

DSDTT Priority System for
Occupational Safety and Health Document and Research Needs

Prepared by

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16. Abstract (Limit: 200 words) A priority system has been developed for the Division of Standards Development and Technology Transfer and for NIOSH to recommend and provide the rationale for determining what research to conduct, what documents to develop, and what standards to recommended. The factors which distinguish this new priority system from the old one were three fold. First, the new system identifies and recommends priorities for subjects which warrant documentation of occupational safety and health hazards and calls for the issuing of formal recommendations and guidelines. Secondly, the system, and therefore the recommendations made under the system, carry with them the support of the Priority Rationale Statement. Thirdly, the existing Current Awareness System of the Priorities and Research Analysis Branch will be integrated with the information retrieval and occupational safety and health surveillance programs of NIOSH, rather than remaining independent as they had been in the past. Appendices included information concerning the identification of hazardous substances from specialized data bases, parties to be invited to nominate subjects for evaluation, surveillance input into priorities selection processes, requests for information from NIOSH divisions and regions on industrial hazards, the Federal Register notice requesting information for profile preparation and evaluation, and a description of a profile.			
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Preface

With passage of the Occupational Safety and Health Act of 1970 and the Mine Safety and Health Act of 1977, major steps were taken toward securing safe and healthful work environments. The Occupational Safety and Health Administration (OSHA) of the Department of Labor was given the responsibility to promulgate and enforce safety and health standards applicable to the work environment. The Department of Health, Education, and Welfare (DHEW), now the Department of Health and Human Services (DHHS), with the establishment of the National Institute for Occupational Safety and Health (NIOSH), was given the responsibility to provide the scientific basis or criteria for these standards. NIOSH provides this scientific basis through research directed toward eventual recommendation of safety or health standards.

Early in the development of criteria documents, which convey NIOSH's formal recommendations for occupational safety and health standards, NIOSH recognized that its limited time and resources had to be utilized to the best advantage. With this recognition, the Division of Criteria Documentation and Standards Development (DSDCD) developed a priority system for its documents. The priority system described herein, for documents and research, is a refinement and extension of the initial system.

The Division of Standards Development and Technology Transfer (DSDTT), the successor to DCDSD, has been evaluating the development process and content of criteria documents. An issue central to their development is the process used to select subjects. A report entitled Evaluation of the NIOSH Criteria Documentation Program, prepared in 1979 under contract by Policy Research Incorporated (PRI), focused attention on priority setting for criteria and other information documents. Indeed, the first five of nine recommendations to improve the criteria document program relate to priority setting and information gathering. The last four recommendations pertain to criteria document development and address the quality and desirable content of the documents.

In the summer of 1981, the Division's Priorities and Research Analysis Branch (PRAB) was asked to develop a conceptual model for a new system to set priorities for (1) documentation of occupational safety and health hazards and (2) Institute research. The outlined model submitted was approved by the Division in September. PRAB was then asked to develop the model into a working system. The five recommendations of the PRI Report relating to document priorities are addressed in this new priority setting system. They are:

1. Development of two types of documents, one to meet OSHA and Mine Safety and Health Administration (MSHA) needs, the other informational.

The new priority system will identify subjects for criteria documents as well as other document needs. Also, the system presented herein will provide two channels through which OSHA and MSHA can input their priorities.

- (a) Routine, non-crisis hazards by annual nomination. Nomination in this case will be sought by letter and by NIOSH liaison members who are already actively communicating with their counterparts in OSHA and MSHA. Such nominations will go through the system in a routine manner. The Priority Rationale Statement described herein for the nominated subject will reflect the importance placed on it by OSHA or MSHA.
- (b) Emerging OSHA/MSHA concerns, including standards updating. These can be submitted at any time and can be introduced into the priority system through its current awareness activity and update cycle.

2. Improvement of coordination efforts between NIOSH and the other Federal agencies.

NIOSH at this time has active membership in working committees of the Toxic Substances Control Act Interagency Testing Committee (TSCA ITC), the National Toxicology Program (NTP), OSHA, and MSHA. NIOSH staff on these committees will be "recruited" on behalf of PRAB to coordinate and solicit nominations more actively. The Current Awareness System described herein will ensure that information on activities of other agencies are considered in subject screening, research analysis, and preparation of Priority Rationale Statements.

3. Nominations from knowledgeable sources in the private sector and the Federal government.

After several years of soliciting nominations in the Federal Register, it has become clear that this input alone is not adequate or sufficiently comprehensive to cover all hazards in the workplace. Parties responding to Federal Register solicitations often nominate subjects relevant only to their individual interests and concerns. These nominations must be augmented to guarantee adequate coverage of hazards. Early in the process, letters will be sent to specific parties in the private and public sectors to indicate NIOSH's resolve to solicit information. Also, notices of substantial risk to health or the environment sent to the Environmental Protection Agency (EPA) from the private sector (manufacturers or processors) will be used as one of PRAB's sources for nomination of candidates. The Current Awareness System, which tracks emerging exposure and effects information, includes other private sector activities that can trigger nominations. Based on subsequent acquisition and analysis of information, the field of subjects can be narrowed. Solicitation of information in the Federal Register on these specific subjects will be more productive than a general call for information.

4. Improvement of health recordkeeping.

The improvement of health recordkeeping is not in itself a function of any priority system. However, this system uses health data, when available, to help identify hazardous agents and to initiate searches for

information. NIOSH is the leader in collecting occupational health and exposure data nationwide using standardized procedures, such as the Registry of Toxic Effects of Chemical Substances (RTECS), National Occupational Hazard Survey (NOHS), National Occupational Exposure Survey (NOES), NIOSH Technical Information Center (NIOSHTIC), and when it becomes available, National Occupational Hazard Survey for Mines (NOHSM).

5. Flexibility in determining the number of criteria documents.

The priority system will not yield a predetermined number of recommendations for criteria document development. The multiplicity of possible actions to be recommended ensures that health concerns will be addressed and critical information transmitted, even when criteria documentation may not be necessary or possible. The novelty of this priority scheme is its design to simultaneously address different types of priorities (i.e., research and document needs).

Other issues raised in the PRI Report that relate to priority setting include the establishment of an external advisory group and setting priorities on a five-year basis.

An advisory group is not precluded in this priority system. Before the Institute Director approves the priorities recommended to him by DSDTT, an advisory group could review the recommendations and their justification, and approve or disapprove. Experience in other priority setting exercises, (such as NTP, TSCA Interagency Testing Committee, and National Cancer Institute's Chemical Selection Working Group), shows that such an advisory group must have a high level of expertise in various fields and must be able to transcend political considerations. Several alternative routes for expert review can be envisioned, for example, using one of the existing advisory groups such as NIOSH's Senior Advisory Staff, or the National Advisory Council on Occupational Safety and Health (NACOSH).

The five-year priority setting requirement is not practical or necessary. The priority system will address explicitly both document and research needs annually. Documents will not be recommended unless the prerequisite data are available. Research will be recommended to fill information gaps. Further, one priority may be conditional on the results of another. For example, recommendations for toxicity testing of a chemical may not receive high priority until worker exposure potential is assessed.

In developing this proposal for the DSDTT Priority System for Occupational Safety and Health Document and Research Needs, the PRAB staff identified two issues which require further development before full system implementation:

- o The system is intended to accommodate both safety and health issues. The input of safety issues and data into the system is currently under development with the Division of Safety Research (DSR). Safety hazards will be handled in a manner analogous to that developed for health hazards, described herein.

- o The system utilizes extensive input from the Institute's surveillance activities. In addition to use of NOHS, NOES, NOHSM (when available), and Health Hazard Evaluation (HHE) data, mechanisms are being developed to input occupational disease endpoints from surveillance activities, reports of vital statistics, morbidity and mortality studies, and other sources of safety and health information. Methods are being explored to incorporate such information in early screening steps of the system, and the Institute's perception of the major occupational safety and health issues can be reflected in the recommendations for priorities and their justification.

Several other issues that should not be resolved at the Division level but should be addressed by Institute management during review of this proposal are:

- o The system does not provide specific opportunity for input or review by the NIOSH Senior Advisory Staff, although Institute management may desire this. After review of this proposal, Institute management possibly will exercise its prerogative in this matter.
- o The system is intended to provide a scientific and technical basis for recommending Institute priorities. Other factors, such as availability of relevant expertise and allocations of resources, must be addressed by Institute management, Office of Program Planning and Evaluation (OPPE), and Division Directors in developing Institute plans.
- o The PRAB staff has deliberated on the advisability of having greater participation of NIOSH Divisions in the analysis and decision-making steps of the process. To initiate the system and operate it in a timely fashion will be an enormous task; having NIOSH-wide ad hoc or standing committees involved in analysis and screening during system start-up would be overly burdensome. It should be remembered that all affected components of NIOSH have several opportunities in the cycle to input subjects and comment, and that, importantly, products of the system are only recommendations. Broader NIOSH participation in screening and analysis can be sought after initial implementation of this plan.

