GEN 55 (REV. 6/74)

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TO (Name and Location)	DATE
* As Listed	August 11, 1977
FROM (Name and Location)	REFERENCE NO.
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Subject: Position Paper on Proposed Medical Surveillance System

The "position paper" on the proposed medical surveillance system is attached for your comments and review. It will accompany the RFA.

Thank you.

Dave Barrett
C. D. Barrett, Industrial Hygienist

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Attachment

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SUMMARY

PROPOSED MEDICAL SURVEILLANCE SYSTEM

In the Chemical Company, relatively large numbers of employees are exposed to various toxic chemicals throughout their work life. Unfortunately, we have only a limited understanding of the chronic health effects of many of these chemicals. Typically, our chronic toxicological information is based on limited animal test data. Particularly noteworthy is the lack of epidemiological studies that correlate medical findings with carefully documented exposure levels and employee work histories. Without such cross validation studies we cannot be assured that we are providing our employees with a safe work environment. Furthermore, we are forced into a position of having to rely on the Federal Government to develop safe exposure limits for our products. Even when the proposed Federal exposure limits appear to be overly restrictive, such as in the case of formaldehyde, we are not in a position to either support or refute the proposal since we lack the necessary epidemiological data. A proposal is discussed for developing a computerized medical surveillance system. The objective of the system would be to link personnel, medical and exposure information in a common data base. Much of this information is already being collected. Such a system would allow the company to closely monitor the health experience of employees in relation to their exposure and work histories. Valuable epidemiological data would be provided.

Computer costs are estimated at $200,000 for development and $20,000 per year for operating expense. Within the Chemical Company, the system could be implemented and maintained with no additional manpower. Corporate Medical would require one additional employee. According to the proposed time frame, development would be initiated during the last quarter of 1977 and the program would be implemented during the second quarter of 1979.

Considering such factors as the volume of data, the complex interrelationships that often exist between occupational illness and causative agent, and the long-term retention requirements for health data, it becomes apparent that without computer assistance "newly discovered" correlations between work environment and disease will be lost in a statistically unanalyzable mass of data.

INTRODUCTION

In the Chemical Company, relatively large numbers of employees are exposed to various toxic chemicals throughout their work life. Protecting these employees from suffering from any acute or chronic health effects is one of our most challenging occupational health objectives.

Acute health effects are often obvious. They can normally be evaluated either by studying accidental exposures in man or by following straightforward animal testing procedures. In contrast, chronic health effects are insidious. They often present no warning signs at the time of exposure and the disease may have a long latency period between actual exposure and development of symptoms. Futhermore, the evaluation of chronic health effects is understandably complex and costly. Serious questions arise concerning the validity of extrapolating animal "chronic exposure" test results to man. It is generally agreed that such test results must be cross-validated by following the health experience of man in relation to exposure. Safe, yet reasonable, exposure limits can be established only after such validation studies are performed.

Unfortunately, we have only a limited understanding of the chronic health effects of many of the chemicals that are produced or used in our plants. Typically, our chronic toxicological information is based on limited animal test data. Particularly noteworthy is the lack of epidemiological studies that correlate medical findings with carefully documented exposure levels and employee work histories. Without such cross validation studies we cannot be assured that we are providing our employees with a safe work environment. Furthermore, we are forced into the position of having to rely on the Federal Government to develop safe exposure limits for our products. Even when the proposed Federal exposure limits appear to be overly restrictive, such as in the case of formaldehyde, we are not in a position to either support or refute the proposal since we lack the necessary epidemiological data. The chemical industry as a whole must take the initiative in developing occupational health programs that will provide the necessary epidemiological data for defining safe levels of exposure. The purpose of this position paper is to describe such a proposed system for Celanese Chemical Company.

PROPOSAL

Description

Figure 1 is a flow diagram of the proposed medical surveillance system. The system would assign appropriate medical surveillance to each exposed employee while linking personnel, exposure and medical records. It would also process hazardous chemical information, training requirements,

and safety and accident data.

