personnel and provide additional Field and Headquarters resources to support the investigations program.

During FY 1977, a pilot project was initiated in all area offices to allow the Commission to assess the accuracy of the data as provided by the consumer and reported by the investigator. The project has now been completed and the data are currently being reviewed. Following the analysis of the data and appropriate to the findings, the necessary resources will be made available to implement an appropriate ongoing data assessment program. This will allow for the identification of investigators who have specific needs for additional training and, where desirable, the reassignment of individuals into fields of endeavor for which they are best qualified. The data assessment program should result in an overall improvement in the management of personnel and the quality of reporting.

Field resources have been allocated in FY 1978 to provide for the first level review of all completed case assignments submitted to Headquarters.

Although it is expected that the reports to be received from the new NEISS hospital coordinator program will be of higher quality, the Commission will commit the necessary resources relating to quality control and program feedback. In addition to the monitoring of all cases received by Headquarters, a random number of reports will continue to be selected and analyzed using select evaluation criteria. Whenever a report does not meet the Commission's criteria, the case will be evaluated and rejected. An analysis will be provided the investigator relating any deficiencies needing correction prior to its being considered for acceptance.

Recommendation 5: Training investigators to provide the product-related injury data necessary to identify and analyze product hazards.

Discussion:

Essential to any investigation is the completeness of the data in relationship to the needs of the user of the data. With the concept of Program Managers in the Office of Program Management will come a predetermination of the specific information that is needed for each product type. To provide the investigator with the ability to collect all relevant and needed data through a comprehensive analysis of the incident, guidance and instruction are being provided the investigator in the following manner.

Specific instructions in the form of investigative guidelines will be developed for each product category receiving investigatory attention and particularly those cases selected through the random sample approach.

Through the contract mechanism all currently available investigative guidelines are being reviewed and updated from the viewpoint of the Commission's priorities and current data needs.

The investigators' investigation manual, CPSC Order 9010.24, is slated for complete revision in FY 1978 to improve clarity, and provide for consistency of information commensurate with current policy and improved investigative methodology.

Where the data needs for any product category are unique and specific, structured interview formats are and will continue to be developed to assist the investigator in conducting the investigation with assurance that the data needs are understood and obtained.

In FY 1978, it is planned that field personnel will routinely share with Headquarters the responsibility for all aspects of data collection (e.g., contract administration, training investigators, monitoring of contractors and hospitals performance, first level evaluation of investigation reports, maintaining a data assessment program, involving hospital and consumer public relations, etc.). This will lead to the continuous involvement of those associated with data collection, thus resulting in a greater depth of knowledge about the whole of the data collection program. With an involvement in all aspects of data collection on a continuous basis will come a degree of specialization and provide for increased career development opportunities.

To assure proper management of Field and Contractor data collection activities, resources have been allocated in FY 1978, for the initial orientation of newly hired persons. In addition, a basic investigations training course will continue to be conducted for those involved in injury data collection.

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Recommendation 6: Continuing to search for ways to obtain additional information on the types of injuries not included in the Commission's product-related injury surveillance system.

Discussion:

Although the NEISS, including both surveillance and investigations, will remain the primary source of information available, CPSC recognized the need, as the report notes on page 30, to supplement the NEISS through other sources of information and special surveys. The CPSC, through its Death Certificate Project, since October 1976, has had agreements with all vital statistics jurisdictions within the United States. Although the death certificates often do not include causal information and may not be followed for investigation in some states, this project provides the Commission with necessary specific product-related fatality measures for program planning and establishing priorities. In addition, CPSC is developing a medical examiners and coroners reporting system designed to alert the Commission of consumer product caused deaths.

CPSC will continue to count on newspaper clipping service and the monitoring of the consumer hot-line as methods to alert it of potential consumer product hazards.

The Health Interview Survey supplemental data collected in 1975 are currently being analyzed to calibrate the NEISS and provide broad measures of product-related injuries not treated in hospital emergency rooms.

There are currently no plans to develop any other ongoing data collection procedure. Instead, as data needs arise which cannot be met by NEISS, the Death Certificate Project, or other available sources of data, ad hoc surveys will be considered.

Priorities (Chapter 4)

The report correctly notes that, until recently, the Consumer Product Safety Commission had no systematic mechanism for setting priorities. The report also describes how the Commission has taken several steps during the past 18 months to correct this situation, notably the July 1976 publication of eight priority-setting criteria and the June 1977 designation of high, medium, and low priority product hazards. These actions are not, the report implies, mere ad hoc solutions to a temporary problem. Rather, they comprise a most important step, a comprehensive Commission effort, initiated long before the report was written, to do just what the reports recommends: develop procedures for setting policy and establishing hazard priorities.

The June 1977 hazard designations were part of what was termed a "Mid-Year Review," the first in what is expected to be an annual series of planning determinations by the Commission. This review was and will continue to be a means by which the Commissioners can focus staff resources on high-priority activities in the upcoming year's operating plan. The Commission's FY 1978 operating plan specifically incorporated all decisions made during this review.