Synopsis

A new priority system for the Division and the Institute is being developed within the Priorities and Research Analysis Branch, Division of Standards Development and Technology Transfer (PRAB, DSDTT). The goal of this priority system is to recommend and provide the rationale for priorities for Institute research, document development, and recommendations for standards to be forwarded to OSHA and MSHA. The new priority system differs considerably from previous Institute priority systems. The distinguishing aspects of the new system are:

1. The new system will identify and recommend priorities for subjects warranting documentation of occupational safety and health hazards and issuance of formal recommendations and guidelines. The system will also identify priorities for subjects deserving research designed to provide information for more complete hazard assessment or for hazard amelioration. Former priority activities of the Division focused primarily on subjects for criteria document development.
2. Each recommendation of the new system will be supported by a Priority Rationale Statement, accompanied by an information profile. Formerly, the scope of a problem was not adequately defined and subjects were not adequately justified.
3. The new system will integrate PRAB's existing Current Awareness System and research analysis capabilities with information retrieval and occupational safety and health surveillance programs of the Institute. Formerly, priority activities were conducted independently of other information retrieval and surveillance activities in the Institute.

The system will operate on an annual cycle so that its output can be utilized in Institute program planning. It establishes a mechanism for frequent input from NIOSH research programs and the current awareness activity. It will rely on information retrieved by the NIOSH Clearinghouse and will employ extensive research analysis by PRAB staff, sometimes augmented by analysis resources available to PRAB through an existing interagency agreement. These activities will make it possible to integrate emerging problems into the system as they arise.

The body of this document describes the goal, objectives, and essential features of the system. Most features are described only briefly in the text (with detailed descriptions in the Appendices), so the reader may focus on the logic and sequence. There are exceptions: subject scoring (screening), standards and recommendations update cycle, and preparation of Priority Rationale Statements. These are explained in the text, as they represent priority setting approaches or components new to the Institute.

The design of a priority system must consider at a minimum the kinds of information available, the applicability of the information, and the methods of analysis of the information. The process that yields the priority subjects should provide a clear and defensible selection which should reflect the knowledge and expertise of the occupational safety and health community at large. The system should also demonstrate awareness of information gaps, and as these gaps are recognized and filled, the system should be capable of adapting accordingly. These desirable characteristics will be present in the new system. Some of the specific features of the system include:

- 1) Initial input. The annual cycle will be initiated with three simultaneous activities: a) soliciting from knowledgeable individuals in other Federal agencies, academia, industry, labor, and professional societies subjects they believe warrant NIOSH's attention, b) programming of existing computerized data bases, including NIOSH's RTECS, the EPA's Chemical Substances Inventory (EPA Inventory), and NIOSH surveillance files (e.g., NOHS) in order to identify a large number of chemicals which later can be screened to yield a subset of subjects of probable concern, and c) contacting NIOSH divisions and regional offices for their nominations; this will be augmented by input from PRAB's Current Awareness System. A list of chemicals and other subjects (numbering perhaps a few thousand) will be generated by combining nominations, industrial chemical agents with known serious effects, and emerging concerns from the Current Awareness System. A set of computer-based abstract chemical profiles, which can be obtained presently from RTECS and PRAB current awareness files, will be produced for each chemical on this list. Abstract profiles for subjects other than single chemicals will be prepared from the respective nominations.
- 2) Continuing input from NIOSH divisions and regional offices. An informal mechanism for frequent input into the Current Awareness System, and hence the priority system, will be established. PRAB Priority Cards will be distributed to divisions and regional offices for use by researchers and field professionals to report new problems or information they encounter. Conveying this information to PRAB would be at the discretion of the individual investigator.
- 3) Subject scoring (screening). Scoring by PRAB will provide an initial screen to reduce the number of subjects to a manageable number (approximately 100) for further investigation and analysis. Based on information contained in abstract profiles, each chemical will be assigned numerical scores for production volume, size of the potentially exposed worker population, and toxicity. An alphanumeric score will be used to reflect the amount of toxicity information available and to identify the critical health effect(s). Analogous appraisals will be made for subjects other than single chemicals. The scoring exercise will yield a preliminary list of candidates for profile development.

- 4) Solicitation of further information. Preliminary candidates will be submitted to the NIOSH Clearinghouse, DSHEFS, DBBS, DRDS, DSR, and NIOSH Regional Offices for additional, more specific information on production, importation, market trends, uses, estimates of exposure, toxicity, and other adverse effects. After review of this additional data, further investigation of some of the preliminary candidates may be deferred. The remaining, or final list of candidates for profile development, could include 50-100 subjects. This list will be published in the Federal Register with a "Request for Information," to which all interested parties will be invited to respond.
- 5) Profile preparation. Information profiles that characterize the nature and extent of information available will be prepared for each subject. All identified information pertinent to a subject will be used to prepare a profile. Through an interagency agreement, PRAB can augment its own manual searching and analysis capabilities to develop profiles quickly for a small number of subjects which may enter the cycle late, but warrant serious consideration.
- 6) Analysis and Priority Rationale Statements. A scientific review of each information profile and supplemental scientific papers and reports will be required in the development of Priority Rationale Statements (PRSs). Each PRS will describe the conclusions of PRAB reviewers on each subject and will address the strength of data available for document development and information gaps that identify research needs. Specific health endpoints will be evaluated for each subject. Relevant findings of toxicity or other adverse effects will be related to information on exposure and production to (1) identify occupational safety and health issues and (2) determine appropriate NIOSH activities to address each problem.
- 7) Ranked priority lists. Specific document or research needs, identified in the PRSs, will be categorized and placed on one or more of the following lists: (1) document development, (2) field studies, (3) biological and behavioral studies, and (4) physical sciences and engineering. Entries on each list will be ranked according to high, medium, or low priority, based on the extent and severity of the potential workplace hazard. A cover memorandum will explain the ranking of entries on the lists and direct attention to the respective PRSs for specific information.
- 8) OSHA and MSHA standards and NIOSH recommendations update cycle. An independent selecting process will be applied to subjects for which OSHA or MSHA standards have been promulgated and/or NIOSH has published formal recommendations. A subject will be considered a priority candidate if new information from selected sources indicates a change is needed in OSHA, MSHA, or NIOSH positions.

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DSDTT Priority System for Occupational Safety and Health Issues

I. BACKGROUND

In the past, the division emphasized the development of criteria documents. Subjects for criteria documents were selected initially from a ranked list prepared in 1972. The ranking was determined by multiplying the estimated number of workers exposed by a severity rating assigned by a panel of experts. This system worked reasonably well in that it identified some major hazards that needed to be addressed, but the field of occupational safety and health was also undergoing rapid expansion. New sources of information, such as the results of the National Occupational Hazard Survey (NOHS) and the National Cancer Institute's Carcinogenesis Bioassay Program, needed to be examined. A formal priority setting system gradually evolved. Since 1977, this system has contained the following elements:

- . Solicitation of criteria document nominations from other divisions.
- . Screening of nominations and preparation of internal hazard summaries.
- . Request for information in the Federal Register and other selected sources.
- . Preparation of information profiles on the nominated subjects.
- . Requests to NIOSH research divisions and OSHA for review and comment on information profiles.
- . Recommendation to and final selection by NIOSH Director of subjects for criteria documentation.

Topics for special hazard reviews and literature updates were selected by separate informal mechanisms. Subjects for special hazard reviews were selected in response to requests for information from OSHA, from special problems identified in criteria documents or Current Intelligence Bulletins, and from nomination forms submitted by individuals in NIOSH. For literature updates, each NIOSH division was asked to nominate subjects which were then examined to determine if an update was necessary.

Limitations of the existing priority system include:

- 1) Institute priorities were identified only with regard to document development, and no research needs were identified.
- 2) It has resulted in some criteria documents that have been criticized as being unnecessary or trivial, one example being carbon dioxide, which is a widespread contaminant but which has relatively minor health effects.

- 3) It has identified criteria document efforts where data were insufficient to complete the project or to permit NIOSH to come to meaningful conclusions.
- 4) The Institute's surveillance programs and current awareness capabilities were not fully utilized.
- 5) The priority system did not allow the research divisions to fully avail themselves of current awareness and research analysis capabilities in DSDTT.