A coded "employee data base" would be created to store employee information such as job classification, work location, vital statistics, and other key information. Maintained by Industrial Relations at each plant, the file would be regularly updated to reflect the latest job status of each employee. Specialized medical exam requirements, training requirements, qualitative and quantitative exposure information would all be defined according to a job coding system. This coded information would then be "run against" the "employee data base" to convert the requirements and exposure information to an employee basis (Steps 1-3). In Step 4, the standardized exam requirements would be categorized for input. Steps 5-7 demonstrate an essential medical function of the system. Accordingly, medical exam schedules would be regularly issued at each of the plant locations. The local Industrial Relations Organization would schedule the employees for their exams with the contract physician. The results of completed exams would then be coded for standard input. Other medical information such as morbidity and mortality records would also be categorized. The system would also have the capability of storing hazardous chemical information and safety and accident reports (Steps 9-10). The hazardous chemical file would interface with the existing Toxic Substances Control Act (TOSCA) data file.

All of the information in the program (Steps 1-10) would be "linked" in a common data base. The information could then be retrieved in various formats (Step 11). Table I lists some of the reports that could be provided.

Arrangement of Data

The data would be arranged in the system to allow optimum flexibility (Figure 2). Since occupational health is a rapidly changing field, flexibility is a major system objective. Changes such as the addition of new fields of data could be easily made. Furthermore, with only minimal modifications the program could be later implemented in other companies in the Corporation.

Retrieval Capabilities

The proposed system would be for data base processing and would not include any on-line retrieval or updating of information. It would not require the purchase of any additional hardware equipment.

As illustrated by the reports in Table 1, simple manipulations of data could be performed. However, the system would not initially have the capability of performing complex correlations or manipulations as would be required

in certain epidemiological studies. This later capability would be provided at a later date under a Phase II development project.

Organizations Involved

Charlotte System Services, Corporate Medical, Industrial Relations, Technical, and Product Safety Organizations would be primarily involved in the development and maintenance of the system. Since the medical module is the major component, the Corporate Medical Organization would play a major role in development and maintenance. The Product Safety Organization would be responsible for coordinating the overall program development. Each organization involved would be required to assist System Services in developing the necessary forms and coding systems. This support would be a necessity for success and cost control.

Time Frame

Figure 3 presents the time frame for development and implementation. Accordingly, development would be initiated during the last quarter of 1977 and the program would be implemented during the second quarter of 1979.

Charlotte System Services Computer and Manpower Cost

The Charlotte System Services development cost would be approximately $200,000. This cost would be spread over a three year period as follows:

- 1977 - $ 20,000
- 1978 - $129,000
- 1979 - $ 51,000

Operating costs are estimated at an average of $20,000/year with $10,000 allocated for 1978 and $30,000 for 1979. The higher estimate for 1979 results from the additional expense in initially adding present records to the system.

The Phase II computer development cost for providing sophisticated retrieval capabilities (as would be required for certain epidemiological studies) is estimated at $75,000. This cost would not be incurred until 1981 or 1982 at which time we would begin to have a large enough "pool" of data to be of epidemiological value.

Chemical Company Manpower Requirements

During program development, the Chemical Company and Corporate

Medical Department would have to provide strong manpower support to System Services. Assuming that the present health chemist job assignment is retained as a full time position, no additional Chemical Company manpower would be required during the development and maintenance of the system. It's estimated that one additional permanent employee would be required in Corporate Medical to code medical data.

Time requirements and associated indirect costs during development are estimated as follows:

- Corporate Associate Medical Director - 4 Months
- Product Safety Organization - 5 Months
- Industrial Relations - 15 Months
- Technical Organization - 12.5 Months

Assuming a rate of $50,000/man year, the cost would be equivalent to $160,000. However, it should be emphasized that at least 65% of this "one time" cost would be required in developing an improved "manual" medical examination program. An improved exam program must be developed regardless of computerization.

