FINAL

A RE-DESIGN OF THE HEALTH EFFECTS DIVISION

By
The Design Team
Phase II, Implementation Planning
Health Effects Division
Office of Pesticide Program

April 28, 1997

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I. INTRODUCTION

. The Health Effects Division (HED), in its efforts to re-organize the division, established a Design Team to re-design the division. The Design Team came under the auspices of the Implementation Team. Members of the Design Team were elected by a process in which the HED staff nominated members for the Design Team. Three Implementation Team members and 15 new members were nominated for the Design Team. The HED staff that served as members of the Design Team are:

Marion Copley	Paula Deschamp	Elizabeth Doyle	Tammy Edwards	Jeff Evans
Roger Gardner	Caroline Gordon	Marvin Hawkins	Sue Hummel	David Liem
Paul Lewis	Rick Loranger	Kathy Martin	Christina Olinger	
Randy Perfetti	John Redden	Karen Whitby	Jess Rowland (Team Leader)	

The Design Team was assisted by Ms. Trish Silber of the Catalyst Consulting Co., who served as the facilitator.

The Design Team, the Implementation Team, and a number of other division staff members participated in a kickoff meeting for the design phase. The output of this meeting was a set of Design Drivers which would guide the work of the Design Team. These design drivers are a set of conditions and aspects of the organization design which must be achieved for the design to be successful. The design drivers were developed using the analysis of the Implementation Team and input from Division staff. The design drivers included the following:

- **Significantly Improved Communication**

e.g.,
- continue/enhance the weekly notes of the Division Director adding priorities.
- address across-branch communication issues.
- need to improve the overall communications: laterally and vertically.
- better inform the staff of policy/decisions made/changed etc.

- **Maintain / Enhance Scientific Disciplines**

e.g.,
- ensure consistency/integrity.
- ensure sound scientific decisions.
- achieve optimum mix of disciplinary and interdisciplinary expertise.
- address impact of risk managers.

- **Embed Empowerment**

e.g.,
- staff input into decision making; staff input recognized.
- establish accountability/responsibility.
- establish goal orientation.

- establish clear, mutual expectation.
- educate ourselves with limits of empowerment.

- **Instill Flexibility**

e.g.,
- allow growth, change and re-evaluation of the design.
- allow for shifting priorities.
- start planning ahead.

- **Establish Goal and Purpose**

e.g.,
- link our goals to design.
- link our design to the mission of OPP.

- **Redefine Management and Leadership**

e.g.,
- clear definition of the role of management.
- managers must buy-in to the new paradigm.
- managers address accountability/responsibility.
- managers do more administration and performance management.
- managers manage work load/priorities, etc.

- **Significantly Improve Customer Relationship**

e.g.,
- ensure customer needs/requirement are well defined and met in all design aspects.
- ensure our accountability to customers and their responsibility to us and have it be evident.
- ensure that we have well-defined relationships with clear mutual expectations.

After establishing these design drivers, the Design Team began its design work by evaluating the overall definition of HED as a division (the boundaries) as viewed by the HED staff, the HED management, its customers (Registration Division, Special Review and Reregistration Division), the Implementation Team and its relationship with its customers. The Design Team evaluated the fundamental role of HED, the necessary resources available in HED and the policy in HED. The primary role of HED is risk assessment which requires scientific expertise and job skills in the disciplinary and interdisciplinary areas. Resource management in HED consists of scheduling, prioritizing, staffing and budget. Policy in HED is defined as science policy and legal mandates. Since we are a scientific organization, it is important that the new design allows us to maintain credibility in the scientific community.

As described in Appendix A (BOUNDARIES) of this document, the Design Team determined that while HED's roles are well defined, they are not well managed. There are a series of issues which must be addressed regarding how HED and its customers manage our expectations, relationships, mutual resources and policy matters. The Design Team

determined that we should attempt to address these issues where possible in our new design and that our relationship with our customer needs focused, long-term attention. The Team also agreed that our relationship with our customers and our performance will improve if we and our customers more actively manage our expectations and agreements.

Following the assessment of the definition of the boundaries, the Design Team evaluated the four major core work processes that were identified by the Implementation Team. The work processes evaluated were Data Review, Peer Reviews, Risk Assessment and Policy Development/Special Projects. The design drivers identified were used in the evaluation process of these four core work process. The Design Team concluded that improvements are needed (and must be enforced) in the data review, peer review and risk assessment processes and made some recommendations for the policy development and special project process. The Design Team developed the recommendations on these core work processes to make these processes more efficient and produce the desired outcomes. These recommendations are based on roles and responsibilities, independent of current job descriptions and personnel.

Upon completion of the task of evaluating the core work process, the Design Team began the re-design within the constraints of the basic structure that was provided by management. The team was not entitled to change the basic branch structure/functions which included a mix of "interdisciplinary" branches doing complete risk assessment, "disciplinary" branches involved with only hazard or exposure assessment, a risk characterization branch working with the disciplinary branches in doing risk assessments and a science analysis branch. The Design Team divided into small work groups to evaluate the following nine components of HED's structure and systems

1. **Branch Definition/Work Process**
   - define the approach driving the new HED.
   - "fine tune" the branch structure based on redesigned work process/customer relationship.
   - merge work processes across branches.
   - define the scope of work/mission of branches based on the design drivers and work processes.

2. **Roles, Job/Work Design, Delegation of Authority**
   - redefine jobs/roles to meet staff and customer needs.
   - redefine management's role to meet customer needs.
   - respond to employee survey issues.
   - develop decision matrix for roles to exhibit how decisions will flow thru the organization.

3. **Physical Space.**
   - determine what changes in physical lay out will help us serve our customers better and address design drivers.

4. **Planning, Goal Setting, Budget, Resource Allocation, Work Assignment (Contract)**
   - determine how to ensure HED goals are appropriate, understood and agreed upon.
   - determine how to measure and keep division staff informed about progress towards achieving goals.
   - determine how to ensure HED staff has adequate resources (information, tools, materials etc) to do a quality job.

5. **Communication, Decision Making and Evaluation**
   - determine how to ensure effective, efficient coordination of efforts within HED and other divisions.
   - determine how to promote direct coordination of work between employees rather than supervision.
   - determined how to improve the flow of information vertically and horizontally within the division and the flow of information outside the Division.
   - define elements of effective communication.

6. **Human Resources**
   - determine how to recognize and reward performance that meets/supports our mission goal.
   - determine what key skills are currently missing or underdeveloped in HED and how to develop them.
   - determine how to encourage maximum professional and personal growth.
   - determine how to achieve optimal staffing.

7. **Technology and Tools**
   - determine what kind of resources, tools, competencies are needed to achieve our design drivers

8. **Culture**
   - determine how to encourage/ensure that staff and management act in ways that are consistent with our "vision".
   - determine whether the design supports creating a "culture" we want and whether we are impacting what we want to impact.

9. **Branch/Team Operations**
   - determine what ways must branches/teams operate consistently across organization.

Each of the subgroups completed the task of evaluating the nine areas and their findings were presented to the entire team. The team members discussed in depth the findings of the subgroups, evaluated the critical elements identified/raised in these findings, requested a reassessment if and when needed, and discussed the advantages and disadvantages of the recommendations made by the subgroups. Applying the design drivers, the entire team then evaluated the merits of the findings and/or the recommendations to ascertain their value in the re-design of HED.

The input from you, the staff, was critical to the development of this design. The Design Team considered the concerns raised at the "all hands" meeting last fall, the information gathered by the Implementation Team, and the comments provided (via computer) by HED staff at the "all hands" meeting held in December. After drafting this re-design of HED, the Design Team evaluated its work to answer the question "Have we really addressed the ideas and suggestions provided by HED staff?". Of course, answers to this question must come from you, because you are our customer.

Thus, the task of re-designing HED was completed and the draft document entitled " A Re-Design of HED" was prepared. This document includes the following: An Introduction, a Chapter on the Core Work Processes which contains the sections on the four work processes, and a Chapter for each of the nine areas identified above. Also included in each Chapter is an abstract that summarizes the salient features of the Chapter. The overall definitions of the Division (i.e., the boundaries) are presented in APPENDIX A. A Glossary is presented in APPENDIX B.

A lot of time, talent and thought was spent in the re-design of HED. The Design Team strongly believes that the structure and systems devised in the re-design and explained in this document are concise, clear, coherent and comprehensive. Every area of the "operation of HED" was considered, every effort was made to "look at all angles" from "all levels" (staff, management, customer) and every concern, no matter how trivial, was evaluated. In addition, suggestions from the staff, data gathered from the Customer Survey and issues identified by the Implementation Team were used in this process.

The re-design was presented to HED staff on March 25, 1997 followed by two working sessions on March 26th and 27th to enable the staff to provide their comments, suggestions, ideas and input. Based on the input received from the staff, the Design was refined and this document was revised to reflect those changes. During this process, the Design Team proposed a modificatin to the re-design for future consideration. This proposal is presented in APPENDIX C. The comments and questions by staff as well as the Design Team's responses are provided in APPENDIX D.

The Design Team requests that each staff member read this document carefully in its entirety to get the "big picture", give his/her energy and effort, make a commitment to accept the changes that are inevitable, and give enough time for the re-design to work.

Together, we can and we will succeed in the new re-designed HED.

II. CORE WORK PROCESSES

The following four processes are considered to be basic to the mission of the HEALTH EFFECTS DIVISION.

A. Data Review

B. Science Analysis Review

C. Risk Assessment

D. Policy Development and Special Projects

These four processes are detailed in the following sections.

II. A. DATA REVIEW PROCESS

ABSTRACT

The HED Design Team has examined the impacts of the revised Division structure and the Food Quality Protection Act (FQPA) on the data review process, which includes the flow of data and deliverables as well as the actual examination and critiquing of studies. **The team's conclusion is that no major changes are required in this core process with the exception of the need to address quality control and consistency due to the loss of section heads and the spreading of each discipline over more branches.** In this regard it is recommended that the team peer review process developed by the Pilot Interdisciplinary Risk Assessment Team (PIRAT) and the Chemistry Branches be utilized in conjunction with examinations by branch senior scientists and the creation of a Scientific Advisory Council (SAC) for each discipline.

1. Impact of FQPA

The Design Team concluded that there will be minimal impact of FQPA on the data review process. Studies will still be assessed for their validity with respect to guidelines and whether they provide sufficient data for risk assessment. The latter process is where FQPA will have significant impact considering the requirements for aggregate exposure and common mechanisms of toxicity.

It was noted that some additions may be needed to the Data Evaluation Records (DERs) at a later time in areas such as infant sensitivity (developmental and reproduction studies), residential exposure and common mechanism of toxicity. These process changes will be made as needed as our policies for implementation of FQPA are developed.

2. Impact of Revised Division Structure

The Design Team considered three major changes occurring under the reorganization: creation of interdisciplinary branches; branches designated to serve RD and SRRD; and the loss of section heads.

A. Flow of Data and Deliverables

1) The need for trackers and gatekeepers in each branch versus Information Management and Contract Support Branch (IMCSB) handling this task was discussed briefly along with filing of reviews (electronically and hard copies). It was decided that these issues would be handled by the teams addressing structure, roles, and technology/tools.

2) With the creation of branches to serve RD and SRRD there could be 3 or 4 branches working at the same time on actions for a pre-November 1984 chemical. A mechanism is required to ensure that intra-division communication takes place in these cases. Possible solutions include forming teams across branches for each active ingredient (ai) and making it a part of the process for reviewers to check on other activity in HED. With respect to

the latter point, the Design Team recommends creation of a "Master Scheduling System" which is described in more detail in Chapter X, *"PLANNING, GOALSETTING, BUDGET, WORK ASSIGNMENTS"*.

3) A survey of our customers revealed that assignment of chemicals to specific HED branches is highly desirable so they know to whom to send data and have fewer total organizational units with which to deal. For a detailed discussion on this subject refer to Chapter III, *"BRANCH ASSIGNMENT OF CHEMICALS"*.

4) The customer survey revealed a desire for HED to have points of contact when questions arise. This concept of a customer service representative was addressed by the subgroup for Roles and Responsibilities. Refer to Chapter VI, *"ROLES AND RESPONSIBILITIES"*.

B. Review of Studies

1) QC/QA Process

With the loss of section heads and dilution of the disciplines across six branches, the major concern in the actual data or study review is maintaining consistency. With respect to loss of section heads, the Design Team recommends drawing upon the team peer review process already in place in PIRAT and the Chemistry Branches as a first step in the secondary review process followed by QC/QA reviews by BSS and/or the SACs.

The "QC/QA" process for data reviews is shown in Figure 1.

a) Team Review

The teams in a Branch will check the data reviews for:

- Accuracy of data transcription
- Validity of the methods used
- Review and evaluation of "science"
- Interpretation of study reports
- Scientific accuracy
- Results support the conclusions
- Application of disciplinary science policy

b) BSS

The Branch Senior Scientist (BSS) will be responsible for performing QC/QA for the final "product" (as opposed to the data reviews) for:

- Assure risk assessment policy
- Application of HED/OPP/Agency policies

c) SAC

FUNCTION: The primary function of the SAC will be to maximize consistency and scientific accuracy across chemicals. SACs provide empowerment since the staffing of the SACs will be made up of staff scientists, it moves the secondary and tertiary reviews out of management, and it eliminates the need for review by the Branch Chief. With the scientific disciplines spread over several branches within HED, SACs will provide consistency in science - policy - interpretation which may include:

- checking for adequacy of the reviews (e.g. DERs)
- evaluating the adequacy of the study (i.e., it met the Guideline requirement)
- review and evaluation of science (i.e., interpretation of study results)
- examination of the appropriateness of end points selected in toxicology studies
- evaluation of the appropriateness of the NOELs/LOELs established
- examination of the assumptions used in disciplinary (risk) assessments
- review of appropriate exposure data (transfer factors, use of dermal absorption and clothing penetration, etc.)
- assessment of residue chemistry factors (incorporation of percent crop treated, composition of live stock diet etc)
- Address "Graybeard" issues

The TOX SAC, for example, will perform quality control of the toxicology data package (DERs) that will be presented to the Hazard ID Assessment Review Committee which will enable this Committee to concentrated on identifying hazards for both acute and chronic exposure via all routes of and save time by separating the out the quality control function from this Committee. In addition, the SACs will be available for *ad hoc* consultation, address policy issues and communicate policy decisions across the branches.

PROCESS: The process for SACs operation will be as follows:

- The "product" (i.e., reviews) will be submitted to the SAC for review.

- SAC will review the product in an "informal" manner.

- SAC will not hold regular meetings; meetings will occur as needed.

- SAC will informally interact with the that requests the reviews.
- SAC will meet with the reviewer to discuss and resolve the issues if and when needed.
- SAC will consult with disciplinary experts as needed.
- SAC will maintain a log on the issues raised/resolved/recommended resolutions.
- The Chair of SAC will communicate the conclusions/decisions of the SAC to the /Branch/SARC (as appropriate) and this information will be made available on the LAN.
- SAC member will back up the reviewer who will be presenting to the appropriate SARC. This will enable the SAC representative to "enlighten" the SARC if and when there are questions regarding on the data base and/or the QC/QA process.
- The Chair of the SAC will be responsible for the planning, scheduling, coordinating, and operations of the SAC.

SAC is a decision making body and will be the final arbiter of issues concerning data interpretation for disciplinary reviews.

STRENGTHS: The strengths in having the SACs are:

- With the science disciplines spread over several branches within HED, as well as in AD and BPPD, this process will provide quality control in a central place.
- Enable HED management to tap into the expertise and vast experience of the scientific staff to conduct to quality control reviews and thus empower the staff.
- Having a team of experts in specific disciplines conducting these assessments will maximize consistency and scientific accuracy across chemicals.

2) Signature Authority and Examples of QC/QA Process

Pipeline Studies (from RD, SRRD): For pipeline studies that do not require a Risk Assessment (RA), following the primary review by the Reviewer, the team will perform a QC/QA check. The Reviewer/Team will sign off (from/through) on the study review as appropriate. The completed action will then be submitted to the BSS for his/her review. If the BSS is not an expert in that particular field, then the BSS will consult with the member of the SAC in that discipline who is member of that Branch and/or a senior

specialist in that field, either within the Branch or outside the Branch when the BSS deems it is appropriate. The pipeline study reviews are not routinely evaluated by the SAC because they will be submitted to the SAC when that study becomes a part of the complete data package at a later date (when it is ready for risk assessment). The Memorandum for that action will be signed by the Lead Reviewer/Team through the BSS.

Short Actions (e.g., Section 18, 24(c), amended use) with or without data but with risk assessments (RA): For these short actions, the Reviewer will prepare the RA in consultation *(ad hoc)* with the appropriate SARC (e.g, Hazard ID Committee) and obtain the appropriate endpoints necessary for risk assessments. The SARC is consulted on an *ad hoc* basis to avoid a "formal" meeting which might cause a delay in the review process. The RA product will then undergo a QC/QA review and a review by the BSS. If the BSS is not an expert in that particular field, then the BSS will consult with the member of the SAC in that discipline who is a member of that Branch and/or a senior specialist in that field, either within the Branch or outside the Branch. Following this step, the RA product will be reviewed by the Risk Assessment Review Committee. The Memorandum for this "product" will be signed by the Lead Reviewer/Team through the BSS.

Major Actions (e.g., new chemicals, REDs, tolerance requests): For all major actions that require RA, the data reviews and RED chapters will then be submitted to the team for QC/QA and then to the appropriate SAC for their review followed by an assessment by the appropriate SARC. Following the SARC evaluation, the Risk Assessor will prepare the RA incorporating the decisions/recommendations of the SARC. The RA product will then be reviewed by the team for a QC/QA check and then by the BSS. The RA will be submitted to the Risk Assessment Review Committee. The study reviews will be signed by the Reviewer through the Team. The disciplinary chapters will be signed-by the Reviewer/Team through the BSS. The Risk Assessment document will be signed by the Risk Assessor through the BSS.

3) Timing and Format of Reviews

Several issues on timing and format of reviews within the interdisciplinary branches were discussed. The Design Team recommends that each branch be responsible for shifting resources (including contractors) as necessary so that the individual disciplines complete their reviews at a similar time for integration into the risk assessment. However, in the case of new ai's, taking into account the differing quantities of data and the likely several rounds of submissions to complete all requirements, it is recommended that each discipline produce separate reviews so registrants can be informed as soon as possible of data deficiencies. When all three disciplines are satisfied, an integrated document can be produced, similar to a RED or documents presently produced for new chemicals by the Registration Section of RCAB. These documents summarize the key studies and assess and characterize human health risks. Each discipline would be expected to produce a "CRMS-like" report or status sheet with each review so the overall situation for data gaps

can be easily conveyed. A separate science chapter (toxicology, residue chemistry, occupational residential exposure) will continue to be prepared by the disciplinary and interdisciplinary branches for the documents discussed above.

3. John Doherty Proposal

The Design Team has examined John Doherty's proposal on "SUBMISSION AND REVIEW OF TOXICITY STUDIES IN THE NEXT MILLENNIUM".

Summary of Proposal: Dr. Doherty proposes that "the registrants prepare specifically defined supplements that contain the factual matter of the study including the methods and materials and obvious responses to treatment."

In this system HED reviewers will:

(1) still classify the study;
(2) identify study deficiencies;
(3) identify additional responses to treatment;
(4) write a discussion of the interpretation of the data; and
(5) write the executive summary.

Dr. Doherty further states that "... formats define what and how factual material is to be presented by the reviewers in DERs...The protocols which the testing laboratories follow are very specifically designed to conform to the series 81-1 to 86-1 guidelines."

He also notes that "the utilization of the reviews by the carcinogenicity, RfD, developmental and other HED peer review committees and other EPA staff toxicologists as well as HED risk assessors has established these groups as the most important customers that most critically assess and utilize the review produced by HED toxicologists."

Design Team Comments on Proposal: This would be an improvement in the process because the reviewer would not have to rewrite the methods and materials section. The study author is almost always on the mark in this area.

Electronic submission of the studies would be a valuable addition to Dr. Doherty's suggestion. This would be another alternative to reviewers rewriting the methods and materials section.

One reviewer indicated a shorter version of the suggestion is already submitted with the study as the author's conclusions.

As the primary customer for tox reviews is the current Peer Review Committees, this would give the Committees two evaluations to compare. This would give them an added perspective in making their conclusions.

One reviewer agrees that this could be done easily. Also, as Dr. Doherty points out, the person conducting the study is usually an expert in the particular field. HED toxicologists, though they have specialties, are generalists.

If the necessary information is attached to the submission, it will be easy for the toxicologist to check off the parameters to see if there are any deficiencies (Toxicology Rejection Rate Study).

This proposal will aid in up front "New Chemical" screening. As all information will be submitted in a concise form, the screener can rule quickly on the acceptability of the data. Further, the supplemental submission will act as an early warning to EPA of potentially serious concerns. EPA will be able to quickly respond to a potentially serious issue.

The Design Team's Recommendations:

The Doherty proposal offers a real change in HED operations, and the Design Team recommends adopting the Doherty proposal, with the following modifications:

(1) All Registrants are required to submit all studies via electronic format. This will allow the reviewer to move tables, methods, and materials without transcription errors. This information is necessary because there are multiple parameters (hematology, tumors, body weight, food consumption etc...) for even a short toxicology study. Therefore, toxicology DERs need extensive tables to support the conclusions stated in the DER.

(2) In order to address concerns that EPA is in the "back pocket" of industry, the following points need to be made clear to all parties:

(a) the Registrant's supplemental submission is not a DER.

(b) the data evaluation record (DER) is an independent evaluation prepared by the EPA toxicologist.

(c) the Registrant's supplemental submission will be used as an aid by the EPA toxicologist in preparing the DER. The supplemental submission is not a substitute for the DER.

(3) This new method should be tested in a pilot program and modified as necessary.

(4) The proposal, with these modifications, should be submitted to the Office of the General Counsel for review of issues such as CBI, FOI, copyright, etc.

(5) The proposal should also be examined with regard to international harmonization efforts.

The revised proposal will be reviewed by the Policy Steering Committee for a final decision.

4. Miscellaneous Items

The following topics were also discussed with respect to data review.

1) Coordinators are needed to work with IMCSB in sending data to and receiving reviews from contractors. The secondary review process for contractor documents may also need to be reexamined. For additional discussion on contract administration, refer to Chapter X, *"PLANNING, GOAL SETTING, BUDGET, WORK ASSIGNMENTS"*.