-II. GOAL AND OBJECTIVES OF DSDTT PRIORITY SYSTEM

The ultimate goal of the Institute priority system should be to identify the most significant occupational safety and health issues and to reduce work-related injuries and illnesses as much as possible with available resources. The process of identifying significant occupational safety and health issues should also identify where and by what method the greatest reduction in injuries and illnesses can be achieved. This new priority system is directed toward that ultimate goal by identifying those agents or factors likely to be the most important etiologic agents or determinants in occupational injury and illness.

The goal of the proposed priority system for DSDTT is to recommend and document the rationale for priorities for Institute research, document development, and recommendations for standards. The proposed system annually will provide the research divisions with priorities for their consideration in project development as well as provide DSDTT with priorities for consideration in document development.

Two distinct but interrelated objectives are proposed. One objective will be to provide recommended subjects for documents intended to convey formal NIOSH recommendations, including recommendations for occupational standards. This will establish a documented list of priority subjects for the orderly adoption, scheduling, and initiation of document projects by DSDTT.

The other objective will be to provide the Director, NIOSH with documented recommendations for NIOSH intramural and extramural research. The purpose is to assist research divisions in identifying subject areas where new research efforts could provide information useful in ameliorating occupational health hazards, even if the subject is not yet a priority subject for document development by DSDTT. In this way, research divisions would be informed of information gaps, problem areas, and emerging issues. Institute management and OPPE could then review from their management and

funding viewpoints proposed project plans, as submitted by the research divisions, in the context of the availability of data and future NIOSH needs. Also, such a priority list may suggest opportunities for interdivisional collaboration.

III. CONCEPTS

A. General

The priority setting activity will be supported by current awareness and research analysis activities of PRAB and through cooperation and collaboration with surveillance resources throughout the Institute. The product is proposed to consist of four lists of document or research needs. One list will contain the priority subjects for document development. The other three will contain priority subjects for research in 1) field studies (of interest mainly to DSHEFS, DPSE, DRDS, and DSR), 2) biological and behavioral studies (of interest mainly to DBBS and DRDS), and 3) physical sciences and engineering (of interest mainly to DPSE and DSR). The lists will be accompanied by a set of Priority Rationale Statements (PRSs), with one PRS prepared for each subject. The PRS will provide identification and justification of the document and/or research needs, and will be accompanied by an information profile. It is anticipated that a particular subject may appear on more than one priority list. The PRSs accompanying the lists will provide the users of the lists a means of evaluating relative importance of the recommended priority while weighing their other decision factors.

The recommendations from this activity will be forwarded from the Division to the Institute at the close of the first quarter of any given fiscal year. The recommended priorities will thus be available for consideration during the planning activities throughout the year, for implementation the following fiscal year.

The acquisition and analysis of data available to NIOSH through its numerous sources will yield subjects from which a manageable number (consistent with Institute resources) will be selected by PRAB for further consideration. This initial selection will be based on numerical scoring, which is acknowledged to be only a crude selection process. Information concerning the subjects on the subsequent preliminary list of candidates will be sought throughout NIOSH. Simultaneously, suggestions for other candidates will be sought. After reviewing all incoming information, PRAB will develop a final list of subjects for profile preparation. Comments on this list will be solicited through the Federal Register. The contractor(s) or Clearinghouse will then develop information profiles.

Based on the information gathered, PRAB will:

1. Develop final information profiles.
2. Identify needs for documents and/or research.
3. Prepare drafts of the Priority Rationale Statements.
4. Compile four draft priority lists: Document Development, Field Studies, Biological and Behavioral Studies, and Physical Sciences and Engineering.
5. Submit draft priority lists, PRSs, and profiles to DSDTT for review and approval.
6. Submit final approved lists and accompanying PRSs to the Director, NIOSH, for review and further action.

The priority setting system is proposed to operate on an annual cycle in order to identify projects which are usually funded annually. However, it should be noted that some subjects will remain priority subjects for more than one year. In addition, since most of the preparation of the priority lists will be performed in-house and will rely on current awareness activities, it should be possible to integrate emerging problems into the system as they arise.

A flow diagram illustrating the essential features of the priority system is presented in Fig. 1, at the end of the Appendices.

B. Approaches for Establishing System Inputs

PRAB proposes several simultaneous activities for initiating the annual priority setting cycle:

1. Examine existing data bases containing occupational exposure and health effects data.

An existing routine subsystem for the identification of hazardous substances from specialized data bases has been described. This is represented in box 2 of Fig. 1 and described in Appendix A. In order to identify substances in commercial use in the U.S. which have some chronic and/or acute effects, RTECS will be matched by computer with the EPA Inventory. In addition, chemicals with human, carcinogen, teratogen, reproduction, or mutagen citations in RTECS, but not on the Inventory, will be added to the matched list to ensure that agents with these reported harmful effects are not missed. To further identify chemicals which have occupational exposure information, a match with NOHS will be conducted.

2. Solicit information from knowledgeable sources outside of NIOSH.

At this time the initial nominations of safety and health hazards will come from specific source solicitations outside of NIOSH. These nominations will be solicited from industry, labor, academia, professional societies, other Federal agencies concerned with general industry and mining, or from individuals having specific concerns about occupational safety and health problems. This is represented in box 1 of Fig. 1 and is described in Appendix B.

3. Respond to immediate concerns:

(a) Current awareness information generated from monitoring literature, research results, and other agency activities will be channelled into the priority system and will provide continuous update. This is represented in box 3 of Fig. 1. See Appendix C for a detailed description of the Current Awareness System and its components, the current awareness files, NIOSH computerized files, and the Toxicology Information Response Center (TIRC).

(b) NIOSH divisions and regional offices will be contacted for their nomination/input into the priority setting process (See Appendices B and D). Nominations must be made within four weeks in order for the priority setting process to proceed sequentially. Informal input will be solicited on a continuous basis through use of PRAB Priority Cards (see Appendix D).

A list of safety and health hazards is then generated in PRAB by combining nominations, industrial chemical agents with known serious effects, and emerging concerns identified through the Current Awareness System. A set of computer-generated abstract profiles (preliminary information which can be obtained presently from RTECS and Current Awareness System) will be produced for each chemical subject on this list. This is represented in box 4 of Fig. 1.

C. Subject Scoring to Produce a Preliminary List of Candidates for Further Investigation

The chemical agents that would be under consideration at this point would outnumber, by far, other types of hazards. A scoring exercise will be required early in the system to develop a preliminary list of candidates of chemical agents for later development of profiles (approximately 100). This occurs between boxes 4 and 5 shown on Fig. 1. At this time, scoring will be based on information in RTECS. This scoring can only be viewed as cursory. However, the information at this point should be sufficient to determine those candidates requiring further profile development.

This scoring should be considered only as a screening tool used early in the priority setting process to reduce the number of subjects to a manageable number consistent with Institute resources. Scoring should not be considered a scientific process in itself, as in-depth assessment follows at a later step. A comprehensive examination of scientific and regulatory information is paramount and must be the basis on which final priorities are set.

For chemical agents, the scoring exercise will derive three separate scores in three different parameters: (1) production volume, (2) size of the exposed worker population, and (3) toxicity. These parameters are used as determinants of the significance of potential occupational health hazards. These same parameters are effectively used by other health agencies in comparing and screening relative hazards to the environment and human health. PRAB believes that scoring by separate parameters will convey more meaningful information. A "total score" derived from summing all three of the above parameters is not intended in the proposed scheme because the parameters are not equivalent and the assigned points are not comparable. Furthermore, the specificity of information would be lost by compiling "total scores." Examples of how this approach might be used are given below:

Example

A chemical yielding high scores in toxicity and production categories, but a low score in exposure would reflect a possible candidate for field studies to either verify the low exposure or to otherwise characterize exposure conditions.

Example

Chemicals scoring high in production, but low in toxicity and exposure would not appear likely candidates for document development. Without high scores in the latter two parameters, there would be no real basis for a document.

The scoring exercise described here applies to chemical agents; analogous appraisals could be made for subjects other than single chemicals. For chemicals, scores for the production and exposure parameters would be given according to the following scales.

PRODUCTION

<u>Production volume</u>	<u>Points</u>
Levels 100,000,000 lb or greater	51
10,000,000 to 99,999,999 lb	41-50
1,000,000 to 9,999,999 lb	31-40
100,000 to 999,999 lb	21-30
10,000 to 99,999 lb	11-20
1,000 to 9,999 lb	1-10
Less than 1,000 lb	0

(If a further distinction is required for chemicals above 100,000,000 lb, the scale could be extended above 51 points.)