DISCUSSION

Present and Future Occupational Health Requirements

A responsive occupational health program requires effective hazardous chemical control procedures, a formalized employee training program, a toxicity testing program, the periodic monitoring of employee exposure levels, record keeping of all exposure data, the proper job placement of employees, medical surveillance of exposed employees and the proper analysis of collected data. Most of these components are included in the health standards presently being developed by the Federal Government. The actual Federal requirements will vary depending on the chemical being regulated and on the exposure level of the employee. However, considering our own program objectives and increasing Federal controls, it becomes apparent that without proper management, our occupational health program will not be able to meet our future needs. Some of our most challenging objectives include:

- monitoring the exposure level of the employee throughout his work life with the Company - During the last 18 months, over 500 monitoring studies have been conducted in the Chemical

Company. If sampling requirements are projected over the next 40 years, the volume of data will be staggering.

- providing appropriate medical exams to each employee while closely monitoring employee morbidity and mortality data in relation to exposure - Corporate Medical is presently developing a standardrized "core" examination for all Chemical Company employees. Additional medical tests that are based on job exposure will be developed for certain groups of employees such as all employees that are exposed to benzene. Assuming a 100% participation rate in the exam program, the amount of data collected (including morbidity and mortality information) will be massive over a period of many years.

- maintaining complete work histories on all exposed employees, including such information as job classification, work area assignment, and length of time spent on each job - This objective is especially challenging due to frequent movement of employees from one job to another and due to the changes in chemical processes that regularly occur in the plants.

- long-term retention of medical and exposure records - It is generally agreed that such records should be maintained for periods of time exceeding the life of the employee. For example, the Federal Asbestos Standard requires that records be kept for at least 40 years.

- developing the necessary safe handling and toxicity information on new chemicals being introduced in our plants

Deficiencies of Existing Occupational Health Program

Major deficiencies include:

- Difficulty in maintaining exposure records on an "employee basis"

- Inability to maintain complete work histories on exposed employees

- Limited medical surveillance of exposed employees. Specific problems include low participation rate (less than 50%),

"general type" exams not based on chemical exposure, failure to evaluate morbidity and mortality data, and difficulty in using exam results for proper placement of employees

- Difficulty in retrieving information from manual files and in correlating related health data

- Lack of effective procedures in monitoring the purchase of new incoming hazardous chemicals

Limitations of a Manual Program

The computer will certainly not solve all of our problems. Such activities as developing specialized medical exams, scheduling employees for physicals and monitoring employee exposures will not require computerization. However, for this accumulated information to be meaningful, it must be related. For example, an employee illness, such as a blood disorder, cannot be properly evaluated by the physician unless the employee's work and exposure history are known. Similarly, exposure data is of limited value in determining the safety of a job unless that exposure information can be related to the health experience of the employees performing the job. Considering the volume, interrelationships, and long-term retention requirements for health data, it becomes apparent that without computer assistance "newly discovered" correlations between work environment and disease will be lost in a statistically unanalyzable mass of data.

Advantages of Computerization

Computerization would provide five essential functions:

- Storage of data

- Linkage of personnel, medical and exposure records (and other related health data)

- Manipulation of information into analyzable categories

- Correlation of the categories to answer important occupational health questions

- Retrieval of data

Program Benefits

A computerized medical surveillance system is a costly, long term project. However, the benefits of such a program are significant.

- Preventive medicine is the major justification for development. Realizing the deficiencies that exist in the toxicity information on many of our chemicals, we must structure our occupational health program so that we can either prevent occupational illness from occurring or identify such illness at the earliest possible stages of development. Such "program sensitivity" can be achieved only by closely monitoring the health (and mortality) of our employees in relation to their exposure and work history. Often complex interrelationships exist between occupational illness and causative agents. These interrelationships can be identified only as a result of epidemiological research studies. An example is given in Figure 4. Such a hypothetical study that could correlate long-term exposure to formaldehyde with morbidity and mortality data would provide valuable information to the Company. Other examples include monitoring employees in Pampa that worked with BPL or monitoring the health experience of female operators that work in chemical units. Similarly, important medical questions could be answered. For example, suppose that an employee is suffering from a serious illness such as lung cancer. What is the employee's work and exposure history? Are there any other cases of illness among the employee's exposure group? Should an epidemiological study be initiated among employees in the work area?