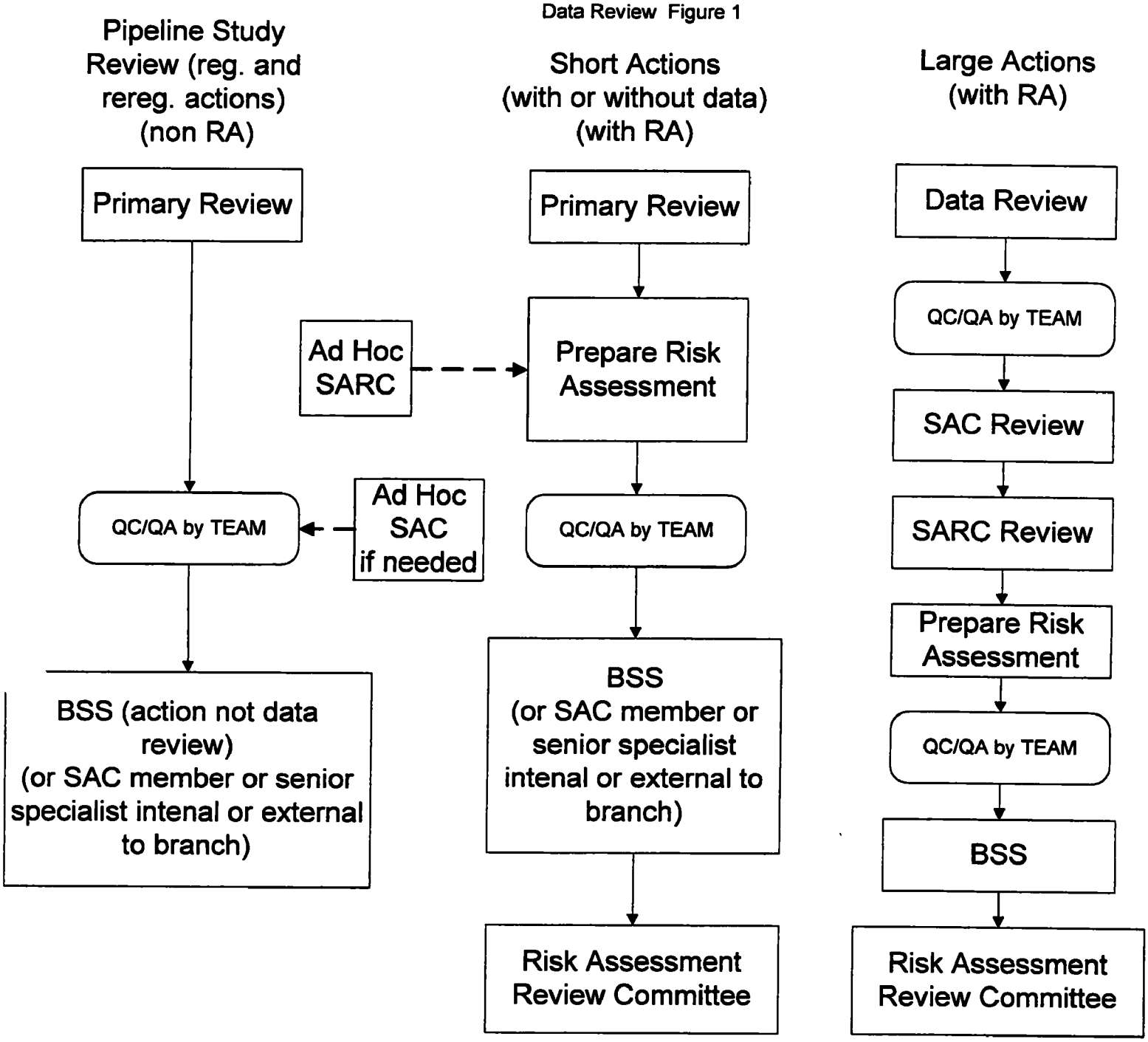
2) Based on the customer survey, the Graybeard group should be retained for review of waiver requests and time extensions. However, the Design Team recommends this function be handled by the Science Advisory Councils (SACs) and the work incorporated into the Master Scheduling System with the SACs maintaining the resulting Division files to avoid redundancy.

3) HED should continue to encourage the development of an electronic data submission process to increase the efficiency of reviews.

4) Screening of new ai's should be placed in the Registration Action Branches (RABs) since the full reviews will be done there.

QC/QA PROCESS

Data Review Figure 1



SIGNATURE REQUIREMENTS

DATA REVIEWS
From Reviewer
Thru: Team
MEMO
From: Reviewer/Team
Thru: BSS

MEMO
From: Reviewer/Team
Thru: BSS

DATA REVIEWS
From Reviewer
Thru: Team
CHAPTERS
From: Reviewer/Team
Thru: BSS
RISK ASSESSMENT
From: Risk Assessor
Thru: BSS

II. B. SCIENCE ASSESSMENT REVIEW PROCESS

ABSTRACT

The Science Assessment Review (previously named the peer review process) process consists of six Science Assessment Review Committees (SARC), each with specific functions and processes. They are as follows: 1) Hazard ID Assessment Review Committee, 2) Cancer Assessment Review Committee, 3) Reproduction and Developmental Toxicity Assessment Review Committee, 4) Metabolism Assessment Review Committee, 5) Mechanism of Toxicity Assessment Review Committee, and 6) Risk Assessment Review Committee. **The Science Analysis Branch (SAB) will have the responsibility for planning, scheduling, coordinating, and administering the committee meetings as well as generating, and archiving the final documents from the above committees.** The final decision on the membership of the SARC should be made by management. The selection process, however, should involve input from the scientific staff including an opportunity for individuals to volunteer for membership. The final documents generated by these committees will be made available on the LAN. The quality control process for toxicology DERs, formerly part of the RfD Committee, is now a function of the specific disciplinary Science Advisory Councils.

INTRODUCTION

The Science Assessment Review process (formerly called the peer review process) consists of six Science Assessment Review Committees (SARC), each with specific functions and processes. The Science Analysis Branch (SAB) of the Health Effects Division (HED) will have the responsibility for planning, scheduling, coordinating, and administering the committee meetings as well as generating, and archiving the final documents from the above committees. The final documents generated by these committees will be made available on the LAN. The SAB will be the contact for the inter- (HED) and intra- (AD, BPPD) divisional requests for all science assessments conducted by these committees. The quality control/quality assurance (QC/QA) process, formerly part of the RfD Committee, is now a function of the Toxicology Science Advisory Councils (TOX SAC). For a detailed discussion on the SAC refer to Chapter II. A., *"CORE-PROCESS - Data Review"*. The six SARCs are as follows:

HAZARD ID ASSESSMENT Review Committee (formerly TES and RfD)
CANCER ASSESSMENT Review Committee
REPRODUCTION and DEVELOPMENTAL TOXICITY ASSESSMENT Review Committee
METABOLISM ASSESSMENT Review Committee
MECHANISM of TOXICITY ASSESSMENT Review Committee
RISK ASSESSMENT Review Committee

1. **Hazard Identification Assessment Review Committee** (figure 1)

FUNCTION: The functions of the Hazard Identification Assessment Review Committee (Hazard ID Assessment Review Committee) are:

- Identify hazards (dose and endpoints) for use in the acute dietary, chronic dietary, and occupational or residential exposure (dermal and inhalation) risk assessments
- Consider exposure scenarios as they relate to a chemical
- Screen for cancer, developmental and neurotoxicity hazards and refer and make recommendations to the appropriate (cancer or repro/dev.) assessment review committees
- Determine the methodology to be used in calculating the aggregate risk
- Determine the kids sensitivity factor
- Compare the results with other organizations (e.g., WHO, CODEX, ATSDR)

PROCESS: This committee consolidates the hazard identification functions currently carried out by the RfD and the TES Committees. In addition, exposure information will be considered in hazard identification. Scientists from the exposure branches with expertise in dietary as well as occupational and/or residential exposure will be present at the committee meetings to provide data on use-patterns and exposure scenarios to support toxicology endpoint selection. This committee will also evaluate open literature data as appropriate.

PRODUCT: A single document is generated incorporating all the hazards identified for the various exposure scenarios and will be available on LAN. This document will include:

- Dose and endpoint for acute dietary risk assessment
- The RfD established with dose and the basis for the RfD
- The dose and endpoints selected for the short-, intermediate, and long-term occupational/residential exposure scenarios
- Indicate the need, or lack thereof, for special cancer and developmental assessments and present a cancer classification as appropriate
- Decisions made on neurotoxicity and the need, or lack thereof, for additional neurotoxicity or developmental neurotoxicity studies
- Determination of the kids sensitivity and aggregate risk methodology

STRENGTHS:

- This Committee combines the two existing committees (RfD and TES) thus increasing its value to the customers.

- Identifies hazards for dietary (acute, chronic, and drinking water) risk assessments at the same time by one group of scientists and eliminates the re-hashing of the data base once by the RfD Committee and again by the TES (acute oral) Committee and thus brings consistency and efficiency to this process.

- Identifies hazard for occupational or residential exposure (dermal and inhalation) risk assessments at the same time by one group of scientists who are aware of the dietary hazards that might have an impact on these (non-dietary) risk assessment.

- Makes hazard identification more consistent for all routes of exposure (oral, dermal and inhalation).

- Makes the evaluation of aggregate risk more efficient because of the consistency gained when hazard identifications for the multiple routes (oral/dermal/inhalation) and multiple sources (drinking water/dietary/occupational) are conducted by one group of scientists in one Committee.

- Addresses the kids sensitivity factor for all routes of concerns (oral/dermal/inhalation) as well as all sources of concern (drinking water/dietary/occupational) at the same time with data on these factors readily available to this Committee during its deliberations.

- Eliminates the current time interval between the RfD and TES meetings as well as the need to re-hash the entire data base at each meeting.

- Having the final document (concerning the quality control) from the TOX SAC will enable this Committee to reach a quicker, confident call on toxicity, cancer, developmental and neurotoxicity concerns.

- Results in a SINGLE DOCUMENT which will provide hazard identification for the various risk assessments.

- Eliminates the need to "wait" for two sets of document (RfD and TES) which in turn will result in better scheduling for the production of risk assessment documents.

2. **Cancer Assessment Review Committee** (figure 2)

FUNCTION: Assess the carcinogenic potential of the chemical based on the recommendations of the Hazard ID Review Committee. Using the weight of the evidence, classify the chemical on its carcinogenicity using the Agency's guidelines as well as indicate the appropriate method(s) for quantification of risk.

PROCESS: The current process for classification and identification of the methods to be used for quantification of risk is adequate. However, improvements are needed in coordination and scheduling in addition to preparing and generating the final document.

- Coordination - need to be responsive, seek out priorities and get in "tune" with the other branches and their requirements to make improvements in coordination of these meetings (e.g., coordinate with RCAB or priorities).

- Scheduling - have **"set" dates** for: data to be submitted for statistical analysis; the Science Assessment Review document to be submitted to the committee; for the review of the draft final document after the meeting; and for the generation of the final document.

- Preparation - need "scope-out" meeting with the toxicologists, statistician and pathologist to discuss the appropriateness of the data that is being submitted with reference to the statistical methods used, tumor data, pathology aspects, etc. (i.e., some kind of check list). This will insure that proper methods are used in the preparation of the cancer assessment documents that will be submitted to the Committee. This committee will also evaluate open literature and epidemiology data as appropriate.

PRODUCT: The current final document is adequate. However, improvement is needed in consistently getting the product (the final document) out to the customers. At the present, it is taking too much time to get the final document out. Having the meeting but not getting the document out on time does not serve our customers well. A process to speed this (getting the document on time) must be identified and put in practice. The final document will be made available on the LAN, similar to the RfD and TES documents that are currently available on LAN.

3. **Reproduction and Developmental Toxicity Assessment Review Committee** (figure 3)

FUNCTION: Based on the recommendation of the Hazard ID Assessment Review Committee, conduct analysis of the reproduction and developmental toxicity data. In addition, this Committee will evaluate the reproductive and/or developmental toxicity potential of the pesticide, determine the Uncertainty and Modifying Factors (UF/MF), and recommend additional studies as appropriate.

PROCESS: This Committee, currently, does not meet regularly and thus is not very "visible" since the reproductive and developmental issues are addressed in the Hazard ID Assessment Review Committee during the screening process as well as discussion centered on kids sensitivity factor. This Committee meeting should be necessary for issues not addressed by the Hazard ID Assessment Review Committee. This committee will also evaluate open literature and epidemiology data as appropriate.

PRODUCT: A Reproductive and Developmental Toxicity Assessment Document will be generated when appropriate and stored on LAN.

4. **Metabolism Assessment Review Committee** (figure 4)

FUNCTION:

- Determine the metabolites and/or breakdown products which should be included in the risk assessment and/or tolerance expression for foods and animal feeds.

- Determine the degradates which should be included in the risk assessment for ingestion of ground and surface water.

- Provide a recommendation on the hazard of the degradate relative to the parent (i.e., equally, less than, or greater than the parent).

- Provide advice on whether additional metabolism data should be submitted or whether toxicology data should be submitted on metabolites, breakdown products, or degradates.

PROCESS: Significant changes to the Committee's function and operation are not required, but the Committee should acquire the additional responsibility of determining whether or not the water degradates (or which ones) should be included in the risk assessment. This committee will also evaluate open literature and CODEX data as appropriate. A summary of the changes addressing these and other issues are listed below.

- An "initiation" meeting will be held between the toxicologists and the chemists to determine the need for an assessment by the full Committee.

- The toxicologists need to be involved in the entire assessment process. The current process tends to be driven by chemistry. This is because evaluation of most chemistry studies depends on the identified metabolites of concern. Management must emphasize that the toxicologist involvement in this committee process is as important as involvement in the Hazard ID Assessment Review Committee to the final division product for our customers.

- An EFED person with expertise in degradates in water should be added to the Committee to help address drinking water issues.

PRODUCT: The final Metabolism Assessment document should be able to stand on its own and will consist of the toxicology and chemistry components, include more information than is provided currently, and provide rationale and references for the decisions made by this Committee. This document will be stored on LAN.

5. **Mechanism of Toxicity Assessment Review Committee** (figure 5)

FUNCTION: The Food Quality Protection Act of 1996 (FQPA) requires the Agency to perform combined risk assessment for chemicals that produce adverse effects by a common mechanism of toxicity. This committee will identify those pesticide chemicals that can be grouped based on a common mechanism of toxicity (action).

PROCESS: To be defined. This committee will also evaluate open literature data as appropriate.

PRODUCT: A final Mechanism of toxicity Assessment document will be generated when appropriate and stored on LAN.

6. **Risk Assessment Review Committee** (figure 6)

FUNCTION: Evaluate the risk assessment document for:

- scientific accuracy
- consistency with Agency's policies
- examine the appropriateness of the uncertainties, limitations and assumptions used in characterizing risk
- validate the methods used in risk calculations
- determine if this document addresses the needs of the risk managers for risk mitigation

PROCESS:

- The draft Risk Assessment Document will be circulated to the Committee members prior to the meeting. This document will incorporate information on risk characterization/risk assessment.

- An appropriate person will present this document to the Division director of HED as well as to this Committee and draw support from toxicologists, scientists from the exposure branches and other personnel as required.

- The objective of this Committee is NOT to RE-EVALUATE the decisions made by the other Committees on hazard identifications, cancer classification, etc. (but modifications may be made if necessary).

- Risk assessments from all science divisions (HED, AD and BPPD) which assess human health will be evaluated by this Committee to ensure consistency in data interpreting, policy and proposed risk mitigation procedures.

- Strictly address the issues that are of concern in Risk Assessment Document (i.e., the factors identified above under functions).

- The process must be swift and effective. Ideally, issues that arise during discussion of this document should be resolved at this meeting itself; however, under certain circumstances revisions and/or clarifications to the document may be necessary. In such cases, it is imperative that the issues must be stated with clarity and resolved quickly.

  PRODUCT: A final Risk Assessment Document will be generated after the meeting incorporating the Committee's decisions.

7. Quality Control Process

FUNCTION: This will be conducted by the Toxicology SAC. For a detailed discussion of SACs refer to Chapter II. A, *"CORE WORK PROCESS - DATA REVIEWS"* .

- Evaluate adequacy of the toxicology Data Evaluation Records (DERs).

- Determine the adequacy of the study (i.e., it met the Guideline requirements).

- Review and evaluate science (i.e., interpretation of study results).

- Ascertain the appropriateness of the endpoints selected in toxicity studies.

- Evaluate the appropriateness of the NOELs/LOELs established.

- Identify data gaps.

STRENGTHS:

- With the science disciplines spread over several branched within HED, as well as in AD and BPPD, this process will provide quality control in a central place.

- Enable HED management to tap into the expertise and vast experience of the scientific staff in the conduct to quality control reviews and thus empower the staff.

- Having a team of experts in specific disciplines conducting these assessments will maximize consistency and scientific accuracy across chemicals and organizational units.

- Allow all hazard identification assessments to be conducted at the same time by separating out the quality control function.

- Maintain scientific accuracy and consistency for interpretation of data within HED as well as with other divisions.

- Decisions made by this committee will be the foundation for the Science Assessment Review Committees.

8. Staffing of SARCs

The staffing of the SARCs should be based on the following qualifications:

- Independent of their current position (management or staff/branch location)
- Must be technically competent in discipline
- Must have credibility with peers and management
- Must be able to look at the "big picture"
- Must be able to hone in on critical technical details
- Must be a player will work in a group
- Must be a problem solver.
- Staffing will be decided by Division Management (i.e., MSD and the Branch Chiefs) with an opportunity for individuals to volunteer for membership.

The selection of committee Chairs and the Executive Secretaries will be made by HED management. The Exec. Secretary will reside in SAB: however, the Chairs may or may not reside in SAB. This structure (for the SARCs) is similar to that of the FIFRA Scientific Advisory Panel (SAP) where the Exec. Secretary: plans, schedules and coordinates the meetings; prepares the data package for the meetings and prepares minutes. The SAP Chair facilitates the meeting.

9. Composition of SARCs

The Design Team has determined that the composition of the SARC should be based on the following factors:

- Need scientific background appropriate to the SARC discipline
- Mixed seniority, independent of grade
- Membership not limited to HED (include AD, BPPD, EFED) or OPP

- Must have good writing skill (to prepare the final document)
- Appropriate skill mix will be decide by Management (MSD & BCs)
- Staggered rotation, every two (2) years (as personnel resources allow)

10. Domestic Animal Safety Committee

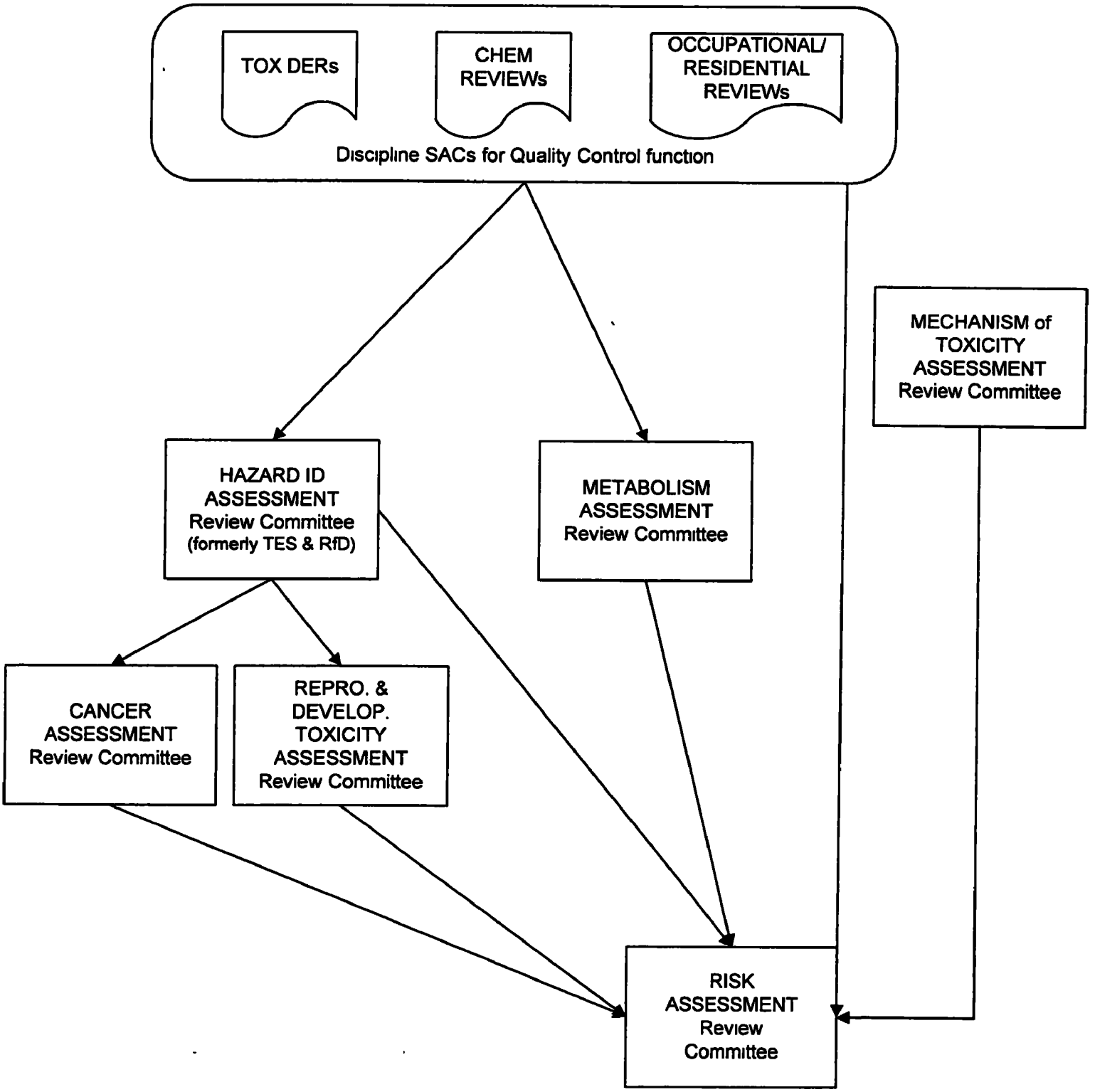
The function of this committee is to insure consistency between branches regarding domestic animal safety issues. The Design Team strongly recommends that the committee structure and function remain as is.

11. Conclusions

Overall, a central location of all the six SARCs and the implementation of the process identified above will improve communication (better scheduling), empower the staff (rotation of membership), install flexibility (chairs serving as backups for each other), meet goals, and improve customer relationship (produce risk assessment documents on time). This recommendation is based on roles and responsibilities, independent of current job descriptions and personnel. The Design Team concluded that the final decisions on the membership of the SARCs should be made by management. The selection process, however, should involve input from scientific staff including an opportunity for individuals to volunteer for membership.