The breakdown of production volume has been adapted directly from the production scale found in the EPA Inventory. The points scale is arbitrary and designed to be convenient during the scoring process.

EXPOSURE

Number of U.S. Workers Potentially Exposed (Users and Producers)

	<u>Points</u>
Over 1,000,000	171
900,000 to 999,999	161-170
800,000 to 899,999	151-160
700,000 to 799,999	141-150
600,000 to 699,999	131-140
500,000 to 599,999	121-130
400,000 to 499,999	111-120
300,000 to 399,999	101-110
200,000 to 299,999	91-100
100,000 to 199,999	81-90
90,000 to 99,999	71-80
80,000 to 89,999	61-70
70,000 to 79,999	51-60
60,000 to 69,999	41-50
50,000 to 59,999	31-40
40,000 to 49,999	21-30
30,000 to 39,999	11-20
20,000 to 29,999	1-10
Less than 20,000	0

(If a further distinction is required above 1,000,000 worker exposures, the scale could be extended above a score of 171.)

The number of workers exposed will be from the National Occupational Hazard Survey conducted by NIOSH in 1972-1974. As data from the newer National Occupational Exposure Survey (NOES) become available, they will be used. The points scale is arbitrary and designed to be convenient during the scoring process.

Although the preceding scoring exercise is based on potential exposure, the same procedure will be used when actual worker exposure data are available. However, the number score should be supplemented with a letter code to identify the value as representing real data. The letter "W" will be used as a coding symbol adjacent to any score derived for actual worker exposure data. When warranted, a subfile of actual exposure information on specific chemicals or groups should be established early in the priority setting process for future reference.

TOXICITY

The scoring of toxicity data is intended to reflect the existence of toxicity information in different areas (e.g., animal teratogenicity or human carcinogenicity). All health effects are weighted equally; each toxicity parameter is assigned a maximum of only one point. Evidence of more serious chronic health effects in humans or animals such as carcinogenicity or mutagenicity would be coded using a letter symbol. This coding component is proposed so that a score will be supplemented by other means of identification to represent specific health hazards. Instead of deriving just a single numerical score for toxicity, the proposed scheme also designates the nature of the hazard. The toxicity score in the proposed method thus will (1) reflect the amount of toxicity information available in different areas because each is scored equally and separately, and (2) permit identification of critical health effects identified by codes.

The letter code to be included in the scoring exercise is indicated to the left of each category.

Points

Reported Effects Exhibited in Animals or Microorganisms

A. Carcinogenicity	1
B. Mutagenicity	1

C. Teratogenicity	1
D. Acute Toxicity	1
E. Chronic Toxicity	1
F. Results from In Vitro Testing	1

Reported Effects Exhibited in Humans

G. Carcinogenicity	1
H. Mutagenicity	1
I. Teratogenicity	1
J. Acute Toxicity	1
K. Chronic Toxicity	1
L. Results from In Vitro Testing	1

MAXIMUM TOTAL POINTS

12

EXAMPLE

Two hypothetical chemicals were scored using the above criteria. The numerical and coded score for each chemical were:

	<u>Score</u>
diethylhexyl PRABate -	5 (A, B, D, E, G)
PRABasic acid -	6 (B, D, E, F, J, K)

Although both chemicals may merit NIOSH attention, there is a distinction possible when evaluating the score for each. PRABasic acid's score of 6 is higher than that of the other chemical indicating more information, but the health hazards of diethylhexyl PRABate, including human evidence of carcinogenicity along with animal data on this, perhaps suggest a greater priority.

Based on the production, exposure, and toxicity scores for each chemical, PRAB will identify those subjects that it believes stand apart from others with regard to potential occupational health concerns. These subjects will be considered as preliminary candidates for profile development. This is represented in box 5 of Fig. 1.

- D. Solicitation of Further Information on Candidates from NIOSH Resources and Through the Federal Register

Subjects which are selected as preliminary candidates are submitted to NIOSH Clearinghouse, DSHEFS, DBBS, DRDS, DRS, and NIOSH regional offices for additional, more specific information on production, importation, market trends, uses, estimates of exposure, and toxicity. This is represented in boxes 6, 7, 8, and 9 of Fig. 1. Suggested memoranda requesting information from NIOSH Clearinghouse, divisions, and regional offices are in Appendix E.

At this step an estimated 80% of the literature will be identified, but not all acquired. Abstracts will be available from some of the computerized data banks searched by the Clearinghouse. Information from all sources on one agent or hazard will be organized and reviewed by the PRAB research analysis team to determine the need for profile preparation.

It can be expected that for some of the preliminary candidates further investigation will be deferred. Also, other new subjects may be placed on the list as a consequence of again soliciting information from NIOSH offices. The list of final candidates for profile development could include 50-100 subjects (see box 10 in Fig. 1). This list will be published in the Federal Register with a "Request for Information." At this point all interested parties will be invited to comment on the candidates or suggest the consideration of additional nominations. A prototype of the "Request for Information" to be published in the Federal Register is in Appendix F.

E. Development of Profiles List and Profile

Information profiles will be prepared for each subject (box 11, Fig. 1). Similar profiles in the past have been produced by contract; it is anticipated that this mechanism will have to be employed again because of limitation of professional resources within the Division. If profiles are to be developed in-house, they would be done by the Clearinghouse. All information on a subject gathered to this point will be used in the initiation of a profile. The profiles will represent a compilation from computerized data bases, surveillance information, technical library resources, responses to the Federal Register, and nonconfidential information in Federal agencies. See Appendix G for a description of a profile for a chemical agent; an analogous profile will be prepared for a nonchemical subject.

F. Research Analysis and Development of Priority Rationale Statements

A scientific review of each subject by PRAB will be required in the development of the Priority Rationale Statement (PRS). See box 12, Fig. 1. Specific health endpoints or biologic effects, including for example, carcinogenicity, genotoxicity,

reproductive effects, respiratory effects, and neurotoxicity, will be evaluated for each subject in the PRS. The PRS discussion will highlight any relevance the subject may have to the major occupational safety and health endpoints, as perceived by the Institute. Relevant findings of toxicity will be related to information on exposure and production to (1) identify occupational health issues and (2) determine suitable NIOSH activities appropriate to address each problem.

Each PRS will be a synopsis describing the conclusions of reviewers on each subject and will address information gaps that identify research needs and the strength of data available for document development. At a minimum, each PRS will include a profile overview and clear and concise recommendations supported by a discussion of production, use, potential for exposure, health effects, and other relevant factors. Each PRS will be used to identify the relationship of the subject to major occupational safety and health issues, and later, as the basis to rank subjects as NIOSH research and document priorities. The scientific review may require the additional assistance of health and safety professionals in other NIOSH divisions and possibly the Senior Advisory Staff. When necessary, expertise outside NIOSH, from other government agencies or the private sector, should also be sought to resolve technical points or to clarify specific issues.

The PRS for each subject will be developed after a scientific review, based primarily on the content of the information profile developed on each subject and the assessment of evidence reported in other pertinent scientific papers and reports. Liaison relationships, established between PRAB and NTP, EPA/TSCA, and other toxicity testing organizations, can also provide information about newly identified toxic agents. Whenever possible, PRAB would utilize newly developed NTP Technical Reports or EPA/TSCA documents that have been drafted or published on chemicals since profile development. Accordingly, PRAB liaison activities can supplement the profiles or add new subjects at this step of priority setting to (1) identify emerging toxicity testing results and (2) correlate observed biologic effects or health endpoints to occupational health issues relevant to NIOSH.

For chemical agents, this final review will address the same categories used earlier in the scoring exercise: (1) production, (2) exposure, and (3) toxicity. Considerations about production and exposure may not change during this later scientific review, unless new information has developed. On the other hand, issues raised about toxicity may differ from those ascertained during the scoring exercise. The quantity of actual scientific data available at this time may justify a review.

The most critical category in this evaluative step of the proposed priority setting mechanism will be toxicity. Whenever data relevant to evaluating possible synergistic toxic effects from multiple exposures are available, they will be evaluated in the context of anticipated industry-wide exposure potential. The scientific review, culminating in a written justification of specific conclusions and recommendations, will be of more substantive value to the development of the PRS than any numerical value or mathematical scale that could be applied.

If occupational exposure information is absent, field research needs will be emphasized in the PRS. The PRS must focus special attention on the toxicity of the chemical subject, since this category is so critical to a later determination of the need or merit of a NIOSH priority. The lack of toxicity information could contribute to a recommendation against document development or identify specific gaps for future NIOSH research programs. Reviewers will consider all scientific data pertinent to the health hazard and will provide, to the extent practical, a relevant overall assessment. Factors to be assessed will include experimental protocol(s), toxic effects observed in more than one mammalian species, human evidence, and the strength of reports describing such findings.