- Legal protection is a second justification for development. Certainly, OSHA does not require that we develop a computerized program. However, such a program would assist us in complying with many specific requirements such as monitoring, medical surveillance, record keeping and chemical labeling. The system would also offer protection against unreasonable compensation claims.

- In future years, the program would assist Celanese in establishing safe levels of exposure for our products. The proposed program would be a complimentary component to our existing animal toxicity testing program. Together, the programs would permit us to cross-validate animal toxicity data by monitoring the health experience of employees in relation to exposure. Such

action should assist in preventing unreasonable health standards from being developed by the Federal Government. The cost to the chemical industry in lost productivity due to overly restrictive exposure standards can only be estimated; however, the figure could be staggering in future years unless industry develops the necessary animal and human toxicological information for establishing safe, yet reasonable, exposure standards.

Programs Being Developed in Other Companies

Many chemical companies are actively involved in the development of computerized occupational health programs. Examples include DuPont, Shell, Monsanto, Union Carbide, Standard Oil, Ciba-Geigy, and others. Shell Chemical Company has already approved an expenditure of $750,000 during 1977, and anticipates spending 5 million dollars in the next five years. Dow has been involved in medical computerization programs for years. For example, they have coded mortality data since 1940 and coded morbidity data since the late 1960's.

Why Not Purchase a Commercial Program?

Commercial programs are being marketed by several companies, the most publicized being Amoco Computer Services. This program was developed by Standard Oil of Indiana at a cost of approximately 1 million dollars. The program, which sells for $150,000, is grossly over complicated and is incompatible with our hardware. After looking at numerous programs, we are convinced that an internally developed program will be the most effective and cost efficient.

Is It Really Necessary to Develop the Complete Program, Now?

Several alternate proposals have been considered. However, unless a program is capable of linking medical, exposure and personnel records, it will be of limited value. The fact that many chemical companies are presently developing such programs is no mere coincidence. In recent years, it has become obvious that the Federal Government cannot establish safe, yet reasonable, exposure standards with the existing store of animal and human toxicological information. Futhermore, controversies surrounding chemicals such as kepone, vinyl chloride, asbestos, methyl butyl ketone and others have convinced most occupational health personnel that the time for development of medical surveillance systems is long overdue.

CONCLUSION

The question is not whether we will be collecting health data, but rather, whether the collected data will be in a usable, retrieval form that will be of any real value to the Company. The proposed medical surveillance program would have the capability of storing, categorizing, correlating and retrieving health information. Hopefully, with proper analysis of data, we would be able to either prevent occupational illness from occurring or identify such illness before it has significantly affected the health of our employees. Furthermore, the proposed system would assist in complying with Federal regulations and would enable the Company to play a significant future role in establishing safe, yet reasonable, health standards.

TABLE I

MISCELLANEOUS REPORTS THAT COULD BE PROVIDED

EXPOSURE DATA ON EMPLOYEE BASIS.

EMPLOYEES REQUIRING SPECIALIZED MEDICAL SURVEILLANCE.

EMPLOYEE WORK HISTORY.

EXAMINATION SCHEDULES, WORKSHEETS, ETC.

COMPLETED EXAMS BY LOCATION.

EMPLOYEES REQUIRING SPECIALIZED TRAINING.

REQUESTED EPIDEMIOLOGICAL REPORTS (MORBIDITY DATA BY JOB TYPE).

ACCIDENT REPORTS (BY CAUSE, ETC.).

REQUESTED MEDICAL REPORTS (SUCH AS EMPLOYEE EXAM HISTORY PROFILE).