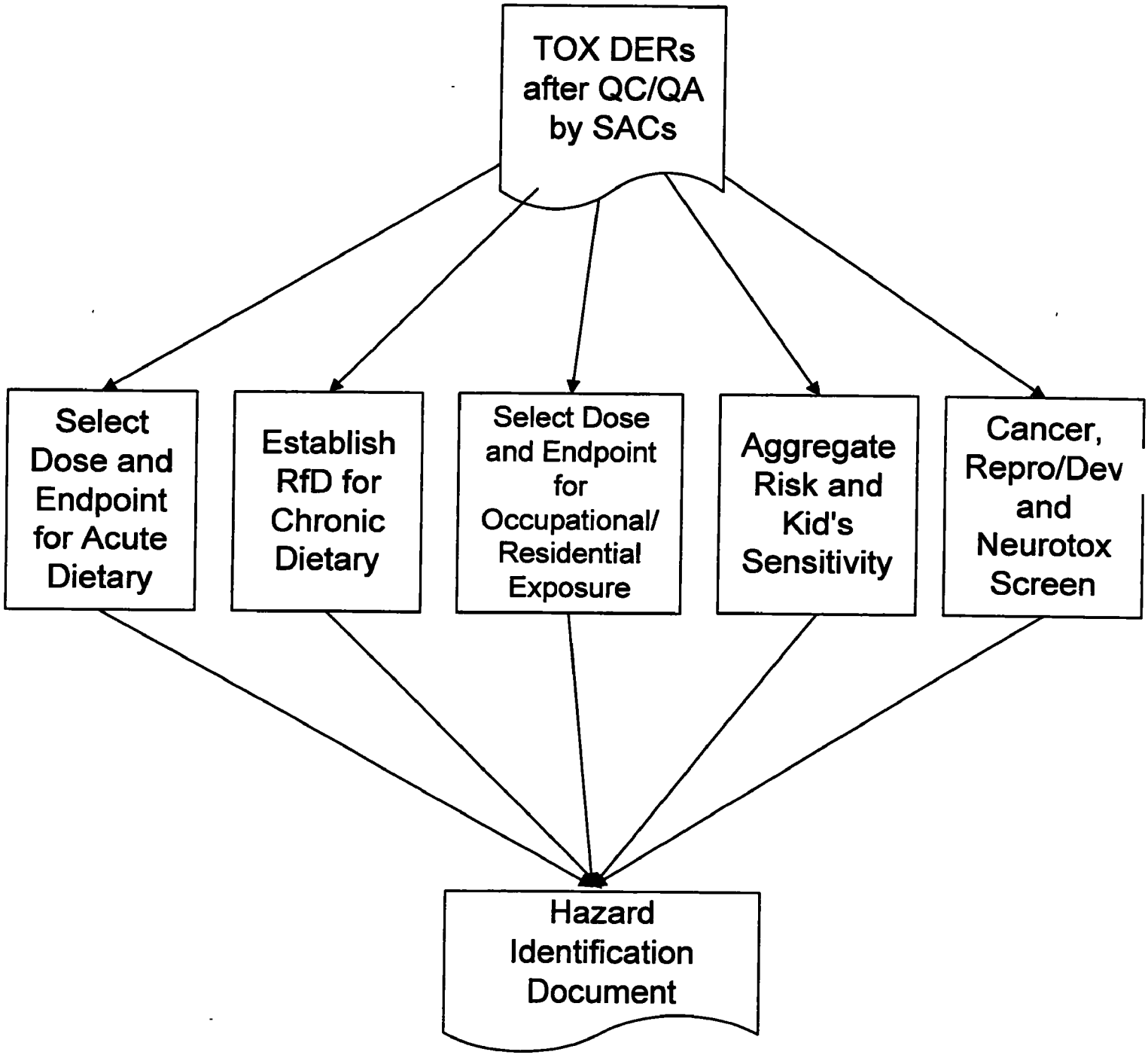
SCIENCE ASSESSMENT REVIEW COMMITTEES

SARC FIGURE 1



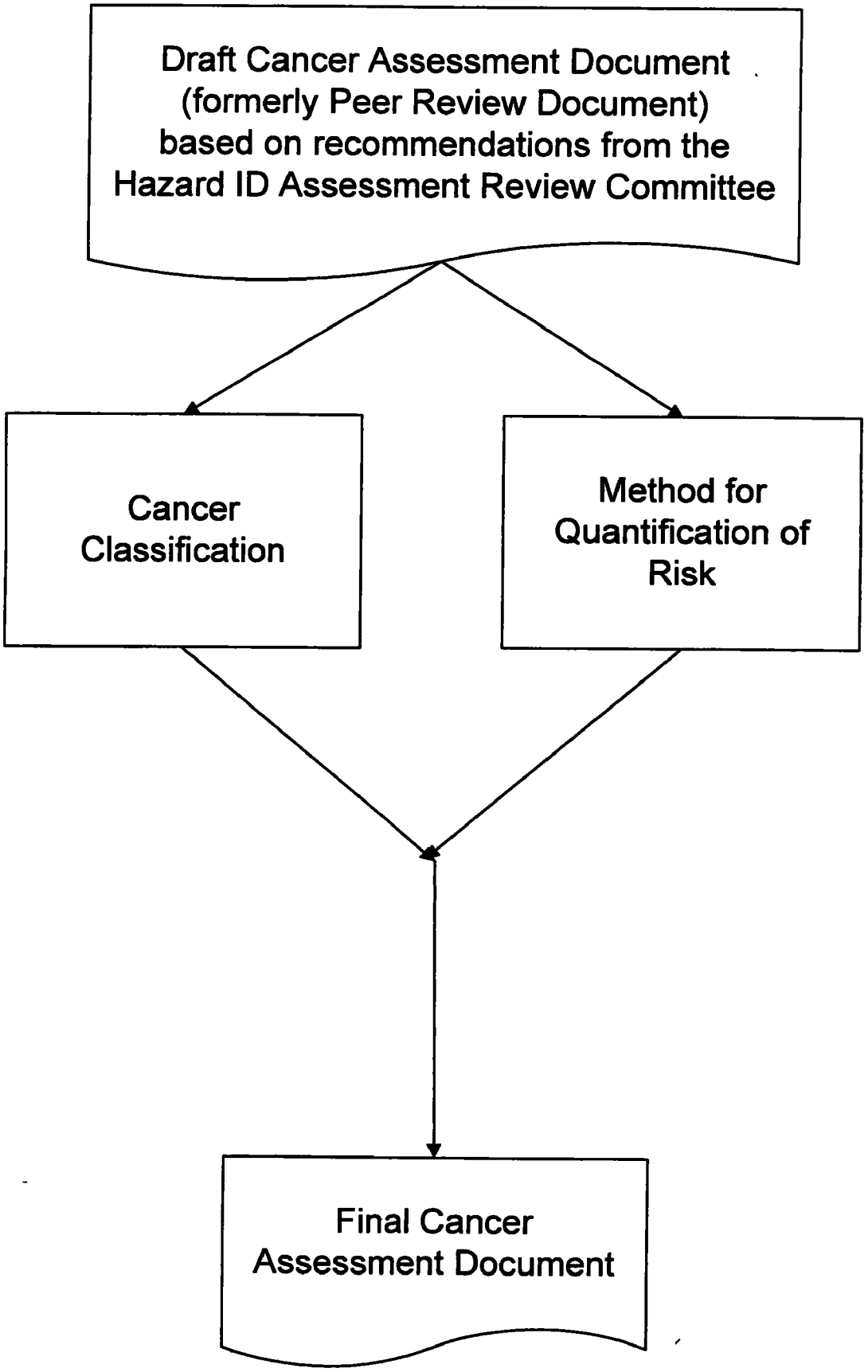
HAZARD IDENTIFICATION ASSESSMENT REVIEW COMMITTEE

SARC FIGURE 2



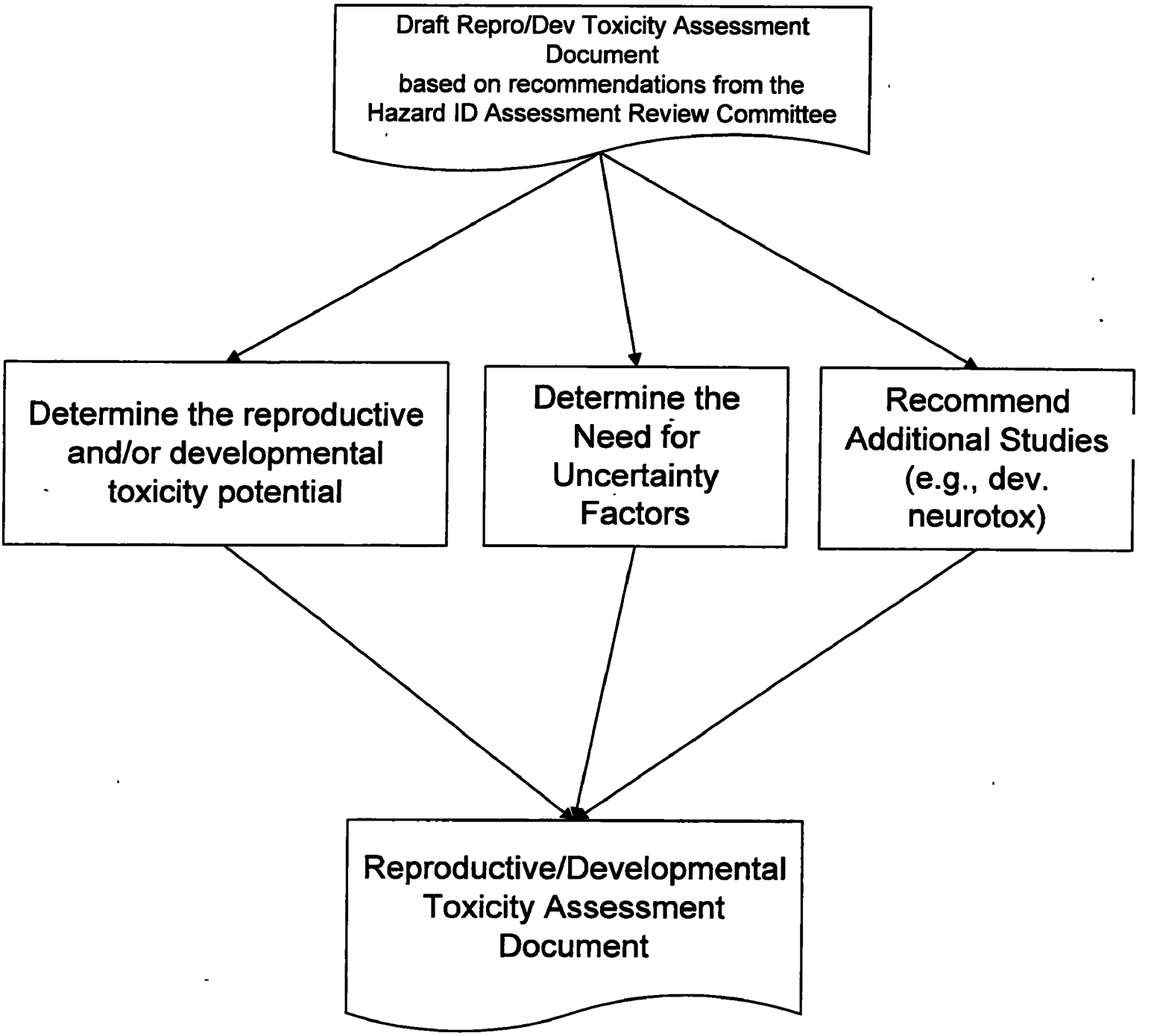
CANCER ASSESSMENT REVIEW COMMITTEE

SARC FIGURE 3



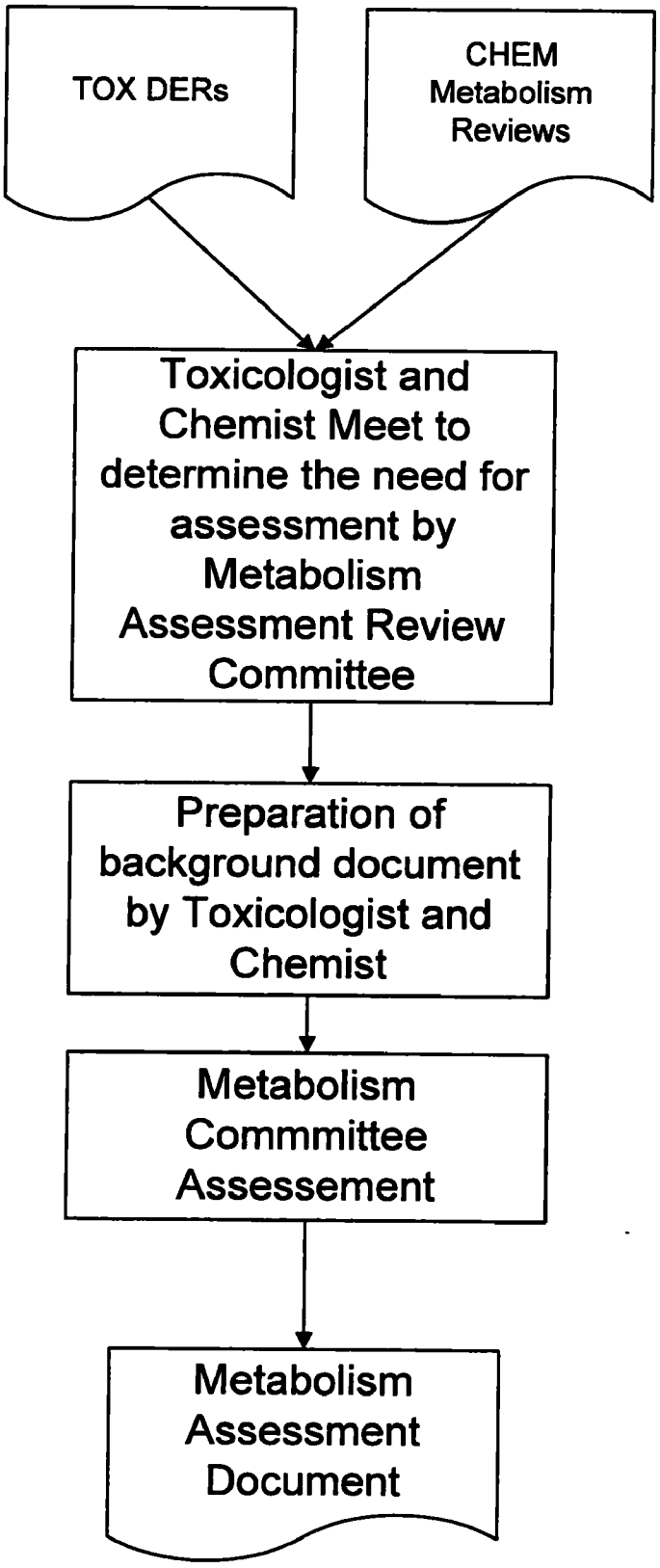
REPRO AND DEVELOPMENTAL TOXICITY ASSESSMENT REVIEW COMMITTEE

SARC FIGURE 4



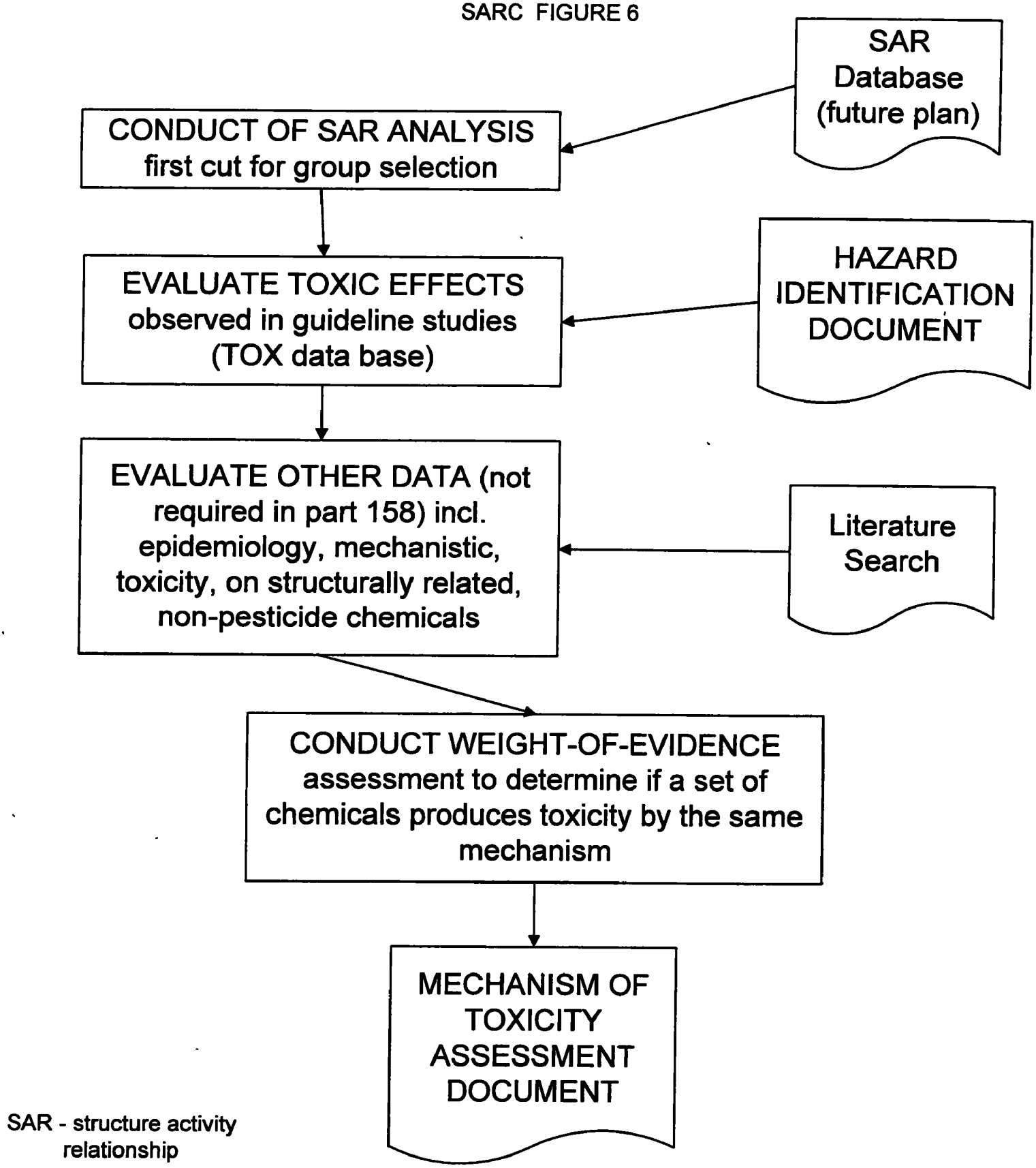
METABOLISM ASSESSMENT REVIEW COMMITTEE

SARC FIGURE 5



MECHANISM OF TOXICITY ASSESSMENT REVIEW COMMITTEE

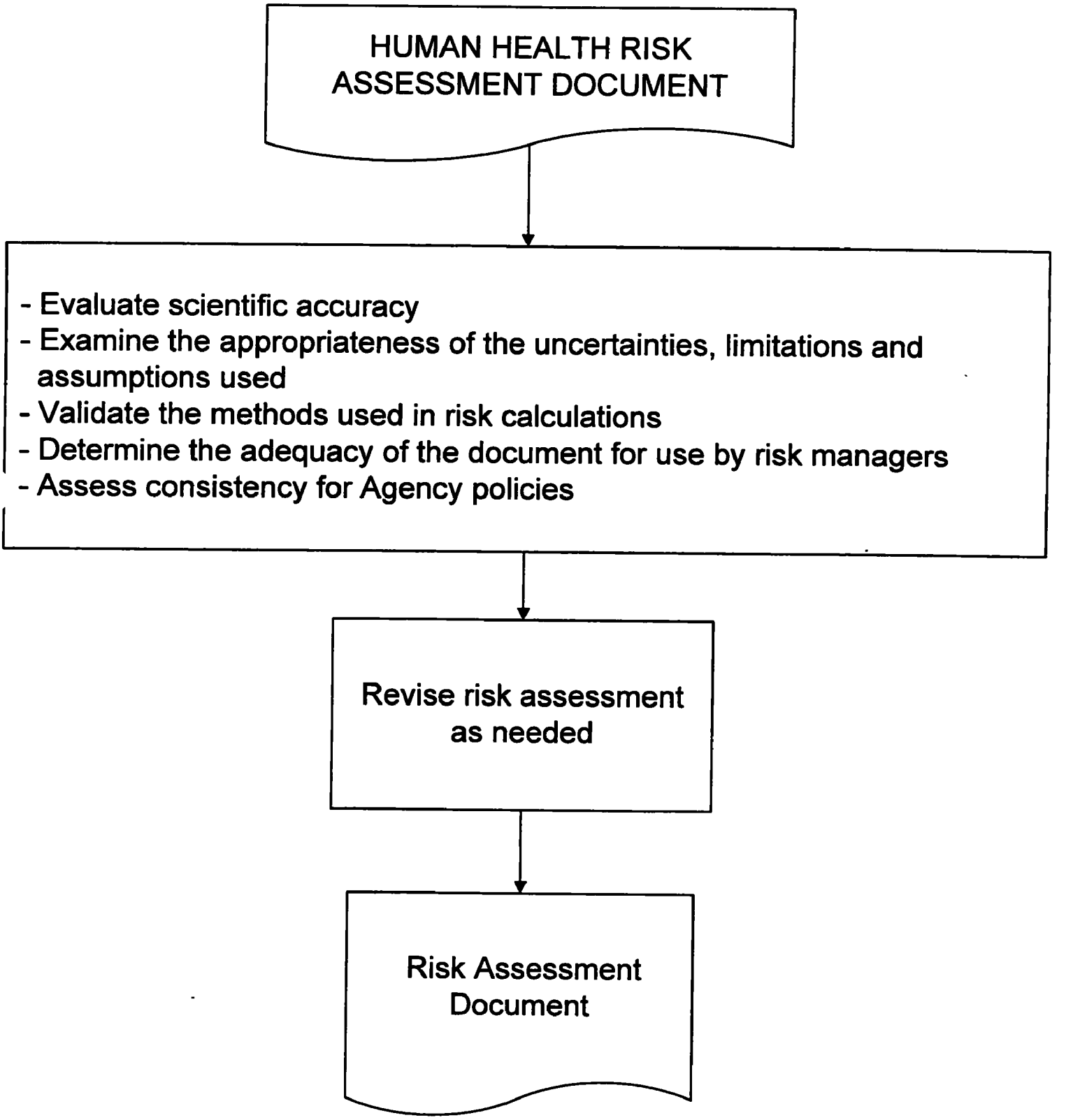
SARC FIGURE 6



SAR - structure activity relationship

RISK ASSESSMENT REVIEW COMMITTEE

SARC FIGURE 7



II. C. RISK ASSESSMENT PROCESS

ABSTRACT

The Design Team has proposed that the new organization incorporate some modifications to the current risk assessment process. **The goals of these changes are to 1) lay ground work for the subsequent multiple chemical assessments, 2) identify which uses are being supported by the registrant, 3) identify reasonable assumptions regarding use parameters (i.e., frequency and duration of use), 4) provide a mechanism for the registrant to advise the Agency of what they believe the appropriate endpoints for risk assessment are, and 5) reduce re-work and registrant rebuttals.** The proposed new process provides for submission of the registrant's risk assessment for any major registration or reregistration action. The process provides for a meeting with the registrant after endpoints have been selected and before the exposure assessment has been drafted. This meeting enables the exposure assessor to include the appropriate scenarios for use in the appropriate manner. Finally, the new process includes a Risk Assessment Review Committee that will include the risk management and all of the science divisions. Ultimately, the Design Team believes that these revisions will help the risk managers to make a well informed decision. An additional issue that still needs to be addressed is establishment of a process for sharing ground/surface water data between HED and EFED.

1. A Revision of the Existing Single Chemical Risk Assessment Process was developed which would serve to 1) reduce rework and rebuttals, and 2) lay groundwork which will be needed for subsequent multiple chemical assessments. See figure 1 for the proposed process.

While the flow diagram describes in detail the entire proposed process for a single chemical, the following points provide additional details for processes that are new.

a) Concurrent with the request for any major action for registration or reregistration, the registrant would be asked to provide information about the product including:

- labels, actual use rates for existing uses, projected market penetration for new uses, formulations, frequency of application, duration of exposure, dissipation, who is actually going to be exposed, activity patterns that may be of significance, percent crop treated (%CT), usual pre- or post- harvest intervals (PHI), their own cut at a risk assessment.

b) After data review but before the exposure assessment, the registrant would be requested to participate in a meeting to discuss the direction in which HED is headed with regard to endpoint selection, assumptions about exposure, any questions concerning the upcoming assessments, questions about drinking water issues. This meeting would also provide an opportunity for the registrant to notify the Agency of data they believe to be pertinent to the risk assessment that was not included. By sharing the information early in the process, the opportunity exists to permit adjustment of the assessment while it is still early rather than waiting until the risk assessment is final and multiple rounds of rebuttals are triggered. Similarly, by including the lead divisions in these discussions, fewer internal rounds of rebuttal may be required.

c) A risk assessment conducted by the Registrant would consist of the use data generated and marketing information they routinely gather. It forces them to review their database and confront the issues early on. Currently, the Registrants are brought in at the end of the process, rebut the risk assessment and we end up rebutting and defending every aspect of our risk assessment. Often, we agree with their conclusions and change the risk assessment. This results in unnecessary work. In other words, the rebutting of every detail is already happening, the Design Team believes it should happen earlier in the risk assessment process. The risk assessment provided by the Registrants will provide a mechanism for them to give information and advise the Agency of what they believe are the appropriate data (exposure, endpoints, assumptions, etc.). Their risk assessment will NOT replace HED's risk assessments.

2. Advantages of the Proposed Process

a) In preparation for the Hazard ID Assessment Review Committee meeting, the lead toxicologist for the action will review the toxicology data set. During this step, endpoints which may be used in the upcoming common mechanism assessment should be identified and recorded, reducing the need to revisit the data set in great detail later.

b) By making the exposure assessor an active participant in the Hazard ID Assessment Review Committee, questions about the relevance of the identified endpoints to the exposure assessment can be dealt with earlier than is currently done. This will reduce later reworking of the product produced and give a more holistic approach with better interdisciplinary interaction. The outcome will be focussed on the question at hand.

Pros

- reduced drafts and revisions
- fewer rebuttals
- rebuttals (i.e., additional data and inputs) prior to the finalization of the risk assessment.
- outstanding data surfaced earlier.
- involves the lead divisions in negotiations.
- improves coordination between lead divisions (i.e., no new registrations during risk mitigation activities on a RED).
- no surprises for management. Investment of time to manage RED/ RD schedule.

Cons

- Extra steps introduced into process. However, results in a higher quality product with less rework (do it right the first time).
- Requires customer (RD/SRRD and registrant) buy in.