Critical to this review are considerations of (1) information gaps which identify research needs and (2) the amount of substantive information that is available for document development. Research needs cannot be identified unless the gaps are noted in the PRS.

G. Listing and Ranking of Research Needs and Document Subjects

Based on conclusions and recommendations in the PRSs, the specific document and research needs will be placed on the following priority lists: (1) document development, (2) field studies, (3) biological and behavioral studies, and (4) physical sciences and engineering (see boxes 13-16 of Fig. 1). It is anticipated that a particular subject may give rise to various research needs appearing on more than one priority list.

Once document or research needs have been specifically identified, the entries on a given priority list will be ranked, based on the extent and severity of the potential workplace hazard. The priorities in each of the four areas will be ranked into high, medium, and low priority, although the severity of the safety or health problems to be addressed or the critical nature of research needs can be ascertained from the PRS for each topic.

H. OSHA and MSHA Standards and NIOSH Recommendations Update Cycle

An independent selection process will be applied to subjects for which: (1) OSHA or MSHA standards have been promulgated or (2) NIOSH has published formal recommendations. This is represented in box 17 of Fig. 1.

Information concerning this special list is continually being entered in the Current Awareness System based on a hand search of recent literature conducted by the Toxicology Information Response Center (TIRC).

PRAB activity on any of these subjects will be triggered by information in one or more of the following arenas:

1. Research activity within NIOSH, the National Toxicology Program (NTP), Chemical Industry Institute of Toxicology (CIIT), and EPA.

PRAB routinely enters this information into its Current Awareness System. A subfile of all chemicals that were topics of NIOSH:

- a. Criteria documents,
- b. Current Intelligence Bulletins,
- c. Special Hazard Reviews, and
- d. Occupational Hazard Assessments

can be easily accessed for screening of pertinent information. Results of testing and monitoring of ongoing tests can be handled by one designated individual in PRAB.

2. Formal petitions to OSHA or MSHA which challenge existing standards or request rulemaking for a new standard.

DSDTT maintains regular contact for NIOSH with staffs in the OSHA Health Standards Directorate and the MSHA Health Policy Planning Group to keep informed of standards activity. PRAB will initiate a preliminary research analysis effort in cases where a petition is argued on the basis of new scientific information. The results of petitioning actions will be noted in the Current Awareness File.

3. Changes in recommendations made by the American Conference of Governmental Industrial Hygienists, Inc. (ACGIH), Committee on Threshold Limits.

The scientific bases for any changes or additions recommended by the TLV committee will be analyzed yearly by PRAB staff.

A subject will be considered a priority candidate if the available information meets one or more of the following criteria:

1. New or reevaluated scientific data challenge an existing OSHA, MSHA, or NIOSH position.
2. New data show the possibility of a health effect not noted in the basis for an OSHA or MSHA standard or a NIOSH recommendation.
3. A recently developed or uncovered use or process presents hazardous exposure conditions which have not been addressed by OSHA, MSHA, or NIOSH.
4. Evidence has accumulated which adds significantly to the basis for an existing OSHA or MSHA standard or NIOSH recommendation.

The information obtained through the process described above will be used for priorities setting and will feed directly into the "Occupational Health Guidelines" updating effort.

APPENDIX A

Identification of Hazardous
Substances from Specialized Data Bases

Appendix A

1. Identification of Hazardous Substances from Specialized Data Bases (Figure A-1)

In addition to nominations for subject hazards, DSDTT has developed an additional procedure for identifying chemicals having hazard potential for workers through analysis of information contained in existing data bases. These include EPA's Toxic Substances Control Act Chemical Substances Inventory (EPA Inventory), NIOSH Registry of Toxic Effects of Chemical Substances (RTECS) and the National Occupational Hazard Survey (NOHS). A detailed description follows of how these data bases are analyzed.

Two basic elements of information needed to recognize the potential hazards of a substance are identification of adverse health effects and a potential for occupational exposure. This subsystem is designed to identify and select from existing data bases chemical substances which may concern worker health, thus highlighting important chemical hazards.

Phase I of this effort is to select the data bases from which to work. Since it is not practical or possible to deal with the total universe of chemical substances, two major data bases, RTECS and EPA Inventory, are used as starting points.

RTECS contains toxicity data for over 50,000 substances and there is an ongoing effort to identify and input into the system both old and new information as it becomes available. The advantage of using RTECS is that the system is at present operational and contains a large segment of the data needed. RTECS is nationally and internationally recognized as the best available compilation of unevaluated data for acute and chronic effects. It has been tested and used by a large number of people; it is continuously and easily updated and literature citations are available immediately in the NIOSH library on microfiche.

EPA Inventory lists approximately 65,000 chemical substances manufactured in or imported into the U.S. in 1977. However, TSCA reporting requirements exclude drugs, pesticides, nuclear materials, tobacco or any tobacco product, firearms and explosives, incidental products only if not used, and mixtures. Another limitation of EPA Inventory is that small manufacturers with total annual sales less than 5 million dollars are not required to report volume ranges or sites. Reporting of volume ranges was only for 1977 with optional reporting as far back as 1975. Amounts of each chemical substance which were manufactured or imported at each site or imported during calendar year 1977 were reported in nine ranges as given below.

0	less than 1,000 lbs.	5	10 million - 50 million
1	1,000 - 10,000 lbs.	6	50 million - 100 million
2	10,000 - 100,000 lbs.	7	100 million - 500 million
3	100,000 - 1 million lbs.	8	500 million - 1 billion
4	1 million - 10 million lbs.	9	over 1 billion lbs.

All nonconfidential reporting is computerized on EPA's CISIS system, which can be accessed by CAS number.

A computerized match (Match I) based on the CAS numbers in the two systems (RTEC/EPA Inventory) described briefly above yielded 4,449 chemical substances. These chemicals have been reported to EPA under TSCA as being in commercial use and all have some chronic or acute effects on animals as cited in the RTECS.

Since 20% of the chemicals in RTECS have no CAS numbers, some important chemicals may have been missed from Match I. A subfile identifying substances with information on carcinogenic, teratogenic and/or mutagenic effects but not having a CAS number will be generated and will be added to Match I, generating Match II. Thus, chemicals with carcinogen, teratogen and/or mutagen (CMT) citations in RTECS that might possibly be produced or imported will be added to Match II.

To identify those chemicals in Match II having available occupational exposure information, a match will be made with the National Occupational Hazard Survey (NOHS) data base, the only such information source, for approximately 8,000 chemicals. In addition, information from the NIOSH Health Hazard Evaluation (HHE) chemical file, the ACGIH Threshold Limit Value (TLV) list and the OSHA Management Information System will be entered into the system at this point to create Match III. In addition, carcinogenic chemicals identified as a result of the OSHA Carcinogen Policy categorization process will be added to this list. Match III will then be a set of chemicals with identified toxic effects including those with CMT information, possibly having a commercial use in 1977, and with some record of occupational exposure. This set of chemicals will create the data base which will be manipulated to generate a significant portion of the list for preliminary screening for priority purposes.

APPENDIX B

Parties to be Invited to

Nominate Subjects for

Evaluation

(List to be made current as needed)

Sample Letter

FEDERAL GOVERNMENT SOURCES

<u>AGENCY</u>	<u>MEMBER</u>
CEQ	Council of Environmental Quality
DOC	Department of Commerce Regulatory Analysis Division
EPA	Environmental Protection Agency Office of Toxic Substances
NCI	National Cancer Institute Division of Cancer Cause & Prevention
NIEHS	National Institute of Environmental Health Sciences National Toxicology Program
NSF	National Science Foundation Division of Chemistry
OSHA	Occupational Safety and Health Administration Health Standards Program
MSHA	Mine Safety and Health Administration

LIAISON AGENCY REPRESENTATIVES

DOD	Department of Defense U.S. Army Environmental Hygiene Agency Naval Medical Research and Development Command National Naval Medical Center
FDA	Food and Drug Administration Scientific Office for Interagency Affairs
CPSC	Consumer Product Safety Commission Division of Hazard Assessment
USDA	United States Department of Agriculture Animal and Plant Health Inspection Service Agency Plant Protection and Quarantine Division

INDUSTRIAL SOURCES

Chemical Manufacturers Association, Inc.