Also, the Commission received from the staff and reviewed a Zero-Base Budget for the 1979 fiscal year. Every staff activity, including overhead, had to compete for scarce resources via an objective rating process. New and ongoing product-specific budget candidates were rated according to weighted criteria which closely paralleled the Commission's eight published priority-setting criteria. Weights for these budget criteria were collegially established by the Commissioners. The objective ratings then became the basis for activity rankings and budget decision packages, according to zero-base budgeting guidance received from OMB. The Commission subsequently made product-by-product, activity-by-activity budget decisions. A 2,300-page budget appendix was prepared to provide a public record of how each budget item was rated and ranked by the staff.

The Mid-Year Review and Zero-Base Budget were immensely time-consuming efforts because the Commission had not had previously any systematic means of setting or implementing priorities. Beginning with the 1978 fiscal year, however, the Commission plans to integrate these actions within a scheduled planning cycle, with specific procedures set for each phase of the cycle. The planning cycle calendar and staff assignments will be set by October 1, 1977.

A key element for giving substance to this planning process will be the long-range program plans to be prepared for each of the eight hazard programs during the 1978 fiscal year. These plans will address the major goals, product candidates, process requirements, and unresolved

issues for the various program areas. These plans will have a dual focus, looking partly to the 1980 budget year and partly to the "out" years from 1981 to 1983. As these plans are completed, the Commissioners will discuss key program issues and provide general guidance to the staff. (More specific guidance will be given in the more operations-oriented planning cycle activities.) In future years, these long-range program plans will be updated as necessary, perhaps annually.

The development of a planning cycle is the central, but not only, part of the Commission's increasing effort to set priorities, monitor their implementation, and evaluate their effectiveness in accomplishing agency objectives. A new office has been established to perform many of these functions and report directly to the Commissioners. For example, this office has coordinated staff efforts to develop Commission policies and guidelines for the regulation of chronic hazards (especially carcinogens).

After the Commission has gained experience in this effort, for example, in two or three years, some account may be made as to how successfully the Commission has implemented its priority-setting mechanisms.

[See GAO note, p. 59.]

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Other Comments

A number of improvements have recently been made in the Commission's management information system in an effort to improve management control and cost accountability. In the revised system, all office staffs will be asked to report their time spent on designated budget items, including (but not limited to) product-specific activities. In doing so, they will indicate what hazard program and what function (such as what regulatory stage) is being served by their work. The staff's periodic reports will be used by senior managers and the Commissioners to assure that resources are being spent on activities commensurate with their designated priorities. This revised management information system will be in place by the end of the 1977 calendar year.

The GAO report also criticizes the Commission for not having undertaken development of safety standards for tents and extension cords as of June 30, 1977. However, tents and extension cords were reconsidered by the Commission in the Mid-Year Review, which was conducted prior to June 30, 1977. In the Mid-Year Review, the Commission decided not to develop a mandatory standard for tents due to industry development of voluntary standards, and all efforts by staff were discontinued at that time. The Commission recently received a request from the National Electrical Manufacturers Association asking the Commission to forego the development of a mandatory standard on extension cords because it has prepared an upgraded voluntary standard. The Commission has directed the staff to examine the technical adequacy of the voluntary standard and to report the results of the analysis. It is expected that this report will be delivered to the Commission prior to the end of this calendar year.

Conclusion

As previously stated, CPSC has been in accord with many of the GAO recommendations as indicated by numerous management initiatives and operational revisions which are already in place. CPSC will continue regular evaluations of its regulatory development process in order to ensure maximum achievement of its statutory mission.

GAO note: Deleted comments refer to material contained in the draft report which has been revised or not included in the final report.

APPENDIX II

CONSUMER PRODUCT SAFETY COMMISSION

STANDARD DEVELOPMENT PROCEDURE UNDER

THE CONSUMER PRODUCT SAFETY ACT

(AS DISCUSSED IN THIS REPORT)

Procedural steps	Explanation	Timeframe (note a)
1. Petition (note b)	Interested party requests the Commission to develop a safety standard or ban a product. It includes a justification for why the standard is needed and briefly describes the contents of the proposed standard.	
Evaluate petition	Commission evaluates the petition to either grant or deny it.	120 days
2. Accepted petition	If the Commission determines that an unreasonable risk of injury exists, it grants the petition. It therefore agrees to either initiate developing a safety standard, or if such a standard would not reduce this risk, ban the product.	
Develop notice to proceed	The Commission discusses the need for a standard, how it will address the unreasonable risk of injury, and evaluate existing standards.	"promptly"

a/Timeframes as specified in the CPS Act. The Commission may extend them for good cause.

b/A petition is not necessary to initiate standard development. The Commission can issue a notice to proceed when it believes an unreasonable risk exists.