3. Common Mechanism Step

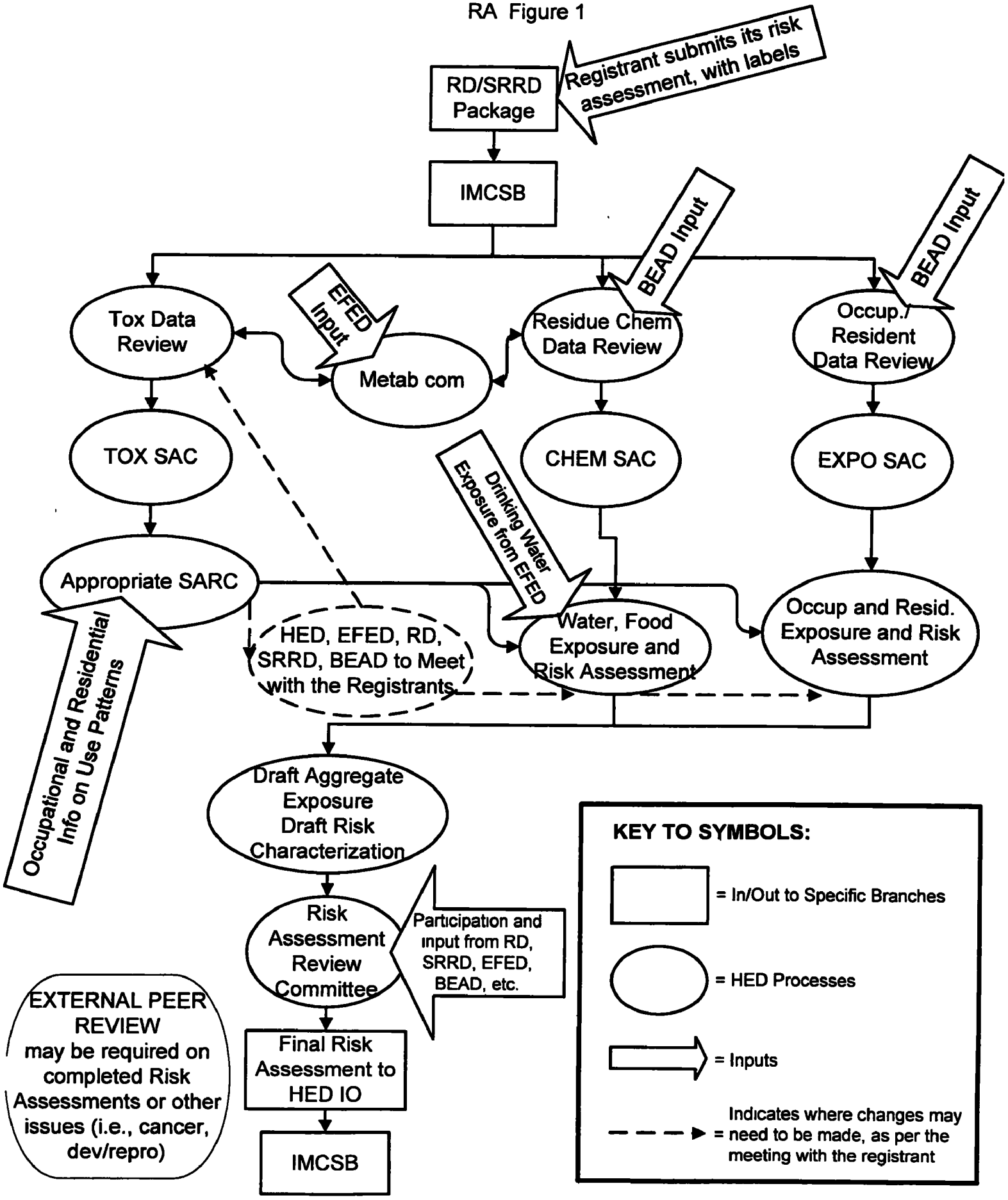
As currently envisioned, the determination of the need for a cumulative risk assessment will be made **after** the single chemical assessments are completed. The process will consist of :

- initial screening by structure for classification
- evaluation of parallel databases. To the extent possible, the number of chemicals to be considered will be reduced by doing this evaluation prior to the cumulative **exposure** assessment.
- a common mechanism, if any, will be identified with an explanation of the possible mechanism, those chemicals which are included and why, those which are excluded and why.
- Peer review (external) of the decision

4. An Additional Issue that still needs to be addressed is establishment of a process for obtaining ground/surface water data from EFED.

RISK ASSESSMENT PROCESS FOR A SINGLE CHEMICAL

RA Figure 1



II. D. POLICY DEVELOPMENT AND SPECIAL PROJECTS

ABSTRACT

Requests for development and/or clarification of pesticide human health policy as well as performance of special projects originate from sources both internal and external (e.g. office director, public, registrant, etc.) to HED. **The establishment of a HED Policy Steering Committee (PSC) would foster consistency in preparation of special project documents.** Membership on the PSC would entail the chairperson of the disciplinary Science Advisory Councils (i.e. toxicology, residue chemistry, and occupational/residential exposure) and the chair of the Risk Assessment Review Committee.

INTRODUCTION

The Design Team recommends that the Core Work Process for policy and special projects will be achieved by the formation of a Policy Steering Committee (PSC). The make-up of the PSC, the method for selecting the persons who will serve on the Committee and the way in which the Committee will function will be addressed.

1. Suppliers and Inputs/drivers

Requests for clarification of pesticide human health policy originate both internal and external (e.g. office director, public, registrant, etc.) to HED. The table below provides a listing of potential suppliers and corresponding input and drivers.

SUPPLIERS	INPUTS/DRIVERS
RD/SRRD	1.Request for new policy/guideline or clarification. 2. Request for special project.
Public, registrant, environmental groups, other Federal Agencies, other EPA programs offices	1. Same as above. 2. Request for review of new Agency policy.
New laws (e.g. FQPA)	1. Required new implementation policies/strategies.
Office Director's Assistant Administrator	1. Requests for new action. 2. Request for special projects.
Internal to HED	1. New science. 2. Request for new policy. 3. Request for special project.

2. Policy Process recommendation: Development of PSC (Figure 1)

To address these policy concerns/considerations, the development of a PSC is recommended. Described below is the process by which the PSC will perform its task.

A. PSC receives task.

B. PSC determines scope of projects and resources to accomplish task (e.g., FTE, outside help from other Agencies, universities, etc.). Supplier plays role as liaison; representatives from AD, BPPD and EFED are informed to ensure consistency in science policy.

C. The PSC identifies the HED team (i.e., HED personnel) and other relevant team members to complete task.

D. Team contacts groups/Agencies/experts for appropriate input and assistance.

E. Performs task.

F. HED/OD/Supplier provides internal review of work product.

G. External Peer Review/SAB/SAP and release draft for public comment.

H. Responds to comments, finalizes document. Distribution via FR, Internet, NTIS, etc.

I. The PSC in conjunction with the HED training coordinator, will also actively research appropriate training opportunities (meetings, courses, etc.), coordinate development of internal HED disciplinary skills, and provide this information to the SACs and staff.

3. Output/Delivery

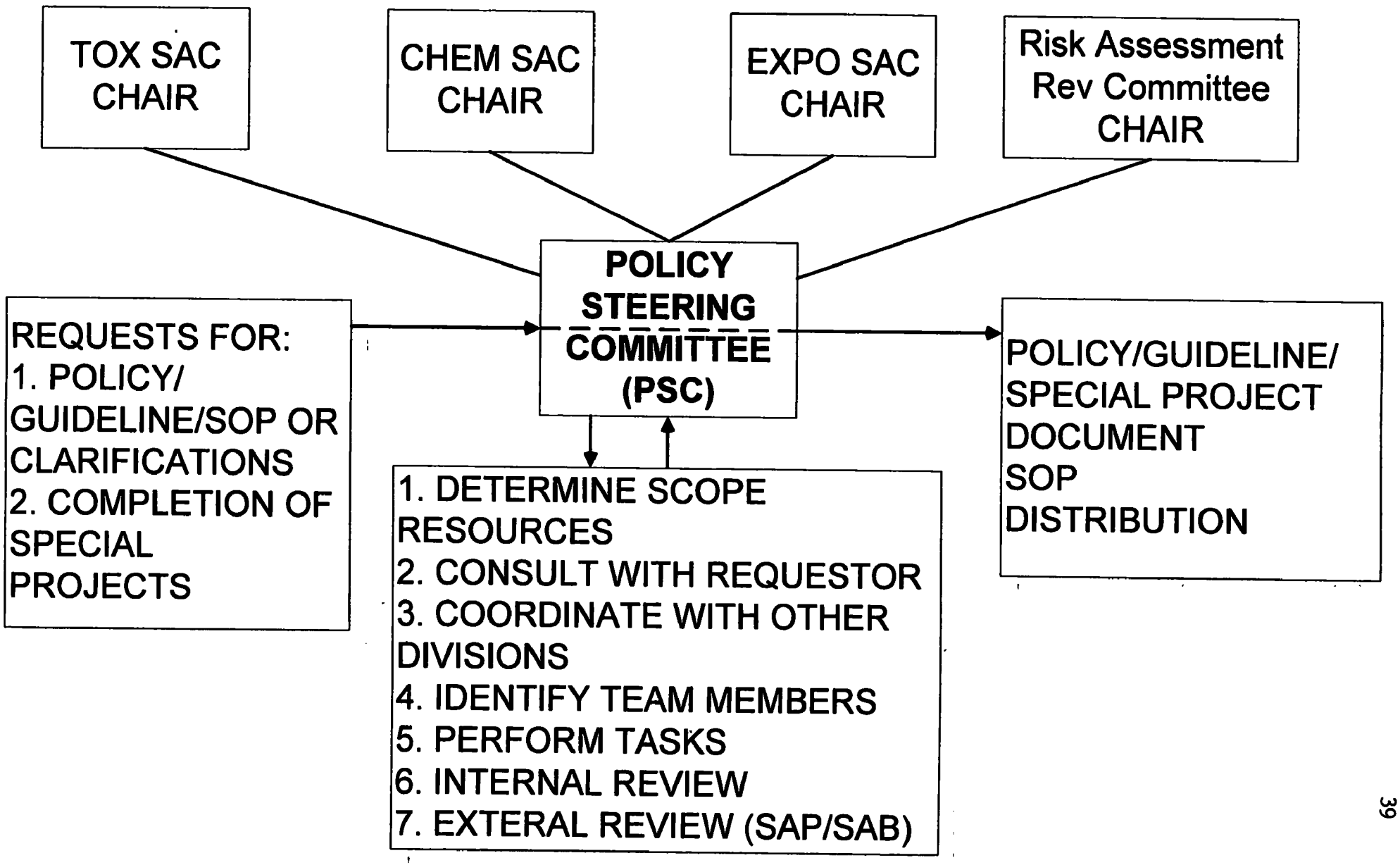
The PSC will deliver special project documents, new or revised guidelines, policy papers and SOP's.

4. Makeup of the PSC

The PSC would entail scientists from each HED science discipline (i.e., toxicology, residue chemistry, occupational/residential exposure, and risk assessment/risk characterization). Membership on the PSC would entail the chairperson of the disciplinary SAC plus the chair of the Risk Assessment Review Committee. In addition, membership on the PSC will be considered as a CJE on the individual's performance appraisal.

COMPOSITION OF THE POLICY STEERING COMMITTEE

POLICY FIGURE 1



III. BRANCH ASSIGNMENT OF CHEMICALS

ABSTRACT

Three options were discussed for assigning pesticides to branches in HED: (A) by pesticide type (e.g., herbicides to one branch and insecticides to another branch); (B) a random mix of all pesticide types to each branch; and (C) subclasses of all pesticide types to each branch. The factors considered in evaluating these options included flexibility in shifting workloads between branches, providing variety of work, addressing common mechanism of toxicity, and having particular staff become familiar with issues on similar pesticides. **The Design Team concluded that Option C should be adopted since it provides a reasonable variety of work and helps to address common mechanism of toxicity.**

Every branch will be assigned a mixture of insecticides, rodenticides, herbicides and fungicides, but the active ingredients will be grouped by chemical class within each branch. For example, Registration Action Branch-I (RAB-I) might be assigned the imidazolidinone herbicides, EBDC fungicides and pyrethroid insecticides, while RAB-II would handle the sulfonylureas, benzimidazoles, and carbamates. Inert ingredients should be considered as one subclass of chemicals and assigned to one of the RABs. Subclasses too large for one branch to handle may need to be spread over two or more branches, especially if major actions are due in a short time frame. Details on how classes are defined and divided among branches will be handled in Phase III of implementation planning.

For those cases where staff very familiar with chemicals having complex regulatory history end up in different branches after the reorganization, the Design Team recommends that teams be formed across branches to complete major actions such as REDs.

The Team also discussed the issue of complexity of actions. For example, should all "short" RD actions go to one RAB? **In order to have flexibility in shifting workloads, provide a greater variety of work for scientists, and allow more staff to participate in high visibility actions, the Design Team strongly recommends that all branches receive a variety of actions with respect to their complexity and time requirements.**

INTRODUCTION

A survey of our customers (RD, SRRD) revealed that assignment of chemicals to the HED branches is highly desirable so they know to whom to send data and have fewer total organizational units with which to deal.

Assuming assignment by branch will be followed as much as possible, processes are needed to designate which chemicals or active ingredients (ai's) go to which branches. A

process is needed to assign existing ai's as part of the reorganization and a separate one for future ai's which have yet to be submitted to RD. Several options are described below. These are presented in the context of Registration Division since the assignment of ai's within that organization is known. HED will be provided registration actions by four product branches in RD oriented around pesticide type (i.e., fungicide, herbicide, insecticide, insecticide/rodenticide) and one branch servicing minor uses and Section 18 exemptions. The following are three options for assigning ai's to the Registration Action Branches (RABs). Although SRRD has not determined how they will be dividing chemicals, the same options below would be applicable to the reregistration oriented branches in HED.

A. OPTIONS: The three options discussed in detail by the Design Team are as follows:

OPTION A (Pesticide Type)		OPTION B (Random Mix)	
RAB-I	RAB-II	RAB-I	RAB-II
Herbicides Fungicides	Insecticides Rodenticides	Herbicides A1, B2, C1... Insecticides A2, B2, C2... Fungicides A1, B1, C2...	Herbicides A2, B1, C2.... Insecticides A1, B1, C1... Fungicides A2, B2, C1....

OPTION C (Chemical Subclass of Each Pesticide Type)			
RAB-I		RAB-II	
Herbicides	A1, A2, A3... C1, C2, C3...	Herbicides	B1, B2, B3... D1, D1, D3...
Insecticides	B1, B2, B3... D1, D2, D3...	Insecticides	A1, A2, A3... C1, C2, C3...
Fungicides	A1, A2, A3... B1, B2, B3...	Fungicides	C1, C2, C3.... D1, D2, D3....

1. Option A: Align with RD by pesticide type (e.g., RAB-I handles fungicides and herbicides while RAB-II does insecticides and rodenticides).

   The advantages are:

   - It minimizes the number of branches involved with a particular type of pesticide (particular staff become more familiar with the issues on similar pesticides).

   - It would also help to address the issue of common mechanism of toxicity.

   The disadvantages are:

   - It reduces flexibility in matching workloads.

   - Reduces the variety of work for the scientists ("burnout").

   The variety of work issue was one of the major concerns raised by HED staff at earlier meetings on the reorganization. The difficulty in shifting workload was observed in the past when the Toxicology Branch split into two branches (one for herbicides and fungicides and one for insecticides and rodenticides).

2. Option B: Assign a more or less random mix of ai's to each RAB.

   The advantages are:

   - Maximizes variety in work and flexibility in shifting workloads, including sending some new ai's to Toxicology/Chemistry and Exposure Branches.

   - It would permit the chiefs of the RABs to assign future ai's to that branch having more resources.

   The disadvantages are:

   - Requires more coordination across branches for consistency as more units are involved with a particular type of pesticide.

   - Does little to address common mechanisms of toxicity.

3. Option C: Subclasses of chemicals to each RAB (e.g., imidazolidinone herbicides, EBDCs, pyrethroids to RAB-I and sulfonylureas, benzimidazoles, carbamates to RAB-II).

The advantages are:

- Represents a compromise of Options A and B with respect to variety of work and reducing the number of staff and branches dealing with particular ai's.

- It could in large part address the common mechanism of toxicity issue as well.

One disadvantage is:

- Reduced ability to shift workloads between branches.

B. FACTORS TO CONSIDER IN ASSIGNMENTS:

There are two additional factors to consider in assigning ai's to both registration and reregistration branches. First, are there any personnel especially familiar with particular ai's? In cases where staff have spent years on pesticides with complex regulatory history, reassignment to new reviewers would result in significant delays while they become familiar with the issues. However, keeping all the reviewers on a given ai after staff reassignment could conflict with branch chemical stewardship (e.g., the tox, residue, and occupational exposure personnel could end up in three different branches). In these instances consideration may need to be given to forming a team across branches to complete a major document such as a RED.

The second factor is difficulty of assignments. In the case of RD actions, there has been a suggestion that all "short actions" (Sect. 18s, 24cs, amended uses) be assigned to one RAB. With such a system the minor use/section 18 branch in RD would have to deal with only group in HED. However, all the product oriented managers in other RD branches would then have to deal with two HED branches for each chemical. The reviewers in the "short action" RAB would also have to deal with a constant barrage of short deadlines as is presently being experienced by PIRAT. Having both RABs do all types of actions provides a greater variety of work to reviewers. Similarly in the reregistration area, there is considerable variability in the complexity of generating REDs. Reregistration ai's could be divided such that some branches focus only on the more involved REDs while others work on simpler ones. It is

recommended that such an approach not be followed in order to help prevent "burnout", sharpen skills, and allow more staff to participate in high visibility actions.

C. CONCLUSIONS:

The Design Team selected **Option C** and concluded that chemicals should be assigned to branches by chemical subclasses within each type of pesticide. This option was chosen because it provides a reasonable variety of work for reviewers and also helps address the issue of common mechanism of toxicity. Every branch will be assigned a mixture of insecticides, herbicides and fungicides, but the active ingredients will be grouped by chemical class within each branch. For example, Registration Action Branch-I might be assigned the imidazolidinone herbicides, EBDC fungicides and pyrethroid insecticides, while RAB-II would handle the sulfonylurea herbicides, benzimidazole fungicides and carbamate insecticides. Chemicals not belonging to a subclass could be distributed randomly among branches. It was also concluded that inert ingredients and safeners should be considered as one subclass of chemicals and all assigned to one of the Registration Action Branches. In the case of subclasses too large for one branch to handle (e.g., organophosphates), the chemicals may need to be spread over two or more branches, especially if major actions such as RED's are due for numerous members of the class in a similar time frame. Details of the process of how classes are defined and divided among branches will be handled in Phase III of implementation planning.

With regard to chemicals whose actions come from Registration Division, all the active ingredients need to be divided into only two groups as there are only two Registration Action Branches (RAB) in HED. For reregistration, there are several possible ways to divide the chemicals since there are seven branches doing data review and/or risk assessment. After discussing several options, the Design Team recommends dividing the reregistration chemicals into two groups similar to those for registration. These groups would be assigned to the two interdisciplinary Reregistration Branches. At the weekly division prioritization meetings all the branch chiefs would discuss the pending workload. Actions for selected chemicals on the two reregistration lists would then be assigned to RCAB. The decision to transfer actions to RCAB will be based upon resources available in the branches and the time constraints on completion of the actions. As a rule, entire actions should be redirected to RCAB, not individual studies. RCAB will then coordinate the data review by the Toxicology and Chemistry and Exposure Branches for these selected actions as well as prepare risk assessments (see Figure 1).

The chiefs of the Registration Action Branches will also need to be involved in the prioritization meeting discussions on reregistration actions since some new chemicals designated for the RAB's may be assigned to RCAB and the disciplinary branches as well for data review and risk assessment. It is incumbent upon all the branch chiefs to be familiar with the tasks assigned to their staff and to ensure branch workloads are equitable. This approach should provide maximum flexibility and increase HED's ability to respond to emergencies and shifting priorities.

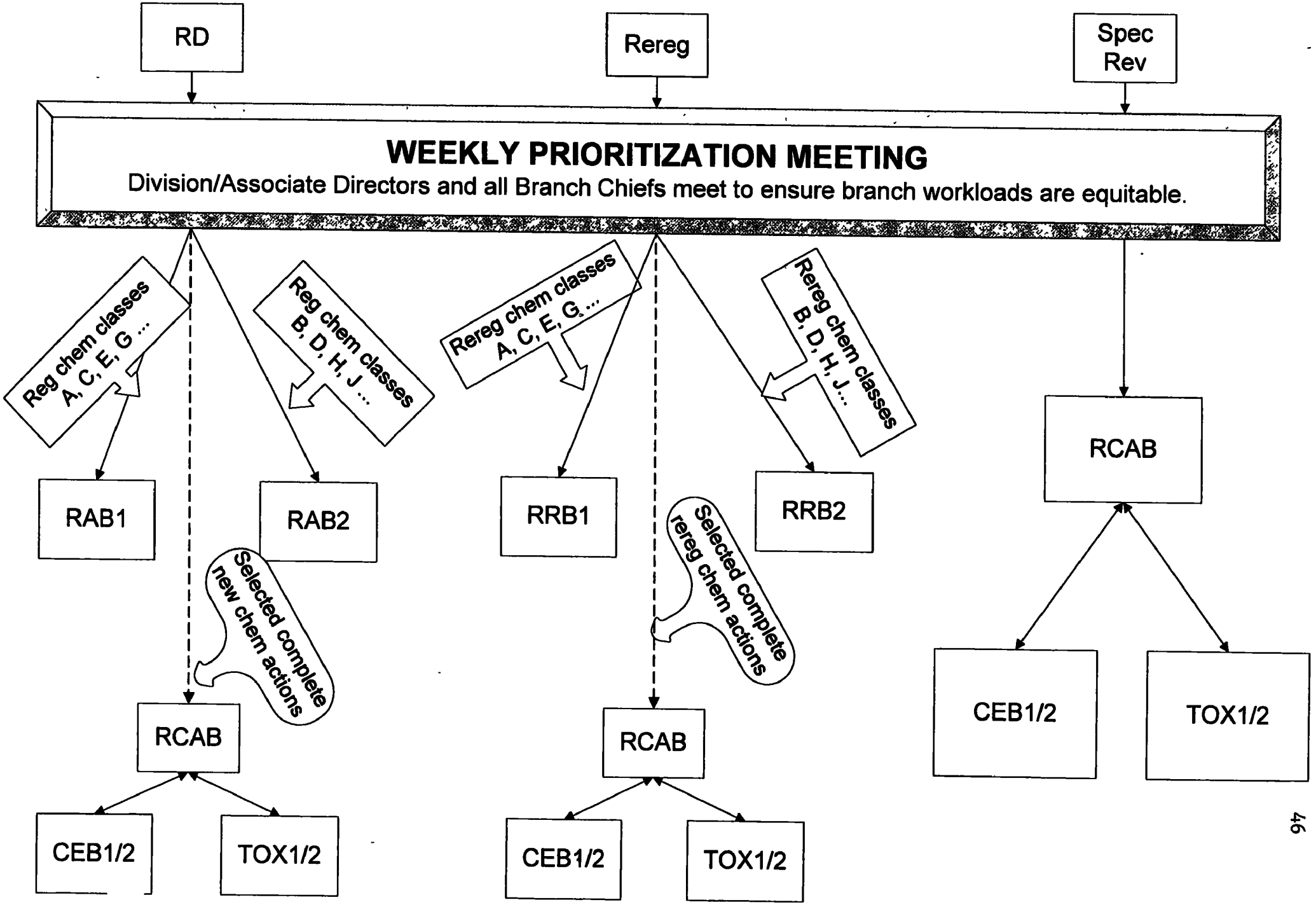
For those cases where staff very familiar with chemicals having complex regulatory history end up in different branches after the reorganization, the Design Team recommends that teams be formed across branches to complete major actions such as RED's.

Related to branch assignment of chemicals, the Team also discussed the issue of complexity of actions. For example, should all "short" RD actions go to one RAB? Should all the complex RED's with many pesticide uses go to a particular branch? **In order to have flexibility in shifting workloads and have a greater variety of work for scientists, the Design Team strongly recommends that all branches receive a variety of actions with respect to their complexity.** Such a process will help prevent "burnout", sharpen skills, and allow more staff to participate in high visibility actions.

Finally, with respect to assignment of chemicals within each branch, the Design Team recommends a team ownership concept of pesticides. Ownership by individual reviewers is questionable since the absence or departure of an individual could create a significant knowledge gap.