LABOR SOURCES

AFL/CIO
Department of Occupational Safety and Health

Oil, Chemical, and Atomic Workers International Union
Legislative Office

ACADEMIC SOURCES

University of Arizona
Arizona Health Sciences Center

University of Illinois at the Medical Center
Abraham Lincoln School of Medicine

University of North Carolina at Chapel Hill
Occupational Safety and Health Educational Resource Center

The Johns Hopkins University
Environmental Health Sciences

The University of Texas
Health Science Center

Harvard University
School of Public Health

University of Utah
Medical Center
DFCM

Mount Sinai School of Medicine

St. Paul Ramsey Medical Center
Department of Medicine

University of Cincinnati
Kettering Laboratory / Institute of Environmental Health

University of Washington
Dept. of Environmental Health

University of California, Irvine
Southern Occupational Health Center

PROFESSIONAL SOCIETIES

Society of Toxicology

American Industrial Hygiene Association

American Conference of Governmental Industrial Hygienists

American Academy of Occupational Medicine

American Occupational Medical Association

NIOSH OFFICES, DIVISIONS, AND REGIONS

Office of Extramural Coordination and Special Projects

Division of Biomedical and Behavioral Science

Division of Physical Sciences and Engineering

Division of Respiratory Disease Studies

Division of Surveillance, Hazard Evaluation, and Field Studies

Division of Safety Research

Division of Training and Manpower Development

Regions

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Regional Offices

Subject: Nominations for the NIOSH Priority System

Dear _____:

Research in occupational health issues and the development of documents conveying National Institute for Occupational Safety and Health (NIOSH) evaluations and recommendations, including recommended standards, is a continuing activity within NIOSH. The documents are publications which are prepared from publicly available, medical, biological, engineering, environmental, chemical, and trade information data.

In an effort to focus our research and document resources on the most pressing occupational health issues, NIOSH has established a priority setting system. This system will be used to identify chemical and physical agents that may produce injurious effects in workers and to determine the extent of occupational exposure. In pursuing this goal, all published or publicly available information that has been found or that has been offered to the Institute in response to requests both in the public and private sectors is collected, reviewed for relevance, and analyzed in the Institute's priority setting system.

We are now in the initial phase of our system. At this time we are requesting by open invitation nominations of subjects for research and/or documentation from specific sources in industry, labor, academia, professional societies, and/or from individuals having specific concern about occupational health problems.

With this in mind, I would like to extend to you an opportunity to introduce into our priority system any information or data at your disposal pertaining to occupational hazard concerns describing use, exposure or exposure levels, acute or chronic health effects, methods for hazard control, or other relevant information necessary to establish a priority nomination.

Your cooperation in helping to establish Institute priorities for research and documentation will be greatly appreciated. Information should be directed to Chief, Priorities and Research Analysis Branch, DSDTT.

J. Donald Millar, M.D.
Assistant Surgeon General
Director, National Institute for
Occupational Safety and Health

APPENDIX C

CURRENT AWARENESS SYSTEM

APPENDIX C

CURRENT AWARENESS SYSTEM

The Current Awareness System is comprised of the PRAB Current Awareness Files, NIOSH Computerized Files, and use of the Toxicology Information Response Center.

Current Awareness File

The NIOSH Current Awareness System (CA) was started in September 1979 in response to the increased toxic substances activity in the Federal and private sectors. The Institute needed to monitor, store, retrieve and be able to rapidly identify potential chemical hazards in the workplace. NIOSH already had the automated Registry of Toxic Effects of Chemical Substances (RTECS) to record acute and chronic effects on animals and humans. Additional data elements related to testing, regulation and other activities were needed to provide a quick, one stop, comprehensive profile of a chemical substance.

In 1979 DCSDS and the Division of Technical Services (DTS) started this project, and it was decided to use the RTECS computerized data base and format for the current awareness file. Since some of the data elements are from unpublished reports and "non-standard sources" which need updating constantly, the NIOSH project officer in Priorities and Research Analysis Branch identifies and provides the data elements and status lines for input into the file. The contractor, Tracor Jitco, enters the data on coding forms, inputs these lines and updates the file. This computerized file is used routinely to support PRAB activities and can be effectively used as a first step to identify and prioritize chemicals for various Institute actions. The priorities setting scheme, Fig. 1, shows how the CA is used in priority setting and tracking activities.

This appendix describes the CA data types and data lines with a brief description of each. Data types listed in RTECS and CA are:

<u>NIOSH Input</u>	<u>Number of Lines</u>
1. Reported in HHE or TA report	532
2. NIOSH Chemical Profile	424
3. NIOSH Current Intelligence Bulletins	47
4. NIOSH Criteria Documents	191
5. NIOSH Manual of Analytical Methods	371
6. Standards Completion Program	--

OSHA Input

1. Regulated Chemicals	595
2. OSHA Candidate for Further Scientific Review	64
3. OSHA action priority	34
4. OSHA Carcinogens	--

EPA Input

1. EPA TSCA 8(e)	35
2. EPA CHIP Reports	61
3. TSCA ITC Selected for Review	104
4. TSCA Section 4(e) Priority List	140
5. TSCA 8(a) Preliminary Assessment Information Proposed Rule	--
6. TSCA EPA Inventory	1193
	5622

DOT Input

1. Department of Transportation shipment regulation	868
---	-----

NTP Input

1. Candidates nominated, scheduled or testing	1076
2. Currently selected by NTP	--
3. Currently tested by NTP	308
4. Carcinogenesis Bioassay completed	--
5. NCI/SRI Summary Sheet data	250

NLM Input

1. On-line-Toxicology Data Bank	2227
---------------------------------	------

International Input

1. IARC carcinogen evaluation	--
2. Canadian Candidate List under the Environmental Contaminant Act.	128
3. Epidemiological Studies in Progress on Carcinogenicity	62
4. Route - species carcinogenicity test	716
5. On First IRPTC Working List, 1980	239

Private Sector Input

1. Threshold Limit Value	628
2. Cosmetic ingredient review priority list	128
3. Monographs on fragrance raw materials	531
4. CIIT priority chemicals	45

Use and Production Indices

1. Production output rate, trends	186
2. Chemical use	1493

NIOSH Computerized Files

In order for the Current Awareness System to supply PRAB with current information relating specifically to occupational health issues, NIOSH resources need to be tapped. The computerized files available in NIOSH which can aid in priority setting are:

1. Current Research File - contains literature on occupational health related research which has occurred in the past three years. The literature is submitted by industry and government agencies in the U.S. and abroad. A match of the Current Research File with the Preliminary List of Candidates for Profiles will be useful in the identification of research gaps and the avoidance of duplicate research efforts.

2. Document Information Directory System (DIDS) - contains NIOSH documents published as well as unpublished. A DIDS search will be performed for each chemical on the Final List for Profile Preparation. PRAB will send the retrieved information to the profile contractor to assist in profile development.

3. NIOSHTIC - contains current and past research journal articles relating to occupational health. A NIOSHTIC search will be conducted for each chemical on the Preliminary List of Candidates for Profiles and be reviewed by PRAB staff.

NIOSH libraries are important for identifying and tracking emerging problems, because they provides PRAB with current issues of all relevant journals.

Toxicology Information Response Center (TIRC) (Interagency agreement with National Library of Medicine)

The National Library of Medicine (NLM) agrees to provide NIOSH services under the terms and conditions as described herein.

Purpose: To provide NIOSH with general toxicology/pharmacology literature search support through the NLM-sponsored Toxicology Information Response Center (TIRC), Oak Ridge National Laboratory (ORNL).

I. Background

Under the Occupational Safety and Health Act of 1970, NIOSH has the legislative mandate to strive to achieve for all workers a healthy and safe workplace. The evaluation of workplace hazards and the development of control recommendations are an essential parts of this mandate. In many cases, NIOSH must evaluate hazard potential and recommend controls in a relatively short period of time when a serious risk to the worker is identified, either by newly released test results, or as a consequence of a workplace disaster. A complete literature search and the acquisition of pertinent literature in a short period of time is the first step in this evaluation process, which may lead to a Special Hazard Review (SHR) or an Emergency Temporary Standard (ETS), or some other type of recommended standard. TIRC is sponsored by NLM's Toxicology Information Program as an information analysis center, and has proven resources and competent scientific staff to provide NIOSH with this information in a short period of time.

II. Services to be Performed

NLM shall provide some or all of the following services of TIRC as requested by NIOSH. Requests for searches and/or reviews of literature shall be made in writing by the NIOSH project officer. Work may be initiated on the basis of a verbal request when there is an urgent need for information. The request shall be subsequently confirmed in writing.