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Procedural steps	Explanation	Timeframe (note a)
3. Notice to proceed	The Commission issues a notice in which it describes the need to develop a safety standard and invites any person to submit an existing standard or offer to develop one to reduce the risks of injury.	
Develop offer	Potential offerors develop proposals to submit an existing standard or to develop a proposed safety standard in response to the notice to proceed.	30 days
4. Offer	Proposal by a party outside the Commission to either submit an existing standard or offer to develop a new standard that the Commission may issue as mandatory.	
Evaluate offer	If the Commission determines that an existing standard would not reduce or eliminate the risks of injury, then it determines if offers are adequate to reduce or eliminate the risks of injury. If it selects an offer, the Commission starts a standard development proceeding.	30 days
5. Agreement	Formal agreement between the offeror and the Commission explaining how the offeror is to develop the standard. It also discusses the cost aspects (may include the Commission contributing to the offeror's costs), the timeframe, extent of consumer participation, and other requirements.	

Procedural steps	Explanation	Timeframe (note a)
Develop standard	Offeror develops the proposed standard and submits it to the Commission, or if no offer is accepted, the Commission may develop the standard.	150 days
6. Recommended standard	The standard the offeror submits to the Commission.	
Evaluate recommended standard	Commission evaluates the offeror's standard for such things as how it conforms to the agreement's requirements, how it addresses the risk of injury, what is the cost impact, etc.	60 days
7. Publish proposed standard	If the standard is accepted, the Commission publishes it as a proposed standard for public comment and possibly will hold public hearings.	
Consider comments	The Commission reviews, evaluates, and considers comments received.	60 days
8. Issue standard	After considering comments and possibly holding a public hearing, the Commission publishes the standard in the Federal Register for issuance. Standards are to take effect no sooner than 30 days after issuance but not more than 180 days, unless the Commission shows good cause.	

PRODUCTS FOR WHICH STANDARDS WERE OR ARE BEING DEVELOPED UNDER THE CONSUMER PRODUCT SAFETY ACT

as of June 30, 1977

Product	Date CPSC granted petition	Proceeding to develop standard: Date started	Proceeding to develop standard: Hospital emergency room injuries	Date offeror submitted recommended standard	Date standard issued	Days since proceeding started to standard issued (to 6/30/77)	Standard's effective date
Swimming pool slides	10/ 9/73	10/24/74	b/42,000	5/30/75	1/19/76	570	7/19/76
Architectural glass	11/ 1/73	5/28/74	c/187,000	1/24/75	1/ 6/77	954	7/ 6/77
Matchbooks	(a)	9/ 4/74	d/6,200	1/31/75	5/ 4/77	979	5/ 4/78
Power lawn mowers	11/16/73	7/22/74	c/64,000	7/17/75	(g)	1,073	-
Television receivers	(a)	2/28/75	c/12,200	7/ 6/76	(g)	859	-
Aluminum wire	8/11/75	11/ 4/75	e/165	(f)	-	604	-
Miniature Christmas tree lights	(a)	3/31/77	h/734	(i)	-	92	-

a/CPSC started to develop the standard on its own initiative, not in response to a petition.

b/Total swimming pool (not pool slides) injuries for fiscal year 1973.

c/Estimates for fiscal year 1973.

d/Estimated for the period July 1-Dec. 31, 1972.

e/Injuries "reported before Aug. 1974."

f/CPSC rejected offers to develop standard and decided to do it in-house. However, in Mar. 1977 a U.S. district court ruled that CPSC did not have jurisdiction. CPSC is appealing.

g/Not issued as of June 30, 1977.

h/Estimate for all Christmas tree lights in calendar year 1976.

i/Not submitted as of June 30, 1977.

APPENDIX III

APPENDIX IV

PRINCIPAL OFFICIALS OF THE CONSUMER PRODUCT SAFETY COMMISSION RESPONSIBLE FOR ADMINISTERING ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
COMMISSIONERS:		
S. John Byington, Chairman	June 1976	Present
Barbara H. Franklin	May 1973	Present
R. David Pittle	Oct. 1973	Present
Thaddeus A. Garrett, Jr.	Jan. 1977	Oct. 1977
Lawrence M. Kushner	May 1973	Oct. 1977
Richard O. Simpson, Chairman	May 1973	June 1976
Constance B. Newman	May 1973	Feb. 1976
EXECUTIVE DIRECTOR:		
Michael A. Brown	Aug. 1977	Present
Michael A. Brown (acting)	Nov. 1976	Aug. 1977
Vacant	June 1976	Nov. 1976
Stanley R. Parent (acting)	Jan. 1975	June 1976
Frederick E. Barrett (acting)	May 1974	Jan. 1975
Albert S. Dimcoff (acting)	Apr. 1974	May 1974
Frederick E. Barrett (acting)	Dec. 1973	Apr. 1974
John W. Locke (acting)	May 1973	Nov. 1973

(10703)