BRANCH ASS GNM ENT OF CHEMICAL ACT ONS

BRANCH ASSIGN FIGURE 1



IV. BRANCH DEFINITION AND WORK PROCESSES

ABSTRACT

In this section the branches are defined and the work processes are described. **It is recommended that the interdisciplinary branches should each be composed of two teams modeled after PIRAT. This team approach would support the recommended data review process.** Each team would be composed of hazard (toxicologists), dietary and occupational/residential exposure scientists, and risk assessors. **The disciplinary branches should be divided into two teams; the teams in the Toxicology Branches should include the expertise in the various fields of toxicology while the team in the Chemistry and Exposure branches should be a mix of staff which perform both dietary as well as non-dietary exposure analyses. The SAB will be composed of two teams: one comprised of the statisticians and the other composed of executive secretaries of the Science Assessment Review Committees (SARCs) and information scientific management specialists. The SAB would "house" all the SARCs;** which are the Hazard ID, Cancer, Reproduction and Developmental, Metabolism, Mechanism of Toxicity, and Risk Assessment Review Committees. The IMCSB will be composed of two teams, divided along functional lines. **Except for the creation of a Master Scheduling System with data input from the Branch Chiefs working as a team, no changes were recommended for IMCSB.**

If the Registration backlog becomes too high, then RCAB and the disciplinary branches may be called upon to assist. The Design Team recommends that it would be best to use the disciplinary branches for major actions such as new chemicals. **RCAB would be responsible for coordination and production of the risk assessment and the disciplinary branches would serve on the team and review the data.**

It is recommended that the Division form three Science Advisory Committees (SACs) for each of the disciplines: hazard (toxicology), dietary exposure (residue chemistry), and occupational/residential exposure. Namely, the Toxicology SAC (TOX SAC), Chemistry SAC (CHEM SAC) and Exposure SAC (EXPO SAC). Members of the SACs will be comprised of one representative from each branch doing work in that discipline. For example the TOX SAC will have one person from each of the toxicology branches, one from each of the registration branches, and one from each of the reregistration branches. The SACs will be responsible for quality control of new chemical and REDs, maintaining consistency and scientific accuracy, address policy issues, be available on an ad hoc basis for consultation, and communication of policy and decisions across branches.

The Design Team also recommends the creation of a Policy Steering Committee (PSC) to coordinate policy, special projects, inter- and intra-agency work assignments, and other activities as needed in HED. The Chair of the 3 SACs and the chair of the Risk Assessment Review Committee will serve as members of the PSC.

A. STRUCTURE FOR DATA REVIEW PROCESS

1. Interdisciplinary Branches

These four branches are responsible for data reviews, risk assessments and the completion of the entire actions. When an action containing data for a complete package (i.e., new chemicals or large REDs) is submitted to these branches and if this package cannot be handled in these branches due to existing workloads (over flow), then that entire package (not some parts) must be submitted to the disciplinary branches. The disciplinary branches will then be responsible for the data review and risk assessment (through coordination with RCAB) of that action.

Registration Branch 1	Registration Branch 2	Reregistration Branch 1	Reregistration Branch 2

The Design Team evaluated two models for consideration as a basic structure within the interdisciplinary branches (IDBs) for Data Review Processes (DPR): a disciplinary model and an interdisciplinary model. The latter is based on the Pilot Interdisciplinary Risk Assessment Team (PIRAT) operating in RCAB for the past year.

A) *The Disciplinary Model:* This model will consists of THREE teams grouped together by disciplines as follows:

1) Hazard Team consisting of toxicologists.

2) Exposure Team consisting of dietary and non-dietary exposure staff (i.e., chemists and occupational exposure scientists)

3) Risk Assessment Team consisting of scientists involved in risk characterization and assessments.

B) *PIRAT model:* This model will consists of ONE TEAM grouped together with a mixture of disciplines; hazard (toxicologist), dietary exposure (chemists), non-dietary (occupational/residential) exposure and risk assessors.

Using the design drivers as the evaluation criteria, the Design Team assessed the two Team Models for the Data Review Process (DRP). Realizing that the Team will also be involved in the Risk Assessment process, the subgroup evaluated the two Team Models for the Risk Assessment (RA) process as well and the results are tabulated below:

Team Model	Discipline		PIRAT	
Design Drivers	DRP	RA	DRP	RA
Communication	B	A/C[1]	C	A
Maintain Scientific Discipline	A	A	B	B
Empowerment	A	A	A	A
Flexibility	A	C	B-	A
Goal/Purpose	A	B	B	A
Management/Leadership	-	-	-	-
Customer Relations	C	C	B	A

[1] If Branch located together then A; if located by discipline then C

Recommendations: For the Interdisciplinary Branches, the Design Team recommends the formation of 2 or 3 Inter Disciplinary Teams (IDTs) using the PIRAT Model based on the following factors:

- Although the Disciplinary Model is best suited for Data Review Process, the PIRAT Model is best suited for the Risk Assessment Process.

- Risk Assessment is the major product and focus of HED's customers and therefore, the PIRAT Model is better for meeting our customers needs.

- Having a mixture of scientists in various disciplines with experience, expertise and knowledge will increase communication, empower the staff, give flexibility to management, which in turn will enable the branch to meet its goal and purpose and have a better customer relationship.

- This model is compatible with the concept of a project oriented team approach in which a "mini-team" consisting of scientists from each of the discipline can work together "on a

project" and not necessarily be "confined" to any team. This can be a hybrid of the PIRAT Model. The number of "mini-teams" in a branch will depend on the work load and available/resources.

- This model will enable the management to have the flexibility to use the expertise of the scientists to rotate in the Science Advisory Councils (discussed later).

For QC/QA procedures refer to *Chapter II. A. "CORE-PROCESS - DATA REVIEW"*

2. Disciplinary Branches

A) *Toxicology Branch (TOX- I and TOX- II)*

Toxicology 1	Toxicology 2

The Design Team recommends two disciplinary driven teams for the DRP in the two toxicology disciplinary branches. Each team should have a mixer of the various toxicology disciplines (e.g., chronic, reproductive, developmental etc). Since the support for Risk Assessment for these branches will be provided by RCAB, the teams were evaluated for only the Data Review Process. As shown below, the results show that the disciplinary teams are best suited for the Data Review Process because of the factors identified; customer relationship, however will suffer due to the "narrow focus".

Design Drivers	DRP
Communication	B
Maintain Scientific Discipline	A
Empowerment	A
Flexibility	A
Goal/Purpose	A
Management/Leadership	-
Customer Relations	C

These branches will serve as the "home base" for training of the new hires, "keeping-up" with the state of the science by discipline, and professional advancement of the staff.

For QC/QA procedures refer to *Chapter II. A. "CORE-PROCESS - DATA REVIEW"*

B) *Chemistry and Exposure Branches (CEB-I and CEB-II)*

The Design Team recommends two teams for the DRP in the two chemistry and exposure branches and these teams will consists of a mixture of scientists with dietary (chemists) and non-dietary (occupational/residential) exposure fields. Such a mix would serve the best interest of these two branches by meeting the evaluation criteria as shown below:

Chemistry/ Exposure 1	Chemistry/Exposure 2

Design Drivers	DRP
Communication	B
Maintain Scientific Discipline	A
Empowerment	A
Flexibility	A
Goal/Purpose	A
Management/Leadership	-
Customer Relations	B

These branches will serve as the "home base" for training of the new hires, "keeping-up" with the state of the science by discipline, and professional advancement of the staff. For QC/QA procedures refer to *Chapter II. A. "CORE-PROCESS - DATA REVIEW"*

3. SAB and RCAB: These two branches (SAB and RCAB) are not identified in the structure dealing with the Data Review Process since they will not be involved in "data review" *per se.*

B. STRUCTURE FOR SCIENCE ASSESSMENT REVIEW PROCESS

1. Science Analysis Branch (SAB)

The Design Team is recommending that SAB be composed of two teams. The first team will consist of the statisticians and staff not directly on Science Assessment Review Committee (SARC). The second team will be composed of the Executive Secretaries of the .

SARCs, and scientific information management specialists (literature search, external peer review, IRIS, 1-liners and SARC data bases). All committee Executive Secretaries should reside in SAB.

The Design Team evaluated the "existing" structure and peer review process vs. the "proposed" Science Assessment Review Process. The "proposed" review process involves: 1) consolidation of the RfD and TES; 2) central location of all the committees; 3) accountability; and 4) ability to meet customer needs. This evaluation was based on the process independent of current job descriptions and/or personnel. The results are shown below:

Design Drivers	Existing	Proposed
Communication	C	A
Maintain Scientific Discipline	A	A
Empowerment	C	B
Flexibility	B	B
Goal/Purpose	C	B
Management/Leadership	-	-
Customer Relations	C	B

The Design Team recommends the following structure in SAB:

Structure: Administration of the 6 Science Assessment Review Committees (SARCs) in SAB; not necessarily all the Chairs.

HAZARD ID Assessment Review Committee	Cancer Assessment Review Committee	Repro/Dev Toxicity Assessment Review Committee	Metabolism Assessment Review Committee	Mechanism of Toxicity Assessment Review Committee	Risk Assessment Committee Review

Process: The SAB will be responsible for the following process: Planning; Co-ordination; Scheduling; Conducting the Committee meetings; Production of Documents; LAN Maintenance; Archiving; and Tracking Report.

Staffing For staffing of the SARC,s refer to Chapter II. B., *"CORE PROCESS - Science Analysis Review Process".*

Composition: For composition of the SARCs, refer to Chapter II. B., *"CORE PROCESS - Science Analysis Review Process".*

Strengths: The Design Team strongly believes that the factors identified below will ensure success of the structure as well as the process in SAB:

A) Consolidation of the RfD and TES "process" under one committee/chair identified as the Hazard ID Assessment Review Committee.

B) Removal of the QC/QA "function" from the existing RfD Committee will enable the Hazard ID Assessment Review Committee to concentrate on identifying hazards for acute and chronic dietary (TES/RfD) as well as Residential/Occupational exposure (TES) risk assessments.

C) Location of the Metabolism Assessment Review Committee will give a solid structure (instead of the current "floating" condition) and also empower the involvement of the toxicologists and the chemists throughout the process instead of the process being "chemistry-driven "as it is at the present time.

D) Location of the newly created Mechanism of Toxicity Assessment Review Committee and the Risk Assessment Review Committee will provide structure and provide an avenue of the much needed interaction of these committees with the other committees as well.

E) Overall, a central location of all the six Science Assessment Review Committees and the implementation of the process identified above will improve communication (better scheduling), empower the staff (rotation of membership), install flexibility (chairs serving as backups for each other), meet goals (identify hazard), and improve customer relationship (produce risk assessment documents on time).

F) The Design Team concluded that the final decisions on the membership of the SARCs should be made by management. The selection process, however, should involve input from scientific staff including an opportunity for individuals to volunteer for membership.

2. Interdisciplinary, Disciplinary Branches (Toxicology and Chemistry/Exposure): All these branches are connected to SAB by providing necessary data to the Science Assessment Review Committee (SARC).

3. RCAB: Connected to the 2 toxicology and 2 chemistry/exposure branches by providing risk characterization and risk assessment and to SAB for Science Assessment Review Committee evaluation. The Design Team is recommending that RCAB consist of one team with a project focus for: 1) coordination of Special Review Risk Assessment with all branches (as noted in the functional statement); 2) coordination of Risk Assessment (REDS and some New Chemicals) with the disciplinary branches; 3) perform special assignments requiring in-depth analysis or rapid response; 4) perform integrated human health risk assessments, represent HED on risk assessment positions and related issue; and 5) maintain liaison with the SRRD and with other Agency offices with related responsibilities. Special Review assignments in multiple branches need to be addressed by the transition team.

C. STRUCTURE FOR INFORMATION MANAGEMENT AND CONTRACT SUPPORT BRANCH (IMCSB)

The IMCSB will consists of two teams with each team having the functions as shown below. Both teams will interact with each other as necessary. The Design Team believes that the functions described below are inter-changeable and thus enable the team to interact efficiently. This structure and process will ensure success of this branch.

TEAM 1		TEAM 2	
Staff		Staff	
Program Analysts	5	Program Analysts	3
Information Management Specialists	2	Information Management Specialists	2
		Environmental Protection Specialists	1
Functions		Senior Computer Specialist	1
		Junior Computer Specialist	1
- Budget Formulation/Execution		Functions	
- Integrated Financial Management System (IFMS)			
- Human Resources		Information Management	
- Contract Administration (PO, AWAM, etc.)		- "Marvin Function": Log actions from RD/SRRD into and out of PRATS	
- Facilities Management (space, telecommunications, property management)		- HED Master Scheduling System (MSS). Input of chemicals to MSS from Branch Chiefs	
- Security		- ADP management:	
- Document Control Officer		- programming, coordination of OPP Lotus Notes, Oracle etc., troubleshooting, training HED staff, custodial.	
- Training Coordinator		- Librarian	
		- Any other LAN data base maintenance support and work with Sr. and Jr. computer specialists	

Process: The IMCSB will be responsible for the following processes: Support to HED in the areas of procurement, contract management, information management and general administrative support.

Extramural Activities: Supports activities by managing procurement, acting as Project Officers (PO) - Work Assignment Managers (WAMs), administering contracts, grants, IAG's etc. and providing liaison to Contract Officers and contractors outside the division.

Information Management: Document Control Officer for records management; communications liaison - LAN and internet dissemination of HED information; plan, create and maintain the division master scheduling database of division review of chemicals, schedules and special projects.

Administrative Support: Budget formulation/execution, personnel, training, travel, facilities, telecommunications, ADP equipment and supplies, property management, etc.

D. STRUCTURE FOR RISK ASSESSMENT PROCESS

RCAB	Registration 1	Registration 2	Re-registration 1	Re-registration 2

For the four Interdisciplinary Branches, the Risk Assessment (RA) process will follow the "Single Chemical Assessment Process" as shown in Figure 1. This process was identified by the Core Work Process subgroup (Refer to Chapter II, *"CORE REVIEW PROCESS - RISK ASSESSMENT"*). The RA process will be self contained in the respective branches since the components of risk assessment (hazard identification, exposure assessment and risk characterization) are produced by their own interdisciplinary teams. The SAB will provide support for SARCs while RCAB will provide support for the Special Reviews.

For the Disciplinary Branches (TOX-1/2 and CEB-1/2) that provide the necessary product for risk assessment (science chapters), the RA process will be handled by RCAB with support from the SAB on SARCs. RCAB will provide support for the Special Reviews.

The Design Team, using the design drivers as the criteria, evaluated the RA process preformed by the Interdisciplinary Branches/Teams.

Design Drivers	RA
Communication	A
Maintain Scientific Discipline	B
Empowerment	A
Flexibility	A
Goal/Purpose	A
Management/Leadership	-
Customer Relations	A

E. STRUCTURE FOR POLICY/DEVELOPMENT AND SPECIAL PROJECTS

The Design Team recommends the creation of a Science Advisory Council (SAC) for each discipline. This structure was also recommended by the Core Work Process subgroup (Refer to Chapter II. D, *"CORE REVIEW PROCESS - POLICY AND DEVELOPMENT"*). These SAC's will be composed of scientists by discipline from each Branch and one person in each

of these SAC's will serve as the Chair of the respective SAC. For a discussion of the function, process and strength of SACs, refer to Chapter II. A, *"CORE REVIEW PROCESS - DATA REVIEW"*. The SACs are as follows:

Toxicology SAC (TOX SAC)	Occupational/Residential Exposure SAC (EXPO SAC)	Chemistry SAC (CHEM SAC)
6 Toxicologists	6 Exposure Specialists	6 Chemists

STAFFING: The Design Team is making the following recommendations for staffing of the SACs:

- SACs will be staffed with scientists by discipline from each Branch.
- Staffing should be accomplished by Division Management (i.e., MSD and the Branch Chiefs) during the Phase III of Implementation Planning (Transition).
- There should be a staggered rotation with term limit of two (2) years.
- Members of the SAC must elect the Chair person who would be a member of the Policy Steering Committee.

In addition to the 3 disciplinary SAC's, the Design Team recommends the creation of a **Policy Steering Committee (PSC)** to coordinate policy (e.g, FQPA), special projects (e.g, guideline revisions and harmonization), inter-agency work assignments (e.g., harmonization of reviews with Canada, California), and other activities as need in HED. The chair of the 3 SAC's and the chairs of the Risk Assessment Review Committee and Division Science Advisor will serve as members of the PSC. As the chairs of the 3 SACs and Risk Assessment Review Committee rotate, so will the members of the PSC.

F. STRUCTURE FOR FLOW OF ACTIONS THROUGH THE BRANCHES

The different types of action submitted to the interdisciplinary and disciplinary branches and the review process ("work -flow") are illustrated in the attached Figures 2-5. Specific steps for these actions in the various Branch ares provided under Branch/Team operations. The types of actions and the "work-flow" are as follows:

Figure 2. Pipeline Study Reviews

Figure 3. Short Actions (Section 18, 24(C), amended registration, new uses)

Figure 4. REDs/New Chemicals - submitted to the interdisciplinary branches

Figure 5. REDs/New Chemicals - submitted to the disciplinary branches (RCAB-driven)

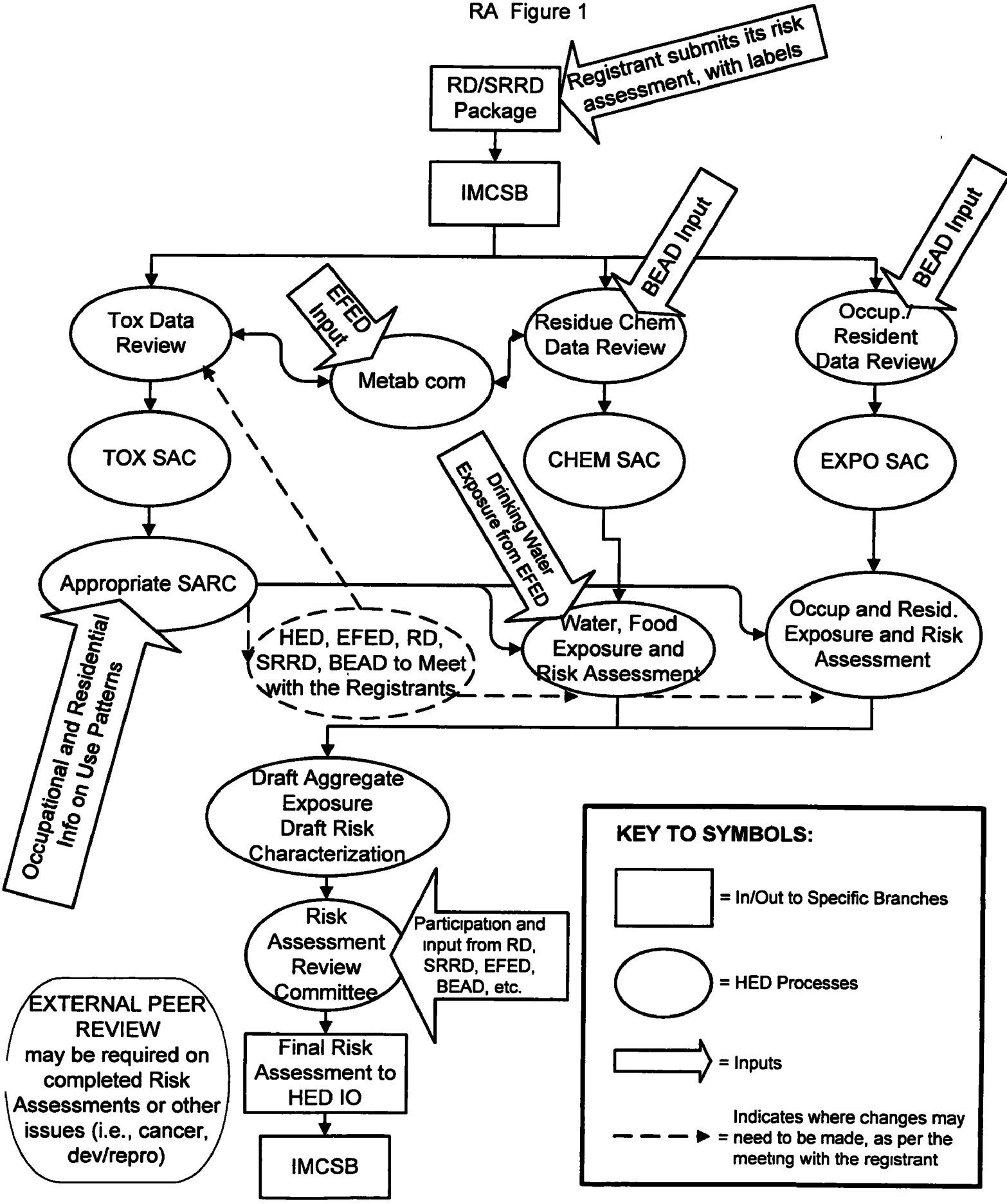
The Design Team recommends that the Implementation Planning Team and/or the Transition Team should work together with the Branch Chiefs, the Associate Directors and the Division Director to work out a process to address the handling of the actions that are currently in the various branches [i.e, existing BEANS (backlogs)].

G. OTHER

The AARP function is **integral** to the function and mission of HED. Every effort will be made to place the AARPs where their interests and skills lay.