SIMPLIFIED FLOW DIAGRAM OF PROPOSED MEDICAL SURVEILLANCE PROGRAM

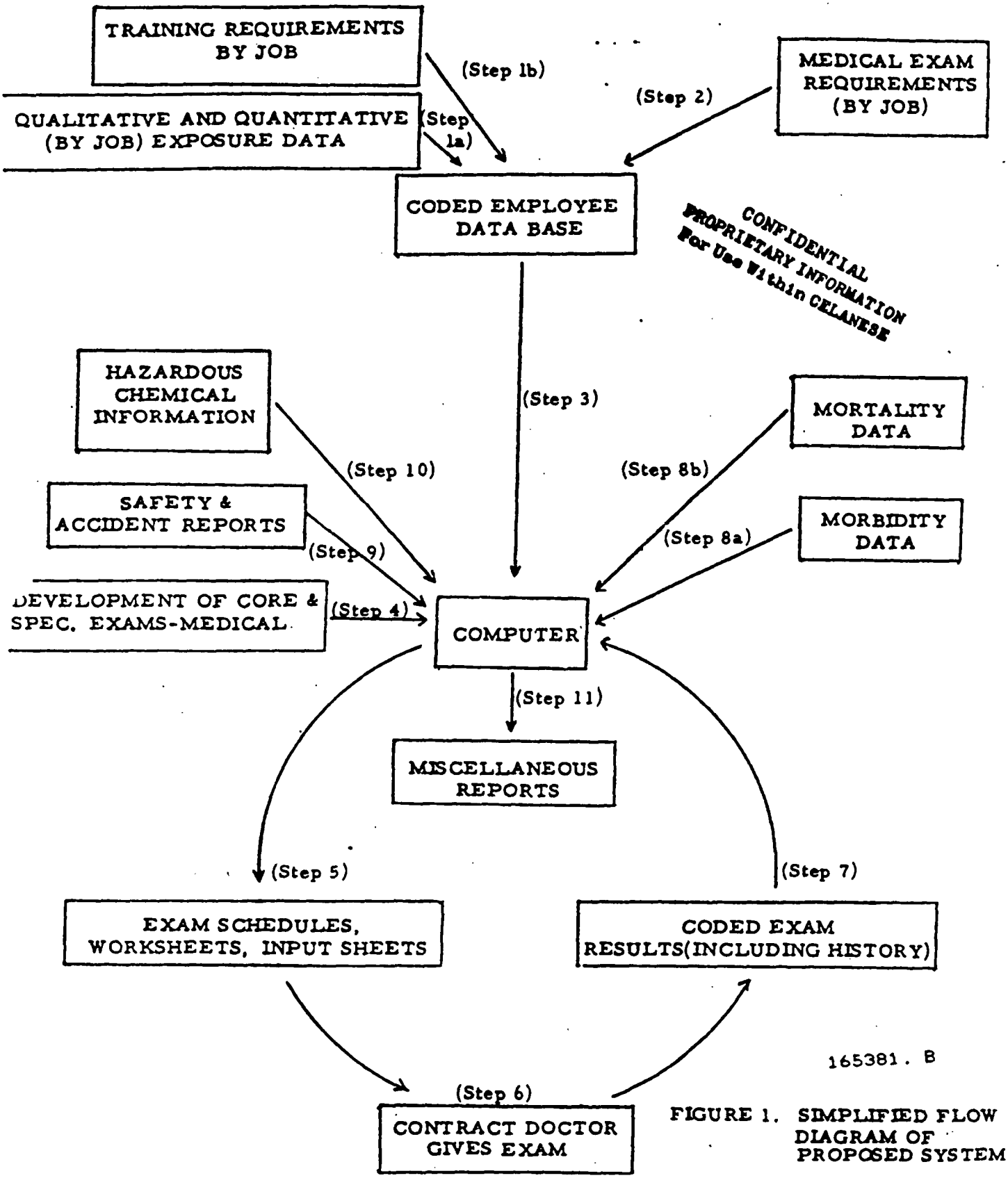

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FIGURE 