- a. Literature searches: delivery of search results that have been compiled from individually processed searches. The results shall be formatted as either bibliographic listings, citations, annotations or abstracts (as agreed upon by NIOSH and TIRC for each request).
- b. Computer printouts containing additional references, abstracts, and other annotations derived from searches conducted using on-line systems (MEDLINE, TOXLINE, CHEMLINE, CANCERLINE, CANCER PROJ, and ORNL computerized data bases, Lockheed/DIALOG, SDC/ORBIT and others), and/or secondary sources (including Biological Abstracts, Chemical Abstracts, Excerpta Medica, Index Medicus, Atomindex, DOE Energy Research Abstracts, and others).
- c. Delivery of complete reproduced literature articles, and their translations (when available), as requested by NIOSH.
- d. Overview or summary of literature which provides a brief, but inclusive summary of the reference literature. Topics include physical and chemical properties, metabolism, and toxicity with special emphasis on the carcinogenic, mutagenic and teratogenic

potential, and reproductive effects. As the need arises NIOSH may request a comprehensive, detailed review of literature which provides all available information on a specific aspect or a subject.

Response time from TIRC may vary according to the specific task:

1. Immediate for a simple query response usually conducted by phone.
2. Approximately eight working days for a bibliography based on a computerized data base search.
3. Approximately three to four weeks for a detailed literature search (including computer and hand searching).
4. Approximately six weeks for preparing an overview or summary.

TIRC is also tracking literature on subjects of interest to NIOSH. TIRC staff search toxicological data bases, Current Contents, and journals previously identified by NIOSH and submit on a bimonthly basis bibliographies on these subjects. Hard copy of pertinent information will be reviewed by selected but as yet unidentified individuals in NIOSH. This procedure is an effective way of monitoring literature on priority subjects and on updating documents. Monitors would be asked to provide written analysis of the received information. Such written feedback need not be an extensive evaluation.

PROTOTYPE MEMO

Director, NIOSH

Surveillance Input Into Priorities Selection Process

Director, DSHEFS

In an effort to update the priorities selection process, the Priorities and Research Analysis Branch (PRAB), DSDTT, has determined that the Institute must serve as its own best resource. If information from the various NIOSH divisions is entered early into the process, an occupational safety and health perspective will be assured.

With particular reference to the Division of Surveillance, Hazard Evaluation and Field Studies, PRAB has identified a number of mechanisms which, if successfully implemented, will not only guarantee early input of NIOSH surveillance activities into the priorities selection process, but also aid in maintaining an up-to-date Current Awareness File. I am asking for your cooperation in carrying out these procedures.

Surveillance Branch (SB);

PRAB considers the information gained through the NOES survey and questionnaire essential to establishing an index for evaluating the extent of exposure. It is understood that the results of the survey will not be available for a few years. Nevertheless, some important information can be obtained during this data accumulation period, which would be valuable input into the priorities setting process. This includes:

1. Chemicals or physical agents appearing in NOES which are not in NOHS.
2. Chemical substitutions and the reasons for making those substitutions as reported in the NOES questionnaire.

Since this information is already coming into the SB periodically, it is to be transmitted by routine memo to PRAB to be entered into the Current Awareness File and maintained for evaluation during the priorities setting process.

Ideally, one or two SB staff members should be named at the earliest convenience to coordinate with the Current Awareness staff. PRAB will contact those SB staff members as soon as the appointments are communicated to me.

Hazard Evaluation and Technical Assistance Branch and
Industry Wide Studies Branch

NIOSH professionals in the field are in a unique position to observe and comment on the workplace environment. During their plant evaluation visits, both the HETAB and IWSB professionals encounter occasional chemicals and processes for which there is little or unknown information. And although these potential hazards usually are noted in the final reports, it is unlikely that they would be identified during the priorities setting process unless a special effort was made to point them out. Thus, important information is discovered too late or disappears into the files.

Therefore, we are introducing the PRAB Priority Card as a means for timely acquisition of pertinent field information. The concept is derived from the now defunct OSHA 9 form but exhibits (see the enclosed prototype) a much simpler format which allows greater freedom to exercise professional judgment.

Use of the PRAB Priority Cards will be at the discretion of the individual field investigator during or following a plant visit and will be sent directly to the PRAB Priorities Development Section. A carbon back-up sheet is available for individual or branch record-keeping.

Your cooperation in helping to establish a genuinely representative and timely priorities setting process will be greatly appreciated.