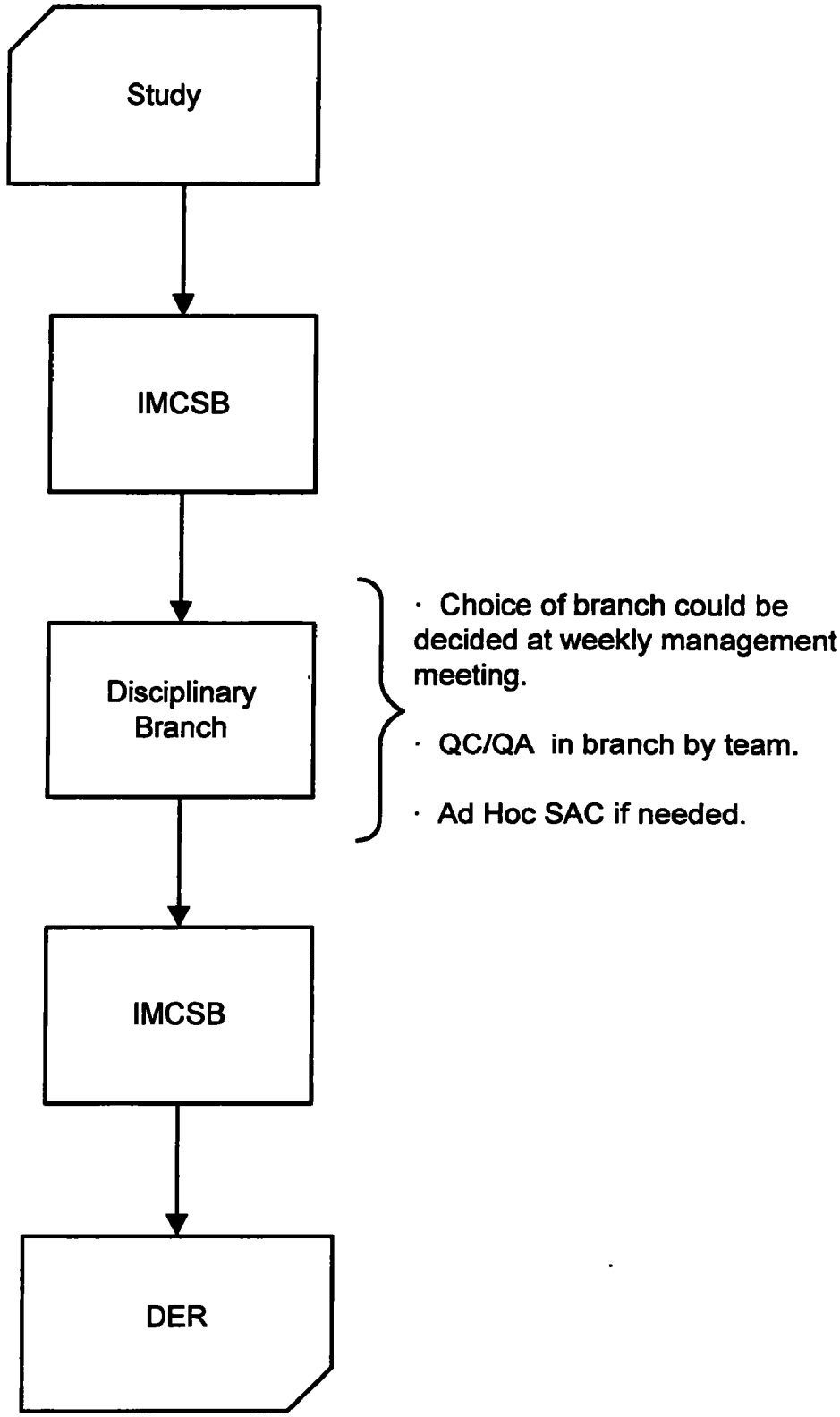
RISK ASSESSM ENT PROCESS FOR A SINGLE CHEMICAL

RA Figure 1



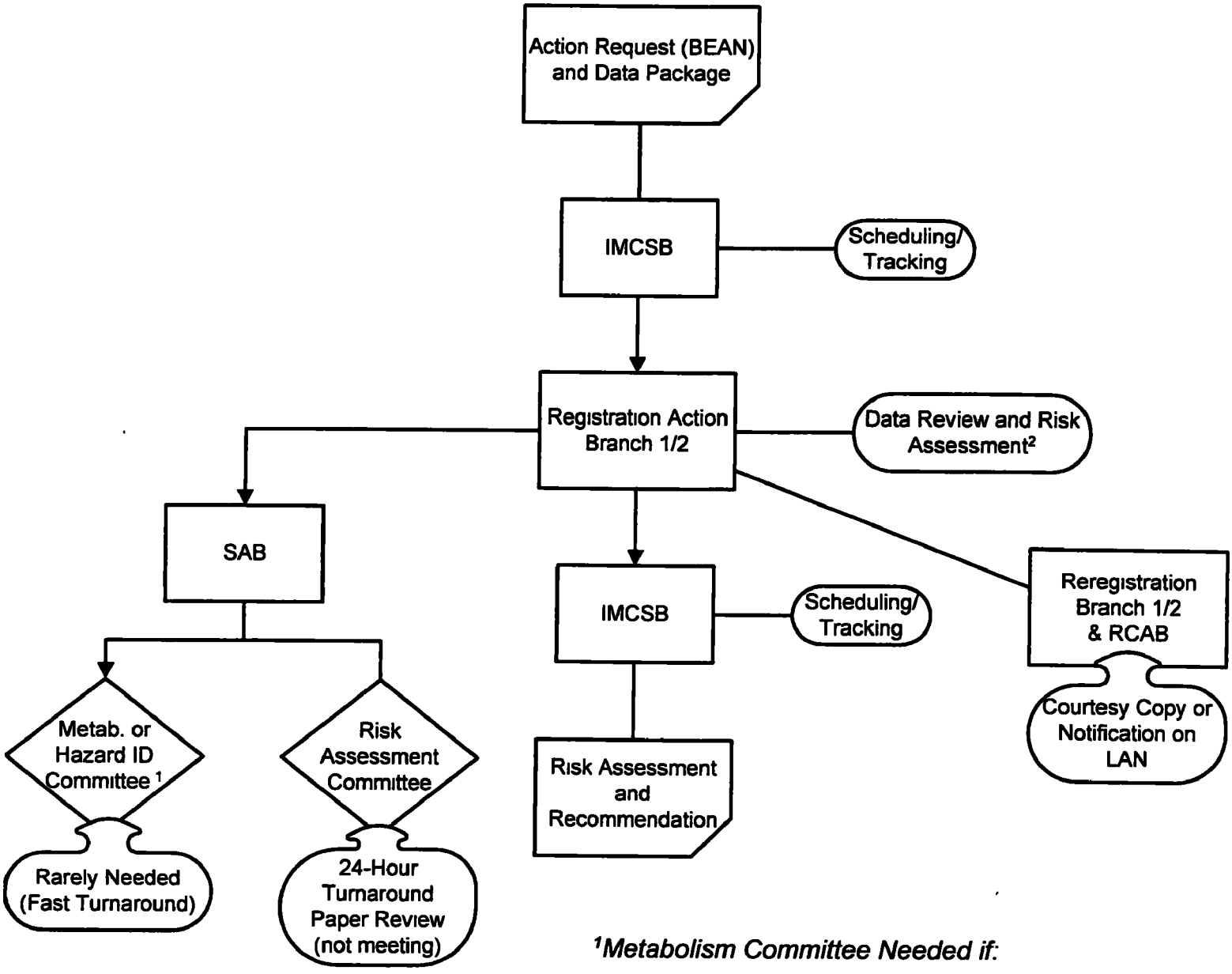
I. PIPELINE STUDY REVIEW

BRANCH DEFIN. FIGURE 2



II. SHORT ACTIONS (section 18s, 24(c), amended registration, new uses)

BRANCH DEFIN. FIGURE 3



[1]Metabolism Committee Needed if:

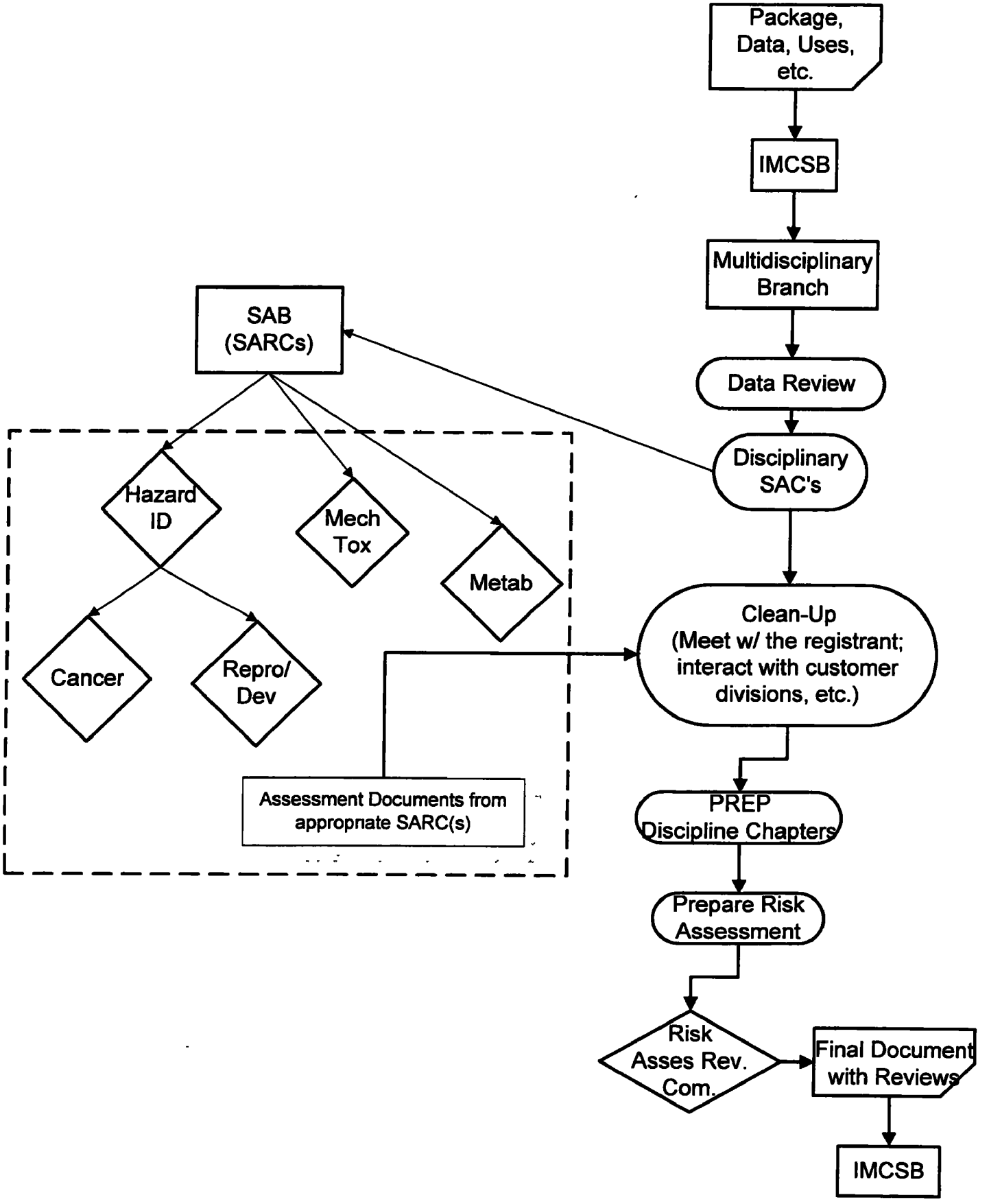
(i) New crop requires new plant metabolism study, or

(ii) New crop has animal feed item triggering livestock feeding study for the first time.

[2] Disciplinary SAC's to be consulted in rare cases. Ad Hoc SARC as needed.

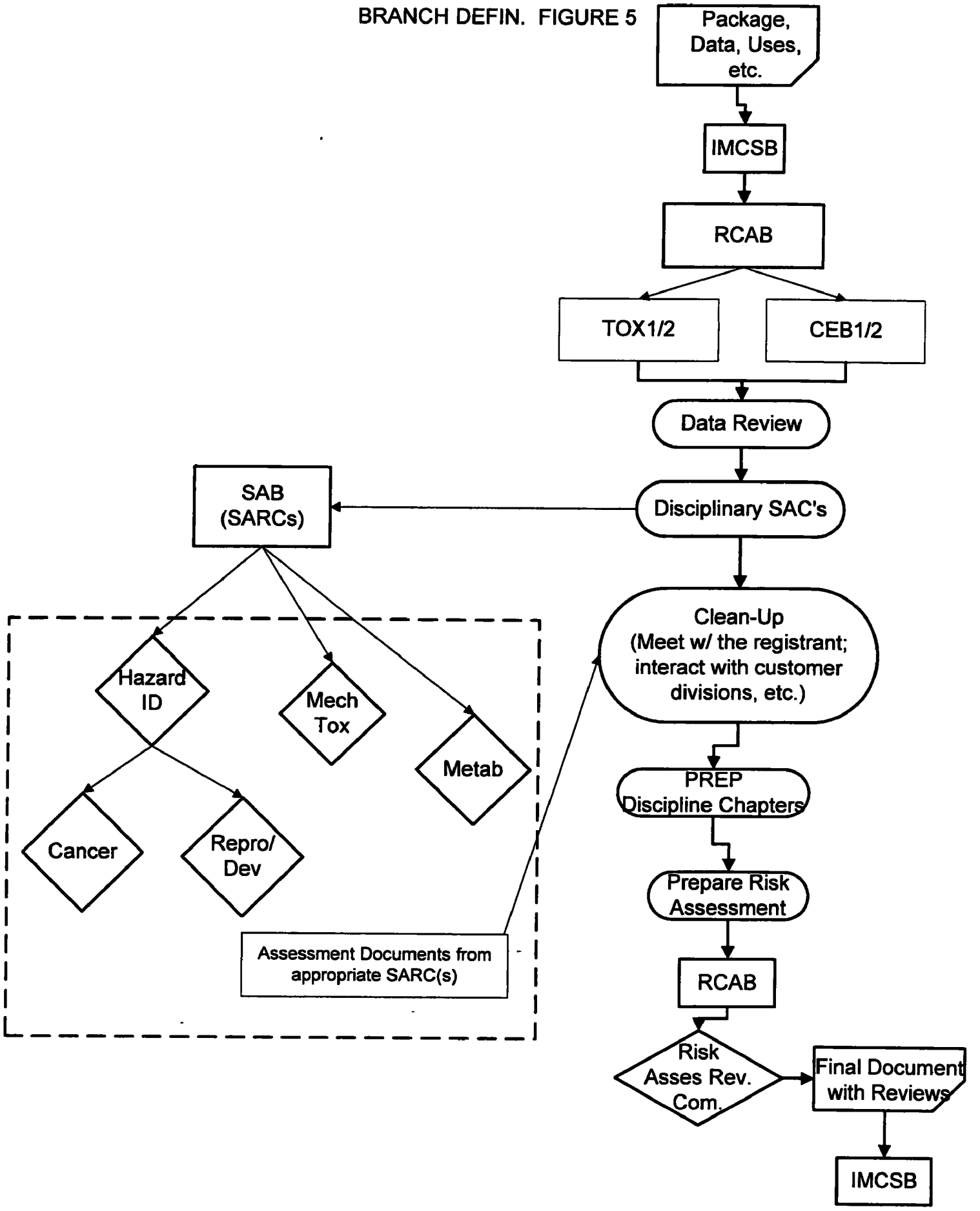
I. RE Ds/New Chem cals Interdisciplinary Branches

BRANCH DEFIN. FIGURE 4



IV. REDs/New Chemicals Disciplinary Branches -- RCAB)

BRANCH DEFIN. FIGURE 5



V. BRANCH/TEAM OPERATIONS

ABSTRACT

The Design Team evaluated the branch and team operations and the flow of work in and out of the Division, across branches, and within a branch/team.

The assignment of actions within HED will be determined by the Branch Chiefs and Division Management in their weekly prioritization meetings. A scheduling system (Master Scheduler) will be developed for the Division. Branch Chiefs and staff will be responsible for reporting on status of actions, appropriate due dates, etc.

The assignment of actions within a branch will be done by consultation between the Team Leaders and the Branch Chief to determine which team will be assigned an action. The Team Leader will bring the actions to the team and the team will decide who will have the lead to each action; this can be accomplished by either a team concept or by forming "mini-teams". The team will also decide on the staff need, the skill mix, the need for quality control/assurance (QC/QA) review by the team, appropriate SAC and presentation to the appropriate SARC.

A. THE OPERATION: Operation refers to the way in which work flows into through and out of a Branch/Team. The Branch/Team operations for the Interdisciplinary Branches (IDBs), Disciplinary Branches (DBs) (Toxicology and Chemistry and Exposure), RCAB, SAB and Information Management and contract Support Branch (IMCSB) are discussed below. The following design provides a consistent pattern for work flow for all of the Branches/Teams in the Division.

1. Generic Branch

The operations of a "generic" branch/team presented in Figure 1 is as follows:

- Work comes into the Branch from IMCSB (or for the Disciplinary Branches, from IMCSB through RCAB) and is logged-in by the Gatekeeper.

- The actions then go to the Branch Chief (BC) and the BC, the Branch Senior Scientist (BSS) and the Team Leaders **will meet at least once a week**:

    - To check on the status of actions already in the Branch in order to assure that every person in the Branch knows what and where actions are in the Branch.

- To decide as to which team receives an assignment. This is made using such considerations as previous experience with a chemical/situation, workload, disciplinary specialty or, in some cases, complexity.

- To prioritize or assign to a team and, if possible, schedule anticipated completion dates for each assignment.

- After the meeting, the Team Leaders along with the entire team decides on:

  - Identify a volunteer for the lead on each action which will have a toxicologist, a dietary exposure scientist and an occupational/residential exposure scientist. One of these will take the lead for risk assessment and completion of the action (a risk assessor).

  - Propose a completion date for an action. The BC, however, will have the final decision on completion dates to accommodate competing priorities (set in HED management meetings).

  - Who or which team will accept responsibility for completion of the action (i.e, risk characterizations) as well as who will present the assignment to the appropriate SAC.

This process can be accomplished by the "mini-team" concept; a "mini-team" taking responsibility for separate actions (See discussion below for Interdisciplinary Branch).

2. Interdisciplinary Branch

The operations of an IDB/Team presented in Figure 2 is as follows:

- In the case of the IDBs, a "mini-team" is formed to complete an action. This is usually the case for larger actions involving interdisciplinary risk assessments. The team will usually consist of a toxicologist, a dietary exposure scientist and a residential/occupational exposure scientist. The "mini-team" will also select a lead person. If a team has a risk assessor, this individual will take the responsibility for writing the final risk assessment document. If no risk assessor is on the "mini-team" then one of the other disciplinary persons will take that responsibility.

- For smaller mono-disciplinary actions, one person having that specialty will take responsibility for completion of that action.

- For larger mono-disciplinary actions, the data package may be subdivided amongst individuals within the branch/team based on the required disciplinary expertise. Again, a lead person is identified for this action.

- For QC/QA procedures refer to *Chapter II. A. "CORE PROCESS - DATA REVIEW".*

- Upon completion, the lead person assembles the parts of the large action and prepares the package for presentation to the TOX SAC.

- The lead person will also present the action to the appropriate SARC.

- The completed product then goes through the Gatekeeper for log-out, electronic filing and forwarding to IMCSB.

3. Disciplinary Branch - Toxicology

The operations of the Toxicology Disciplinary Branch/Team presented in Figure 3 is as follows:

- For the Disciplinary TOX teams the operation involves the same team assignment process. The team will decide on the lead person for each action.

- For smaller actions, one person is assigned and takes the responsibility for that review.

- For large actions data in the action is distributed among the team by disciplinary specialty.

- For QC/QA procedures refer to *Chapter II. A. "CORE PROCESS - DATA REVIEW".*

- Upon completion, the lead person assembles the parts of the large action and prepares the package for presentation to the TOX SAC.

- The lead person will also present the action to the appropriate SARC.

- The completed product then goes through the Gatekeeper (for log-out and electronic filing) and to RCAB.

4. Disciplinary Branch - Exposure

The operations of the Exposure Disciplinary Branch/Team presented in Figure 4 is as follows:

- For the disciplinary exposure teams, the same assignment process is followed. In the case of a large action, appropriate sections will be distributed to the appropriate individuals by discipline.

- For QC/QA procedures refer to *Chapter II. A. "CORE PROCESS - DATA REVIEW".*

- The lead person will coordinate the reviews of the different disciplines. The lead is also responsible for preparing the package and a presenting it to the appropriate SAC, CHEM SAC or EXPO SAC.

- The lead person will also present the action to the appropriate SARC.

As above, small actions, e.g., mono-discipline exposure, one person in the appropriate discipline will have the lead on the action for review.

5. Risk Characterization and Analysis Branch (RCAB)

The operations of the RCAB/Team presented in Figure 5 is as follows:

- Each action will have a lead risk assessor who will have the responsibility for coordinating with the Disciplinary Branches, assembling reviews, scheduling the appropriate SARCs, characterizing risk and compiling the final risk assessment document.

- Inter-Branch teams will be formed and the staff in the disciplinary branches will be part of the risk assessment team. QC/QA of the risk characterization will be addressed by the disciplinary branch team members.

6. Science Analysis Branch (SAB)

The operations of the SAB/Team presented in Figure 6 is as follows:

- The team of statisticians will provide statistical support to all the IDBs and the Disciplinary Branches as needed. They can interact with the various branches in several ways including:

1) help hazard assessors (toxicologists) to characterize hazard;

2) work with exposure assessors in Monte Carlo assessment;

3) be brought into teams doing risk assessments (early on in the process during team meetings) to provide statistical support and participate proactively;

4) interact with the toxicologists, pathologists and the Chair of the Cancer Assessment Review Committee (during the scope-out-meeting) to develop appropriate risk characterization methodologies;

5) provide statistical support for PHED, DRES and other systems requiring this support;

6) assist hazard, exposure and risk assessors on an *ad hoc* basis; and interact proactively with the SACs and SARCs.

- If the work is coming into SAB from a Disciplinary Branch, then the request for input will be coordinated by RCAB.

- The Chair/Exec. Secretaries of the 6 SARCs will plan, coordinate, and schedule the SARC meetings, distribute the draft document and hold the appropriate SARC meeting.

- The Exec. Secretaries of the appropriate SARC will produce the final SARC Document (e.g, Hazard ID Assessment Document or Cancer Assessment Document). For a detailed discussion on this subject refer to Chapter II, *"CORE WORK PROCESS - SCIENCE ASSESSMENT REVIEW"*.

- The Final document will be distributed to the IDBs or RCAB.

7. Information Management and Contract Support Branch (IMCSB)

As shown in Figure 7, for in-house operations:

- The IMCSB will assign the actions coming from RD or SRRD to the appropriate HED Branches (IDB or DB) via PRATs or the HED scheduling system after the work prioritization meeting.

- The pipeline reviews and short action reviews, however, will go directly to the Disciplinary Branches. For a detailed discussion on this subject refer to Chapter IV, *"BRANCH DEFINITION AND WORK PROCESS"*- Figures 2 and 3).

- IMCSB will forward actions on REDs/New Chemicals assigned to the Disciplinary Branches through RCAB for completion of reviews. For a detailed discussion on this subject refer to Chapter IV, *"BRANCH DEFINITION AND WORK PROCESS"*- Figure 4).

- Following completion of reviews, actions coordinated by RCAB will be sent back to RCAB, and sent to IMCSB to be logged out of PRAT and the HED scheduling system, and send to RD or SRRD.

As shown in Figure 8, for HED Mission Support Contracts:

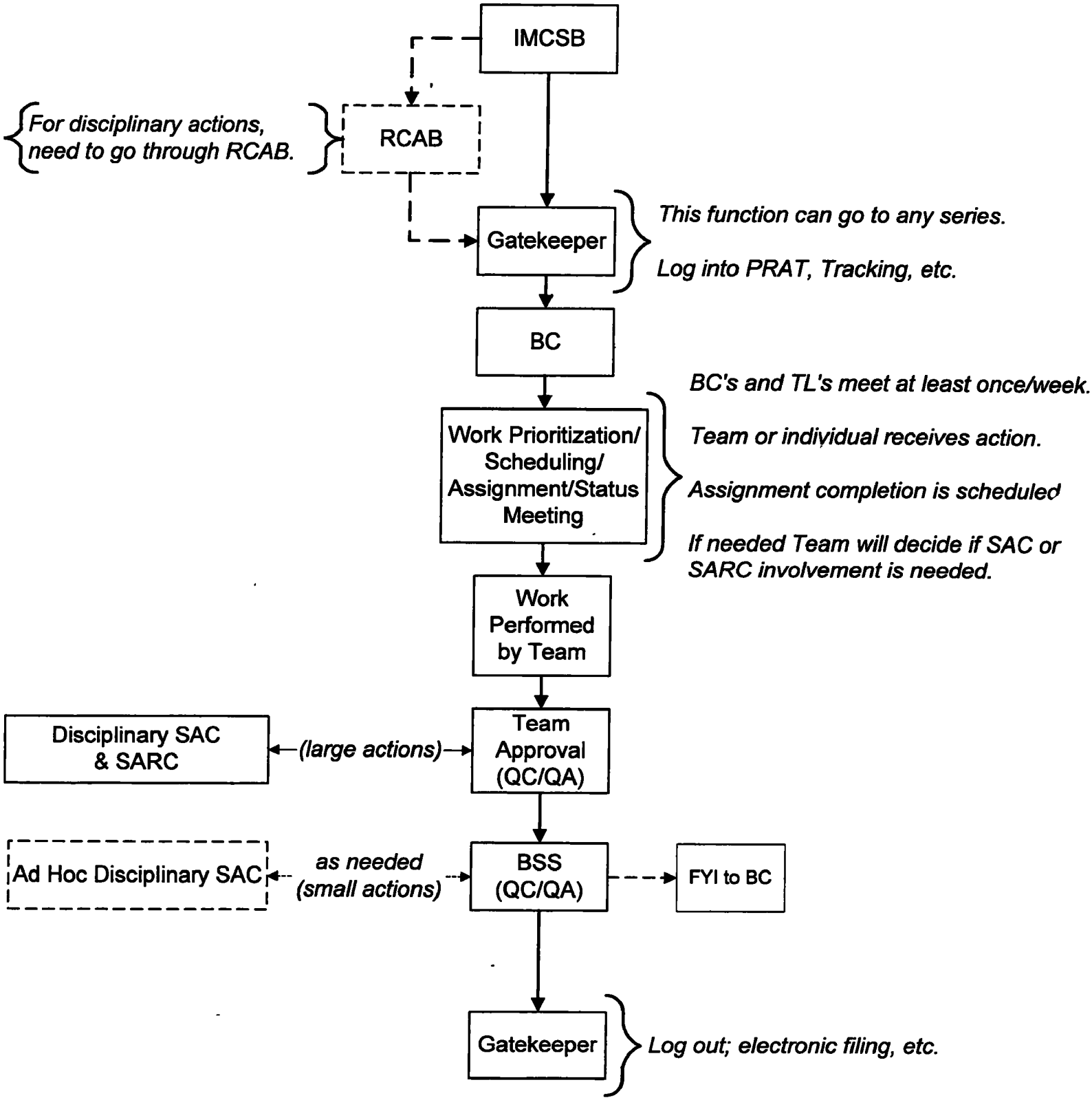
- Actions will go from IMCSB to the Disciplinary Branches or to the IDBs. If an IDB determines that the Contractor is to complete one of their the actions, the IDBs will send the action to the DBs which will determine whether they will do the review or whether it should go to the appropriate Contractor, i.e., all actions which will be completed by the Contractor will go through the DBs. The action goes from the appropriate Disciplinary Branch through IMCSB to the Contractor.