1. SIMPLIFIED FLOW DIAGRAM OF PROPOSED SYSTEM

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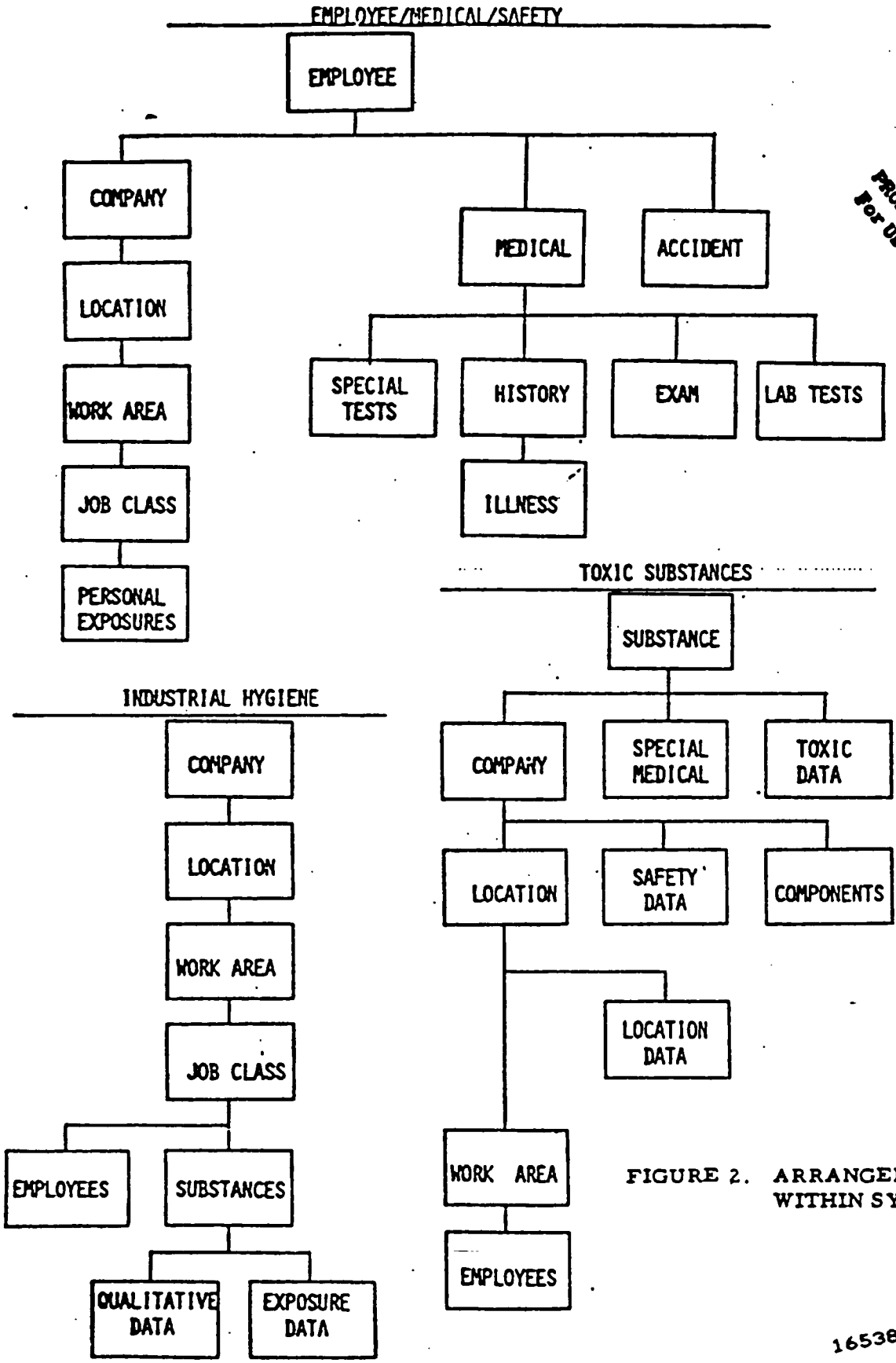