J. Donald Millar, M.D.
Assistant Surgeon General

Attachment

```

*****
*                                     PRAB PRIORITY CARD                                     *
*                                                                                         *
*                                                                                         *
*Description of Potential Hazard or Priority Concern:                                *
*_____ *
*_____ *
*_____ *
*_____ *
*_____ *
*_____ *
*_____ *
*_____ *
*_____ *
*Comments: *
*_____ *
*_____ *
*_____ *
*_____ *
*Contact person, Branch, Phone: *
*_____ *
*_____ *
*_____ *
*Send c/o, PRAB, DSDTT, NIOSH *
*      5600 Fishers Lane, Rm. 8A-05 *
*      Rockville, MD 20857 *
*****

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Attachment:

PROTOTYPE MEMO

Director, NIOSH

Surveillance Input Into Priorities Selection

Director, DPSE

In an effort to update the priorities selection process, the Priorities and Research Analysis Branch (PRAB), DSDTT, has determined that the Institute must serve as its own best resource. If information from the various NIOSH activities is entered early into the process, relevance of priorities to the occupational setting will be assured.

It is clear that DPSE professionals in the field and in the laboratory are in unique positions to observe and comment on the workplace environment. Information or questions concerning a particular process, chemical, sampling/analytical method, or health effect which may be extraneous to the project at hand often cannot be addressed by a busy professional. However, the sum of all these sidelight observations constitutes a valuable data base which at present is unpublished information and in personal files of NIOSH professionals.

Therefore, we are introducing the PRAB Priority Card as a means for timely acquisition of this pertinent information. The concept is derived from the now defunct OSHA 9 form but the card exhibits (see prototype enclosed) a much simpler format which we feel allows greater freedom to exercise professional judgment.

Use of the PRAB Priority Card will be at the discretion of the individual investigator and will be sent directly to the PRAB Priorities Development Section.

Your cooperation in helping to establish a genuinely representative and timely priorities setting process will be greatly appreciated.

J. Donald Millar, M.D.
Assistant Surgeon General

Attachment

PROTOTYPE MEMO

Director, NIOSH

Continuing Input Into Priorities Selection

Director, DBBS

In an effort to update the priorities selection process, the Priorities and Research Analysis Branch (PRAB), DSDTT has determined that the Institute must serve as its own best resource. If information from the various NIOSH activities is entered early into the process, relevance of priorities to the occupational setting will be assured.

Information or questions concerning a particular process, chemical, sampling/analytical method, or health effect which may be extraneous to the project at hand often cannot be addressed by a busy professional. However, the sum of all these sidelight observations constitutes a valuable data base which at present is unpublished information and in personal files of NIOSH professionals.

Therefore, we are introducing the PRAB Priority Card as a means for timely acquisition of this pertinent information. The concept is derived from the now defunct OSHA 9 form but the card exhibits (see prototype enclosed) a much simpler format which we feel allows greater freedom to exercise professional judgment.

Use of the PRAB Priority Card will be at the discretion of the individual investigator and will be sent directly to the PRAB Priorities Development Section.

Your cooperation in helping to establish a genuinely representative and timely priorities setting process will be greatly appreciated.

J. Donald Millar, M.D.
Assistant Surgeon General

Attachment

PROTOTYPE MEMO

Director, NIOSH

Surveillance Input Into Priorities Selection

Director, DRDS

In an effort to update the priorities selection process, the Priorities and Research Analysis Branch (PRAB), DSDTT has determined that the Institute must serve as its own best resource. If information from the various NIOSH activities is entered early into the process, relevance of priorities to the occupational setting will be assured.

With particular reference to the National Occupational Hazard Survey of Mining (NOHM), PRAB considers the information to be gained through the survey activity essential to developing mining-related priorities for the Institute. It is understood that the results of the survey will not be available for some time. Nevertheless, some important information can be obtained during this data accumulation period which would be valuable input into the priority setting process.

Accordingly, information from NOHM is to be transmitted by routine memo to PRAB to be entered into the Current Awareness File and maintained for evaluation during the priorities setting process.

Ideally, a DRDS staff member should be named at the earliest convenience to coordinate with the Current Awareness staff. PRAB will contact the DRDS staff member as soon as the appointment is communicated to me.

It is clear that DRDS professionals in the field and in the laboratory are in unique positions to observe and comment on the workplace environment. Information or questions concerning a particular process, chemical, sampling/analytical method, or health effect which may be extraneous to the project at hand often can not be addressed by a busy professional. However, the sum of all these sidelight observations constitutes a valuable data base which at present is unpublished information and in personal files of NIOSH professionals.

Therefore, we are introducing the PRAB Priority Card as a means for timely acquisition of this pertinent information. The concept is derived from the now defunct OSHA 9 form but the card exhibits (see prototype enclosed) a much simpler format which we feel allows greater freedom to exercise professional judgment.

Use of the PRAB Priority Card will be at the discretion of the individual investigator and will be sent directly to the PRAB Priorities Development Section.

Your cooperation in helping to establish a genuinely representative and timely priorities setting process will be greatly appreciated.

J. Donald Millar, M.D.
Assistant Surgeon General

Attachment

APPENDIX E

Request for Information from NIOSH Divisions
and Regions on Industrial Hazards:

Suggested memoranda to Clearinghouse requesting searches
and to divisions and regions requesting information

Branch Chief, PRAB

Request for Literature Searches on the
Preliminary List of Candidates for Profiles

Chief, Clearinghouse

In following with the Priority Setting System, PRAB has reviewed:

- 1) Nominations from other government agencies.
- 2) A computerized match of exposure (TSCA Inventory) and health effects (RTECS and RTECS subfile on chemicals without CAS numbers.)
- 3) Input from NIOSH divisions.

A list of toxic agents with worker exposure has been developed from the steps mentioned above. Abstract profiles for the agents on the list were then created from RTECS and the NIOSH Current Awareness File. These abstract profiles were reviewed and scored by PRAB and as a result we have a Preliminary List of Candidates for Profiles.

At this point, I would like to request the that Clearinghouse provide searches from the following data bases:

1) from Dialog

- a. Biological abstracts
- b. Exerpta medica
- c. NTIS
- d. SSIE

from Medlars

- a. Medline
- b. Cancerline
- c. Toxline
- d. Toxback

2) NIOSHTIC

3) Current Research File

If your staff identifies other information, such as production, importation, market trends, and uses, from other sources please send it to us along with these searches.

PRAB will review each search when completed by your staff.

I have contacted DSHEFS for NOHS and NOES data, HHE's and TA reports, and DRDS for mining HHE's and NOHSM data. DBBS has also been contacted for information specific to testing and research.

Thank you for your assistance to PRAB during the priority setting process.

(signature)

PROTOTYPE MEMO

Director, DSDTT

Solicitation of Comments and Information on
Initial Priority Candidate List

Division Directors and Regional Offices

Enclosed you will find a proposed list of priority candidate subjects which has been derived from the initial phases of the priority setting process. Please assign selected members of your staff to review and comment on the appropriateness of the subject chemicals.

This list is by no means final and can be modified in response to information and professional opinion offered by your staff. The completed comment package should be sent to Chief, Priorities and Research Analysis Branch (address), by close of business (one month from sending date).

Following review of input from the NIOSH divisions and regional offices, the staff in the Priorities and Research Analysis Branch (PRAB) will prepare a final list of approximately 50 chemicals for more detailed profile development. Subjects not selected for profile development will be reentered into the priorities setting process for consideration in the next round.

Your enthusiastic participation in this process is greatly appreciated.

Richard A. Lemen

Attachment

APPENDIX F

Federal Register Notice Requesting Information
for Profile Preparation and
Evaluation

FEDERAL REGISTER NOTICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control
REQUEST FOR INFORMATION

Certain Chemical Agents

AGENCY: National Institute for Occupational Safety and Health (NIOSH),
Centers for Disease Control, Public Health Service.

ACTION: Notice of Request for Information.

SUMMARY: This notice solicits information for the preparation of information profiles on industrial chemicals. The information will be used for evaluation of exposure and potential safety or health hazards in the workplace in the process of setting priorities for research or hazard documentation.

DATES: Comments concerning this notice should be submitted
by _____.

ADDRESSES: Comments and recommendations should be submitted in writing to: Mr. Richard A. Lemen, Director, Division of Standards Development and Technology Transfer, National Institute for Occupational Safety and Health, 4676 Columbia Parkway (C-14), Cincinnati, Ohio 45226.

FOR FURTHER INFORMATION CONTACT:

Priorities Research and Analysis Branch, NIOSH (301) 443-2100.

SUPPLEMENTARY INFORMATION: Section 20(a) (3) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)) provides that the Secretary of Health, Education, and Welfare (now, Health and Human Services), on the basis of information available to him, shall develop criteria dealing with toxic materials which will describe exposure levels that are safe for various periods of employment. Section 22 (c) of the Act authorizes the National Institute for Occupational Safety and Health (NIOSH) to develop recommended occupational safety and health standards and to perform all functions of the Secretary under sections 20 and 21 of the Act. In order to establish the basis for this criteria development, NIOSH has been authorized to develop and conduct research, demonstrations, and experiments necessary to justify its conclusions. In establishing this basis, NIOSH is proposing to develop, or will consider additional proposals to develop, information profiles to describe current or potential occupational exposures to industrial chemicals and to describe what is known of their biological or toxicological effects. Subsequent to profile development and evaluation, NIOSH will establish priorities for research projects or document preparation which may lead to recommended standards or other guidelines. The following subjects are to be considered for information profile preparation:

(The list of subjects.)

This request is to gather unpublished information pertaining to use, exposures, acute and chronic health effects, existence or concentrations in the workplace, and controls for preparation of profiles on the subjects listed above. Information sent to NIOSH, together with information otherwise available to the agency from published literature and other agencies, will be used to establish priorities for research and/or document preparation.

All information received concerning these subjects, except that information which is trade secret and protected by section 15 of the Act, will be available for public inspection at the foregoing address.

Date: _____, 19 .

J. Donald Millar, M.D.
Assistant Surgeon General
Director, National Institute for
Occupational Safety and Health

APPENDIX G

Description Of Profile

Profile Description

- a. Chemical name
- b. Summary or abstract of the profile
- c. Chemical structure and molecular weight
- d. Synonyms
- e. Chemical Abstract Service number
- f. Registry of Toxic Effects of Chemical Substances number
- g. Chemical and physical properties
 - (1) Description of chemical
 - (2) Boiling Point
 - (3) Melting Point
 - (4) Vapor Pressure
 - (5) Evaporation Rate
 - (6) Solubility
 - (7) Specific Gravity
 - (8) Stability
- h. Production figures and economic trends in production
- i. Uses of chemical

When presenting use data, the major uses of a chemical and amounts used should be given.
- j. Names of companies producing and distributing the chemical
- k. Detailed description of manufacturing process including likely sources of emission into the work environment or points in the process at which worker exposure is likely, see n. below.
 - (1) Manufacturing process of the chemical agent itself
 - (2) Processes and equipment in which the chemical is ultimately used
 - (3) Industries using the chemical

- l. Known impurities or deliberate additives associated with chemical and/or technical grade composition
- m. Number of persons occupationally exposed to the individual chemical
- n. Control technology, i.e., extent of engineering controls, with emphasis on those actually in use, use of personal protective equipment to prevent employee exposure, i.e., used/produced in a closed system. It is not anticipated that the profile preparer would actually conduct industrial hygiene surveys of manufacturing operations to obtain this information.
- o. Biologic effects
 - (1) Animal studies
 - (a) Acute effects, including target organ, LD₅₀, and general toxicologic effects.
 - (b) Subacute or subchronic effects: The exposure period to the chemical substances must be for a minimum of 4 to 5 weeks and experiment duration for not less than 6 to 9 months.
 - (c) Chronic effects including, but not limited to carcinogenic, mutagenic, teratogenic and reproductive effects.
 - (2) Human studies
 - (a) Results of available epidemiological studies
 - (b) Health effects
 - (c) Target organ toxicity
 - (d) Metabolic pathways
- p. Ongoing toxicological or environmental studies in the governmental and/or private sector.
- q. Review in tabular form where available: Department of Labor standard (OSHA and MSHA), NIOSH Recommended Standard, ACGIH Threshold Limit Value (TLV), notice of intended changes of TLV and basis for the change.

- r. Trade associations, research organizations and other persons or organizations having expert knowledge and interest in the subject areas of the criteria document.
- s. Other pertinent data that may be available which would aid in making an assessment of the importance of the chemical as an occupational hazard, as well as research needed to make that assessment.
- t. References

Provide hard copy of references arranged in order of citation. If a reference is cited more than one time within a dossier, the hard copy will be in order of first citation.

Figure 1: PROPOSED PRIORITY SETTING SYSTEM, DSDTT, 1982