B. CONSISTENCY IN BRANCH/TEAM OPERATIONS

The procedures described under the "generic' branch should address the concern about consistency in Branch/Team operations. In general, scientific accuracy and consistency for the Branch/Team operations will be assured by the SACs, the appropriate SARC and the Risk Assessment (RA) process. For a detailed discussion on this subject refer to Chapter IV, *"BRANCH DEFINITION AND WORK PROCESSES"*.

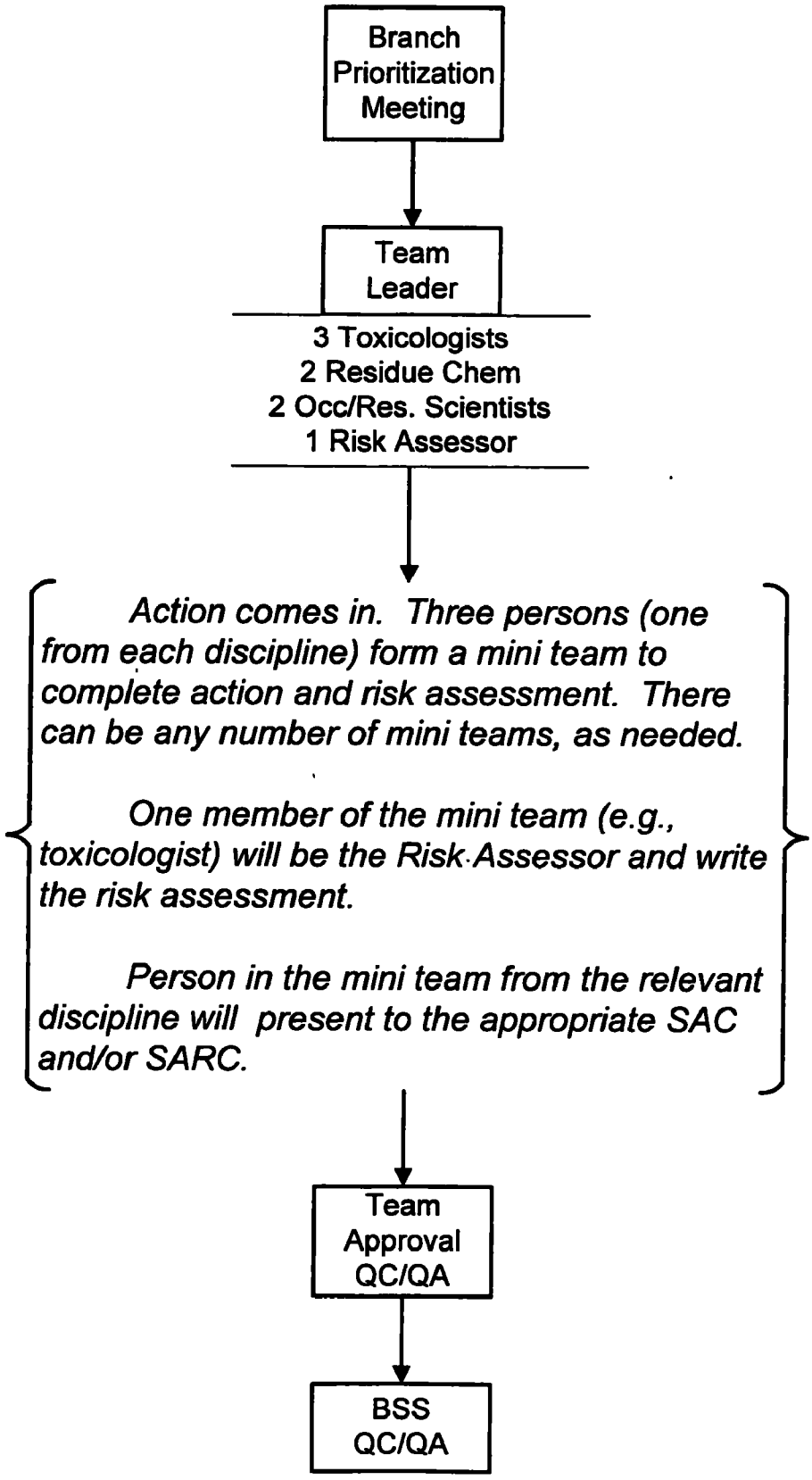
HED'S GENERIC BRANCH

BRANCH/TEAM OPERATIONS FIGURE 1



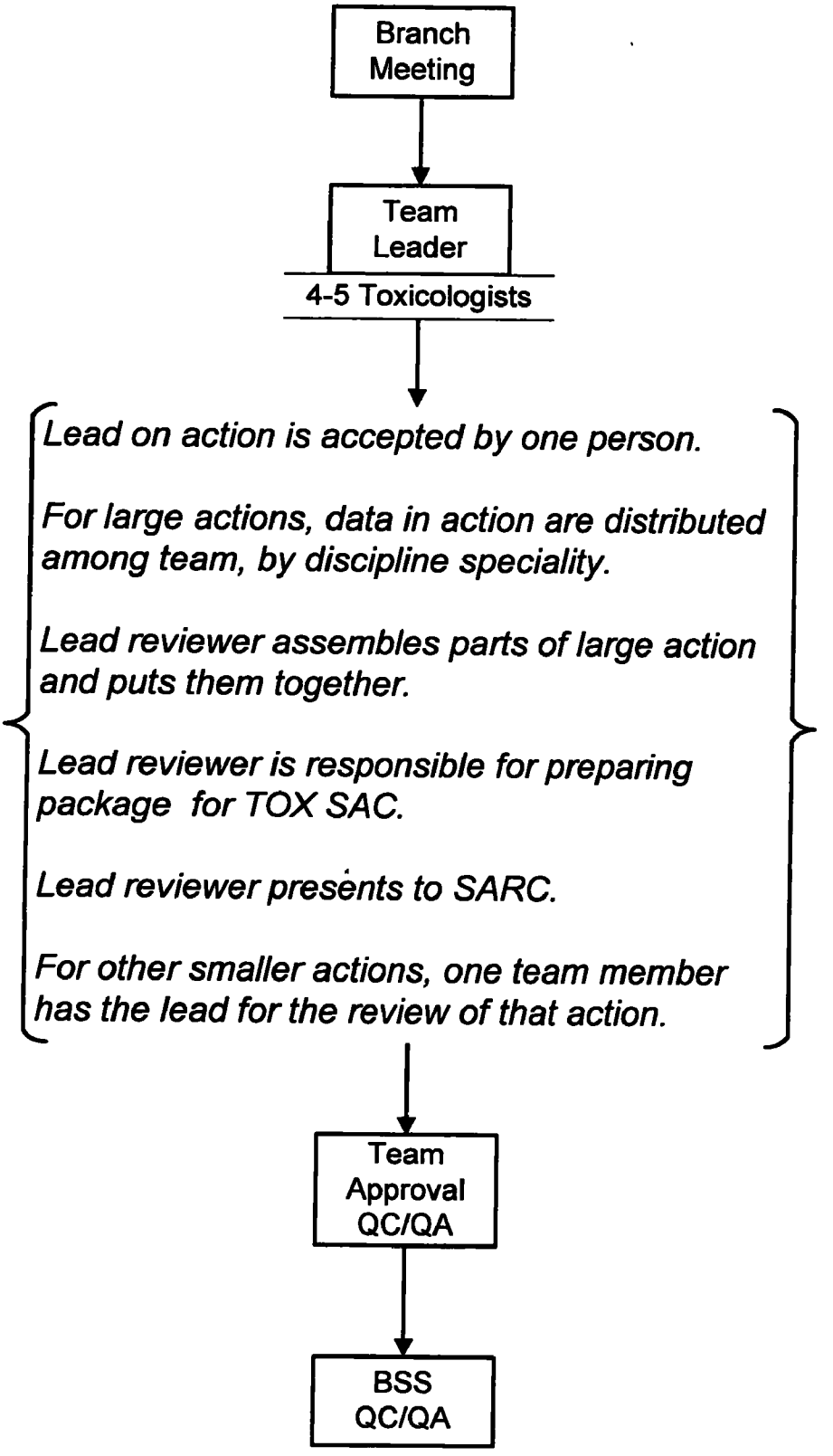
INTERDISCIPLINARY TEAM

BRANCH/TEAM OPERATIONS FIGURE 2



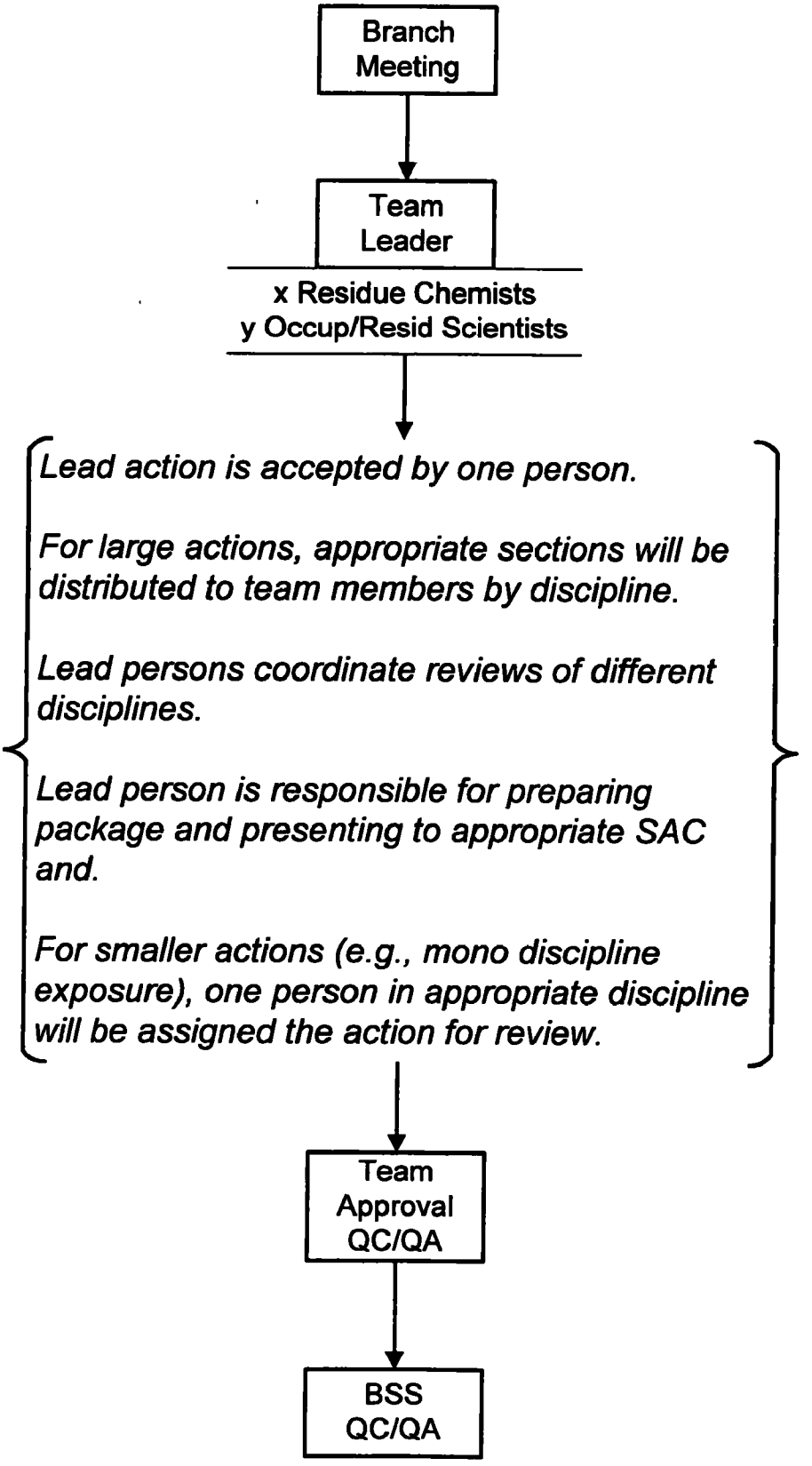
DISCIPLINARY TOXICOLOGY

BRANCH TEAM OPERATIONS Figure 3



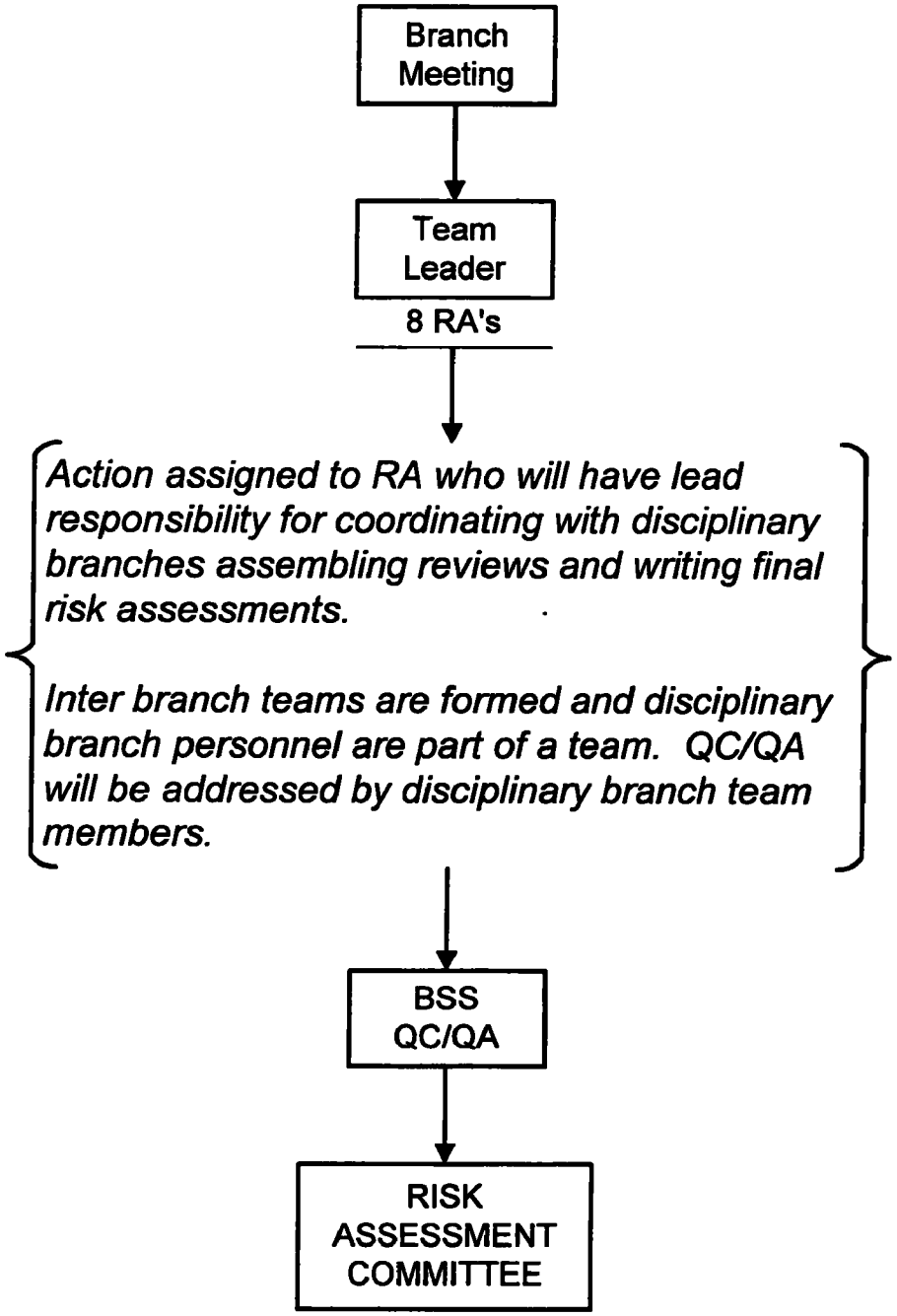
DISCIPLINARY EXPOSURE

BRANCH TEAM OPERATIONS FIGURE 4



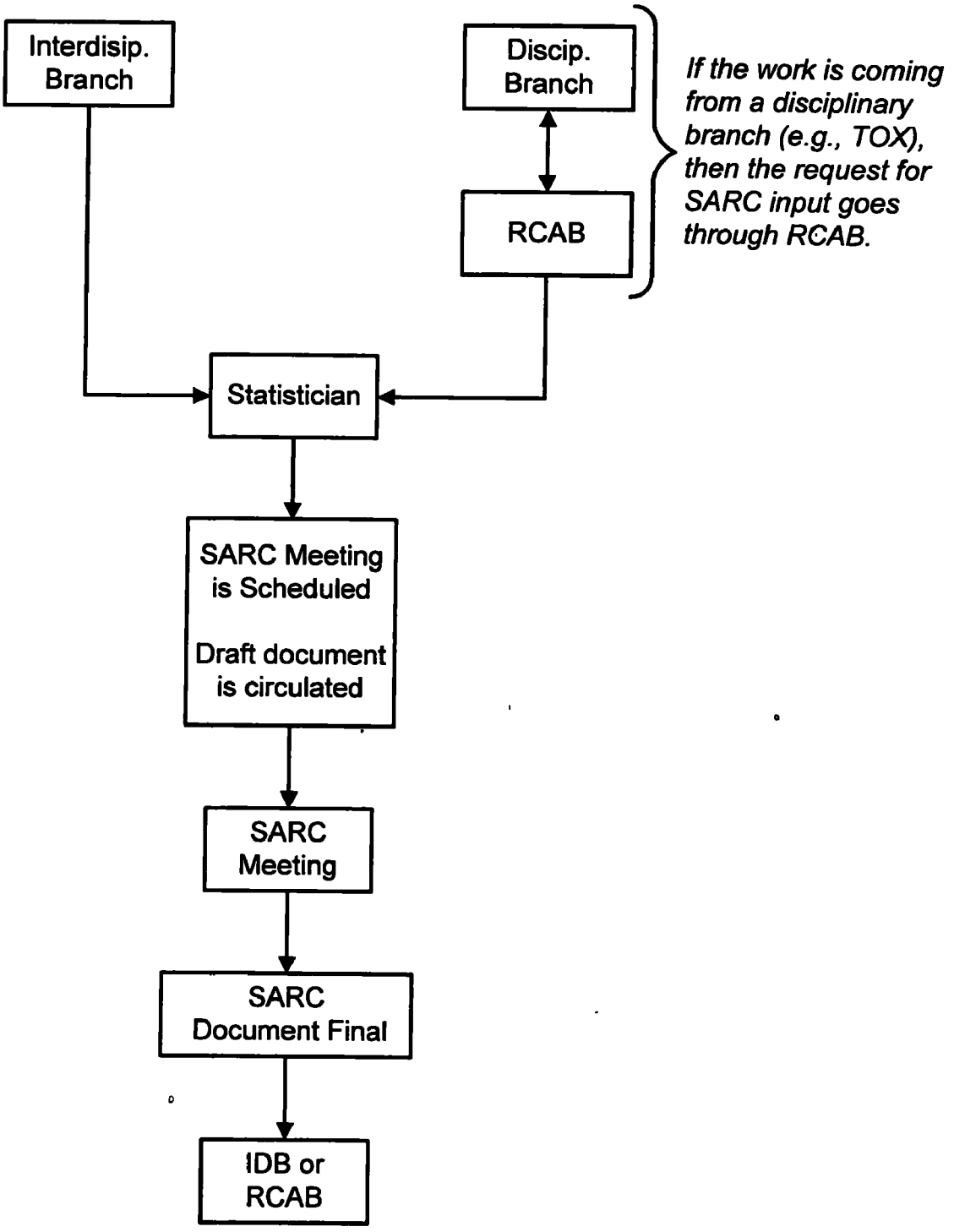
RCAB

BRANCH TEAM OBPRATIONS FIGURE 5



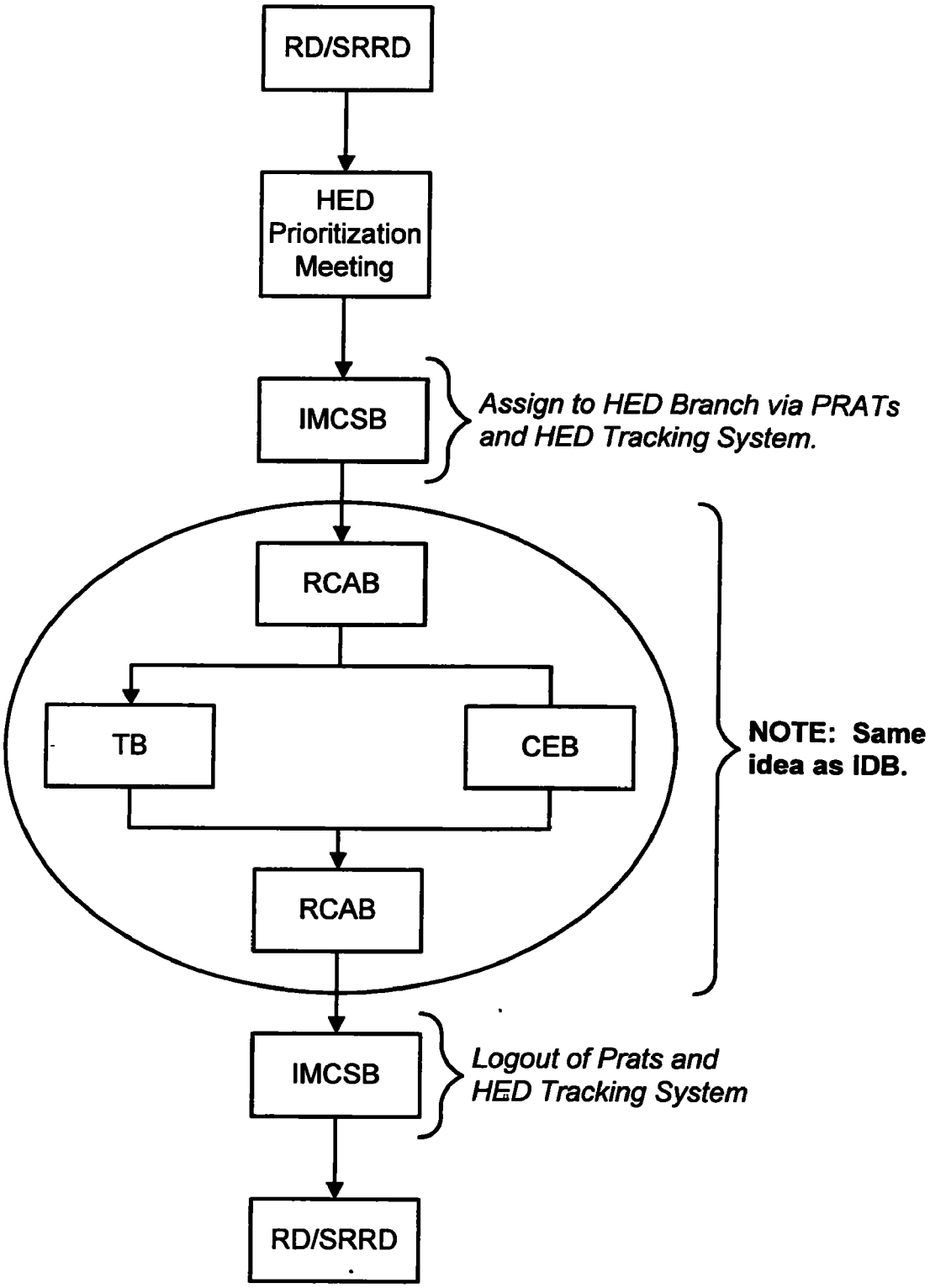
SAB

BRANCH TEAM OPERATIONS FIGURE 6



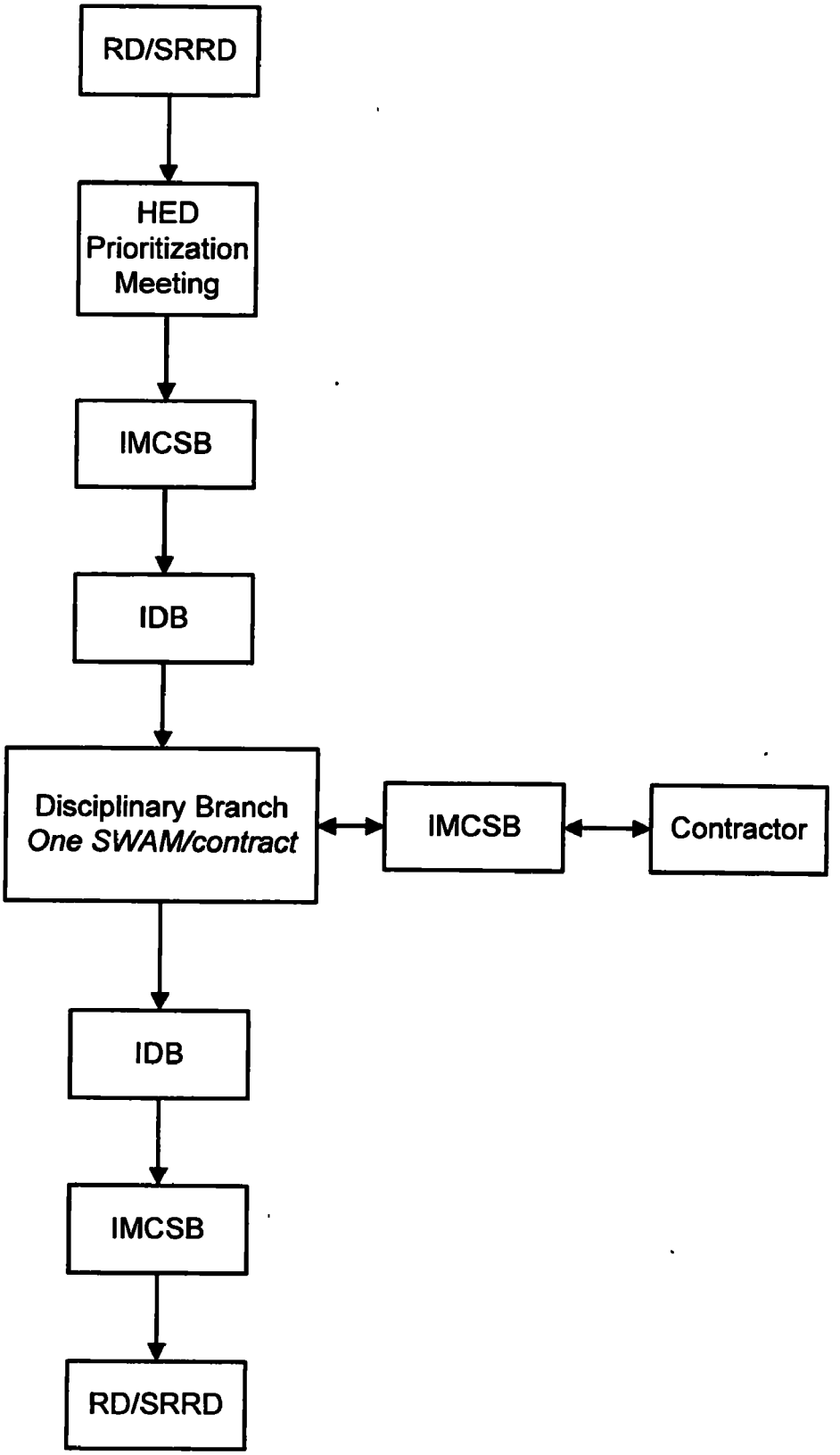
IMCSB -- IN-HOUSE

BRANCH TEAM OPERATIONS FIGURE 7



IMSCB -- CONTRACTOR SUPPORT

BRANCH TEAM OPERATIONS FIGURE 8



VI. ROLES AND RESPONSIBILITIES

ABSTRACT

The recommended roles and responsibilities in the new HED are defined in terms of the product/service goal of risk assessment. The four core work processes of HED (Data Review, Peer review, Risk Assessment and Science Policy/Special Projects) together with administrative support, define portions of the activities for each role. The core work processes are disciplinary or interdisciplinary and they are activities of an individual and or a team. However, the team approach is assumed to be part of almost all activities for each role in HED. **An individual can support or manage a process; a person can inform or consult as part of a process and each person is responsible for or approves products/services provided by HED. This means that an individual in the newly designed division will perform multiple roles, and multiple people will perform a given role.**

Each job in the new HED has more specific characteristics. For example, some jobs can be done by people from many backgrounds (i.e., they are rotational assignments with general skill requirements) while other jobs have more specific skill requirements and can not be rotational. The skill requirements for each job also determine how individuals will be trained (i.e., by course work or mentoring)

This recommended approach is a basis for drafting final Position Descriptions during Phase III of implementation planning.

INTRODUCTION

The objective of this chapter is to identify and define the roles necessary for HED to successfully fulfill its mission. The roles and responsibilities in the new HED should be defined in terms of the product/service goal of risk assessment. Risk assessments have four parts: (1) hazard assessment, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization. The parts of risk assessment require four core work process for HED to successfully accomplish its goal of risk assessment. The four core work process (i.e activities) of HED (Data Review, Peer Review, Risk Assessment and Science Policy/Special Projects along with the administrative support will be used to help identify and define the roles. Each of these core work processes define a portion of the total activities in a given role.

The activities of an individual performing each role also have characteristics. Core work processes can be described as disciplinary or interdisciplinary and the process can be performed by an individual, or it requires a team to function. (Note: the team approach is assumed to be part of almost all activities for each role.) An individual can support or manage a process; a person can inform or consult as part of a process and a person is

responsible for or approves products/services provided by a core process. Given these criteria, an individual in the newly designed division will be able to perform multiple roles, and multiple people can do a given role.

Defining roles is part of defining jobs, but each job has more specific characteristics. For example, some jobs can be done by people from many backgrounds (i.e., they are rotational assignments with general skill requirements) while other jobs have more specific skill requirements and can not be rotational. The skill requirements for each job also determine how individuals will be trained (i.e., by course work or mentoring).

A list of roles, the proportion of time for each role to be devoted to each of the core processes, and responsibilities associated with each role are presented in Table 1. A description of the roles and responsibilities follow the table. This material will be the basis for drafting final Position Descriptions during Phase III of implementation of the re-designed HED.

Table 1. Roles and activities in HED

Roles	Activities				
	Data Review	Sci Assessment	Risk Assessment	Science Policy	Admin. Support
Reviewer					
Hazard Assessor (disciplinary)	65% R/C/I	10% R/A/C/I	10% R/A/C/I	5% C/I	10% R/C/I
Hazard Assessor (interdisciplinary	50% R/C/I	10% R/A/C/I	20% R/A/C/I	5% C/I	15% R/C/I
Exposure Assessor - dietary (disciplinary)	65% R/C/I	10% R/A/C/I	10% R/A/C/I	5% C/I	10% R/C/I
Exposure Assessor - dietary (interdisciplinary)	50% R/C/I	10% R/A/C/I	20% R/A/C/I	5% C/I	15% R/C/I
Exposure Assessor - occupational/residential (disciplinary)	65% R/C/I	10% R/A/C/I	10% R/A/C/I	5% C/I	10% R/C/I
Exposure Assessor - occupational/residential (interdisciplinary)	50% R/C/I	10% R/A/C/I	10% R/A/C/I	5% C/I	10% R/C/I
Risk Assessor					
Risk Assessor	5% I/C	15% R/A/C/I	10% R/A/C/I	10% C/I	15% R/C/I
Team Leader					
Team Leader	20% R/A/C/I	15% R/A/C/I	2% R/A/C/I	5% R/A/C/I	40% R/C/I
Statistician					
Statistician	10% C/I	35% R/C/I	35% R/C/I	10% C/I	10% R/C/I
Chair, Science Assessment Review Committee (SARC)					
Chair, Science Assessment Review Committee	0%	65% R/A/C/I	10% R/A/C/I	10% C/I	15% R/C/I

Roles	Activities				
	Data Review	Sci Assessment	Risk Assessment	Science Policy	Admin. Support
Exec. Sec., Science Assessment Review Committee	0%	10% R/A/C/I	10% R/A/C/I	10% C/I	70% R/C/I
Science Advisors					
Science Advisor (Division)	-	30% C/I	30% C/I	30% C/I	10% C/I
Branch Senior Scientist (disciplinary)	10% R/A/C/I	30% R/A/C/I	20% R/A/C/I	30% R/C/I	10% R/C/I
Branch Senior Scientist (interdisciplinary)	20% R/A/C/I	20% R/A/C/I	25% R/A/C/I	20% R/C/I	15% R/C/I
Customer Service Representative					
HED Customer Service Representative	-	30% I	30% I	30% I	10% R/C/I
Division Support					
Budget Officer	-	-	-	-	100% R/C/I/A
Accounting Officer	-	-	-	-	100% R/C/I/A
Project Officer	-	-	-	-	100% R/C/I/A
Scientific Work Assignment Manager (SWAM)	-	80%	-	-	20% R/I/A
Administrative Work Assignment Manager (AWAM)	-	20%	-	-	80% R/I/A
Human Resource Person	-	-	-	-	100% R/C/I/A
Information Management	30% R/C/I	-	-	-	70% R/C/I
Facilities	-	-	-	-	100% R/C/I/A

Roles	Activities				
	Data Review	Sci Assessment	Risk Assessment	Science Policy	Admin. Support
Custodial	-	-	-	-	100% R/C/I
Security	-	-	-	-	100% R/C/I/A
AARP Grant	5% C/I	10%	5%	-	80% R/C/I
Administrative, Misc.	-	-	-	-	100% R/C/I
Computer Specialist (senior)	-	-	-	-	100% R/C/I/A
Computer Specialist (junior)	-	-	-	-	100% R/C/I/A
Training coordinator	-	-	-	-	100% R/C/I/A

Roles	Activities				
	Data Review	Sci Assessment	Risk Assessment	Sci Policy	Admin Support
Management					
Branch Chief	-	10% C/I	20% C/I	15% C/I	55% R/A/C/I
Associate Division Director	-	10% C/I	50% A/C/I	15% C/I	35% R/A/C/I
Division Director	-	5% C/I	5% C/I	45% R/A/C/I	45% R/A/C/I

R = responsible

A = approve

C = consult

I = Inform

ROLES RESPONSIBILITIES

Hazard Assessor (disciplinary)

- Reviews toxicology data.
- Prepares hazard identification and dose response assessment.
- Performs QC/QA of data interpretation and ensures consistency of interpretation across division.
- Participates in Science Assessment Review Committee (SARC) activities (i.e., Hazard ID Assessment, Cancer Assessment, Reproductive/developmental Toxicity Assessment, Metabolism Assessment, Mechanism of Toxicity Assessment and Risk Assessment).
- Provides guidance and review of sub-disciplinary issues (e.g. mutagenicity, neurotoxicity).
- May serve as work assignment manager, both administrative (AWAM) and scientific (SWAM) for toxicology contracts.*
- May be a member of the Toxicology Science Advisory Council (TOX SAC)/SARC.*

Hazard Assessor (interdisciplinary)

- Reviews toxicology data.
- Prepares hazard identification and dose response assessment.
- Performs QC/QA of data interpretation and ensures consistency of interpretation across division.
- Participates in SARC activities.
- Determines when issues require referring to disciplinary toxicology branch.
- May serve as risk assessor*
- May be a member of TOX SAC/SARC.*

Exposure Assessor (dietary - disciplinary)

- Reviews and analyzes metabolism studies, methods and magnitude of the residue data submitted to support the use of a pesticide on a crop for the purpose of establishing or reassessing a tolerance. In addition, analyzes monitoring and/or crop field trial data for the purpose of estimating anticipated residue levels in commodities. Prepares residue chemistry exposure assessment.
- Performs QC/QA of data interpretation and ensures consistency of interpretation across division.
- Participates in SARC activities (i.e., Metabolism and Risk assessment committees).
- May maintain DRES database.*

*** Responsibility not required for all person(s) in role.**

- May serve as work assignment manager, both administrative (AWAM) and scientific (SWAM) for exposure assessment contracts.*
- May be a member of Chemistry Science Advisory Council (CHEM SAC).*

Exposure Assessor (dietary - interdisciplinary)

- Reviews and analyzes metabolism studies, methods and magnitude of the residue data submitted to support the use of a pesticide on a crop for the purpose of establishing or reassessing a tolerance. In addition, analyzes monitoring and/or crop field trial data for the purpose of estimating anticipated residue levels in commodities.
- Prepares residue chemistry exposure assessment.
- Performs QC/QA of data interpretation and ensures consistency of interpretation across division.
- Participates in SARC activities (i.e., Metabolism and Risk Assessment).
- May serve as risk assessor.*
- May be a member of CHEM SAC.*

Exposure Assessor (occupational/residential - disciplinary)

- Reviews occupational and residential exposure data.
- Performs occupational and residential exposure assessment.
- Performs QC/QA of data interpretation and ensures consistency of interpretation across division.
- Familiar with surrogate exposure, pesticide poisoning database and Worker Protection Standard (WPS).
- Participates in SARC (i.e., provides data on use-pattern for occupational and residential exposure scenarios to the Hazard ID/Risk Assessment committees).
- May serve as work assignment manager, both administrative (AWAM) and scientific (SWAM) for occupational/residential exposure contracts.*
- May maintain Pesticide Handler Exposure Database (PHED).*
- May provides assessment of human incident data.*
- May be a member of Exposure Science Advisory Council (EXPO SAC).*

Exposure Assessor (occupational/residential - interdisciplinary)*

- Reviews occupational and residential exposure data.
- Performs occupational/residential exposure assessment.
- Participates in SARC activities.

*** Responsibility not required for all person(s) in role.**

- Familiar with surrogate exposure and pesticide poisoning database.
- May serve as risk assessor*
- May be a member of EXPO SAC.*

Risk Assessor

- Analyzes and prepares risk assessment/risk characterization for assigned chemicals.
- Facilitates and manages chemical review team.
- Participates in SARC activities.
- Manages review of hazard and exposure component of assigned chemicals.
- Coordinates activities required to conduct risk assessment (i.e., data review, assessment groups, meetings, facilitation flow of information both internally and externally to HED).
- May be a member on the Risk Assessment Review Committee.