FIGURE 2. ARRANGEMENT OF DATA WITHIN SYSTEM

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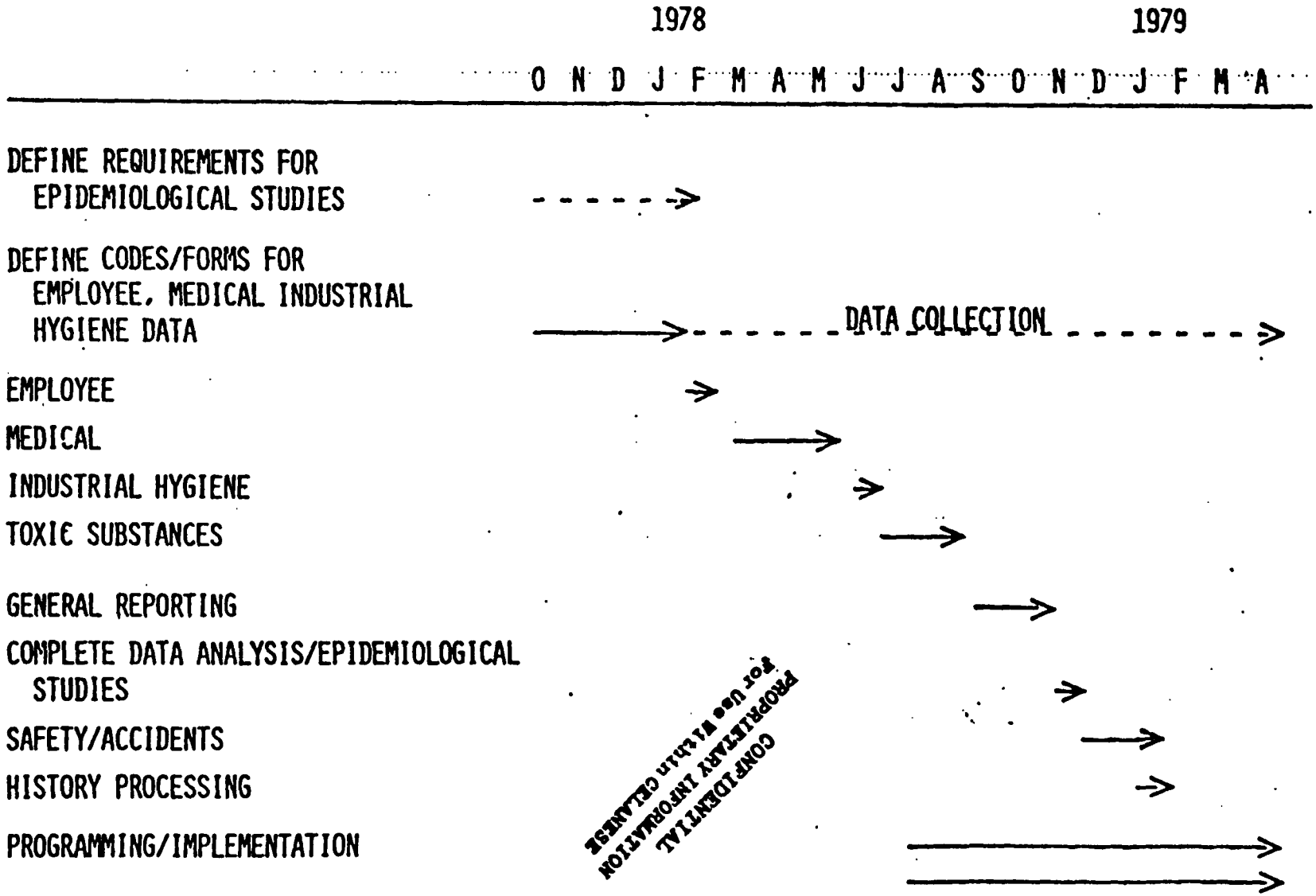

FIGURE 3. PROPOSED TIME FRAME FOR DEVELOPMENT AND IMPLEMENTATION

DEFINE A POPULATION:

. MALES, OVER 40

. WITH 20 YEAR EXPOSURE TO FORMALDEHYDE

. CIGARETTE SMOKERS

CORRELATE:

WITH DIAGNOSIS (RESPIRATORY ILLNESS, SKIN DISORDERS, CANCER, ETC.)

WITH CAUSE OF DEATH (DEATH CERTIFICATES)

WITH RATE OF ABSENTEEISM (DUE TO SICKNESS, INJURY)

FIGURE 4. A HYPOTHETICAL EXAMPLE OF AN EPIDEMIOLOGICAL STUDY OF EMPLOYEES EXPOSED TO FORMALDEHYDE