- May be a member of the SAC/SARC*

Team Leader

- Coordination and facilitation of team meetings.
- Not necessarily the scientific expert on the team.
- Ensures that work is distributed and tracked within the team.
- Provides opportunity for everyone on the team to contribute.
- No supervisory authority.
- Represents team to branch.
- Monitors activity of team.
- Provides positive team interaction.
- Coordinates all primary reviews, QC/QA, SAC reviews, ad hoc SARC input, etc.
- Interacts with BC and BSS.
- Maintains close contact with the fellow TLs in other branches.
- May be a member of SAC/SARC.*
- **Does not handle performance management.**

Statistician

- Help hazard assessors (toxicologists) to characterize hazard as part of the data review process.
- Work with exposure assessors in Monte Carlo assessment.
- Be brought into teams doing risk assessments (early on in the process during meetings) to

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*** Responsibility not required for all person(s) in role.**

provide statistical support and participate pro actively.

- Interact with the toxicologists, pathologists and the Chair/Exec. Secretaries of the Cancer Assessment Review Committee (during the scope-out-meeting) to develop appropriate risk characterization methodologies.
- Provide statistical support for PHED, DRES and other systems requiring statistical support.
- Assist hazard, exposure and risk assessors on an *ad hoc* basis; and interact proactively with the SACs and SARCs.
- Develops risk characterization methodologies (i.e., cancer potency estimators, benchmark dose extrapolations).
- Provides statistical assistance in Science Assessment Review processes.

Science Advisor (Division)

- Represents HED on Agency science policy issues, coordinates activities and follow-up on projects.
- HED contact person for the Office of Research and Development (ORD) for inter-office issues.
- Member of ORD Risk Assessment Forum.
- Encourages consistency with decisions in division.

Branch Senior Scientist (disciplinary)

- Provides QC/QA function for branch actions
- Signs off on data reviews and disciplinary science chapters
- Provides support to the staff at SARC and other presentations
- Interacts with the SAC member within the branch and other branches
- Maintains close contact with the Branch Chief on science and policy matters
- Maintains close contact with fellow BSS's, ADD's and DD
- May be a member of SAC/SARC.*

Branch Senior Scientist (interdisciplinary)

- Provides QC/QA function for branch actions
- Signs off on data reviews and disciplinary science chapters
- Provides support to the staff at SARC and other presentations
- Interacts with the SAC member within the branch and other branches
- Maintains close contact with the Branch Chief on science and policy matters
- Maintains close contact with fellow BSS's, ADD's and DD
- May be a member of SAC/SARC.*

*** Responsibility not required for all person(s) in role.**

Chair, Science Assessment Review Committee

- Facilitates the committee meetings.
- Ensures consensus at the meeting.
- Ensures the committees decisions are clearly conveyed to the secretary.

Executive Secretary, Science Assessment Review Committee

- Planning, coordination and scheduling.
- Prepares meeting materials.
- Takes notes and prepares meeting minutes.
- Prepares final documents in coordination with the presenter.
- Responsible for LAN maintenance, archiving and tracking of SARC committee documents and schedules.

HED Customer Service Representative

- Person who responds to the public and offices outside HED regarding questions on status of projects, reviews, etc. within HED (e.g. HED answer person/representative).

Budget Officer

- Determines input and output and branch distribution of funds.
- Tracks all procurements, maintain HED record of expenditures in all object classes (i.e., travel, training, transportation of items, other contractual services, contracts, Grants, ADP supplies and equipment, supplies and equipment, etc).

Accounting Officer

- Certifies that funds are available to cover requested expenditures (i.e., makes sure budget allocations are not exceeded.
- Commits funds after Division Director approval.
- Tracks commitments and obligations.
- Reconciles books, monthly, quarterly, and annually.
- Sets up books for next fiscal year.
- Tracks and estimates future expenditures (utilities, telecommunications, PC usage)
- Tracks procurements (e.g., contracts, grants, and other expenditures).
- Maintains the HED scheduling system for all activities including travel. This system is used by DD and BC's to plan all HED functions and stay within budget limitations.

Project Officer (PO)

- One for each contract/ discipline
- Develops work assignment for contractors.
- Ensures that the proposed scope of work for the delivery order is within the general scope of work for the overall contract.
- Obtains the proper funding commitments to fund the delivery order (if necessary).
- Develops the Agency's work estimate for delivery order (where applicable).
- Performs research for information to support work orders for the contractor.
- Reviews all vouchers submitted by the contractor for payment against the appropriate

delivery orders and recommends approval or disapproval.
- Maintains electronic system of schedule of tasks, hours assigned and expended on tasks and deliverables.
- Assists in maintaining the technical direction/evaluation of performance of contractor.

Work Assignment Manager (WAM)(Scientific WAM and Administrative WAM)
- One for each contract.
- Establish program objectives.
- Develop requirement formats, guidelines, skill mix.
- Schedule priorities and due dates.
- Estimates technical hours for tasks to be performed in and tasks to be contracted.
- Budget tasks within given funded amounts.
- Develops controls (database performance summary sheet etc.).
- Develop and write purchase requests including specifications and work statements.
- Develop specific plans including financial status.
- Prepare work assignments and/or task orders as needed.
- Voucher certification.
- Coordinate project planning with procurement and contracting officer.
- Evaluation of proposals.
- Participation in the source selection process.
- Monitors work process.

Human Resource Person
- Preparation, processing, negotiation with EPA Personnel Office, and tracking of all recruitments, reassignments, details, promotions (temporary or permanent) retirements, etc.
- Liaison between employees, management, other divisions and personnel office.
- Represents HED in OPP personnel issues.
- Supports information management to branch personnel on personnel issues.
- Designated Agent (DA) for reconciliation and processing.
- Maintains time cards performance contracts and appraisals.

Information Management
- HED CBI officer.
- HED LAN database "Gatekeepers".
- Maintains TOX, Chemistry, OREB reviews on LAN.
- Maintains HED Library including material receive by division staff at professional meeting, training courses, workshops, conducts literature searches, etc.
- Master tracker of all division activities.
- Provides information management of all activities for HED including open season medical insurance, life insurance, Thrift Savings Plan and Leave Bank.
- Maintains scheduling system of all actions per year and tracks "Special Projects" that are not captured on TAIS forms.

Facilities Person
- Maintains space for HED personnel (i.e., phones, voice mail, lights, LAN Hook-ups, telecommunication activities moves, ADP support activities, tracking of activities, PC ownership, hardware and software).
- Responsible for scheduling meeting rooms for division staff.

Security
- Provides CBI clearance for all employees (i.e., EPA employees, Public Health employees, Contractors and AARP employees.
- Responsible for giving security briefings.

AARP Grant
- Prepare recruit packages.
- Negotiate responsibilities with AARP coordinator.
- Plan for fiscal year budget to fund AARP employees.

Administrative, Miscellaneous.
- Ensures that doors are unlocked and CBI is secure during building maintenance.
- Handles requests for "open season" information, repairs of office equipment, preference process rosters, etc.

Computer Specialist (senior)
- Trouble-shooting minor PC problems.
- Responsible for HED computer equipment inventory.
- Works closely with the junior computer specialist in meeting HED's computer needs.

Computer Specialist. (junior)
- Acts as liaison between HED and IRSD on coordination and integration of all EPA systems that OPP will be using (Lotus Notes, Oracle, etc.).
- Programs systems and databases to be used by HED.
- Trains HED staff in use of the division's ADP systems.
- Works with senior computer specialist in learning data languages, programming and systems in HED.

Training Coordinator
- Interacts with disciplinary senior scientists within the division and PSC to maintain a listing of available workshops, training etc.
- Compiles literature of available training both internally and externally.
- Responsible for insuring that training and mentoring of new hires is implemented.
- Responsible for providing training information to division staff.

Branch Chief

- Resource allocation and acquisition.
- Places major emphasis (70-80%) on managing people and resources.
- Has authority on all administrative and personnel matters.
- Conducts performance management.
- Stays familiar with the work of the branch so they can be coached as necessary.
- Pro active with staff relationship; lets DD know when and where to interact.
- Plays a pro active coaching role in scientific area in assisting members of the branch to develop scientific expertise, thinking skill, resourcefulness, and political skills .
- As individuals, participate in scientific and policy projects based on individual expertise within the constraints of the team.
- Stays in close contact with the BSS on scientific matters.
- Pro actively encourages inter-branch collaboration.
- Functions as team member on management team.
- Participates in meetings upon team's request or if a team member needs coaching.
- Serves as first line supervisor to staff level personnel.
- Responsible for planning, scheduling, setting and meeting goals.
- Clearly set branch objectives, expectations and goal.
- Supports customer oriented approach within the division.
- Serves as a role model as a flexible, team player and acting as a part of the HED management team. Offers conflict counseling of employees on personnel issues.
- Develops vision and leadership for branch.
- Willingness to receive recommendations/suggestions from team and peers (both inside and outside the division).
- Sets innovative, realist and practical goals.
- Supports, empowers and develops staff to achieve their full potential.
- Provides staff with reward and recognition.
- May serve as a member of SARC.*

Associate Division Directors

- Acts on behalf of DD, supports and works with DD on strategic and external issues, resource planning and allocation.
- Coaching staff on science as needed.

Associate Division Director 1

- Responsible for registration, risk assessment process, external peer review, information management and space.
- Consults and informs with division science assessment review and external peer review groups on issues.

*** Responsibility not required for all person(s) in role.**

- Represents the division at HED SARC meetings addressing registration because of cross-divisional policy implications.
- Represents HED at RD for external peer review for registration chemicals.

Associate Division Director 2

- Responsible for reregistration and special review, exposure assessment methodology, coordination and relationships with states/other countries (including Codex), budget, FTE planning and hiring.
- Represents the division at HED SARC meetings addressing reregistration and special review because of cross-divisional policy implications.
- Represents HED at SRRD for external peer review for reregistration and special review chemicals.

Division Director

- Establishes and implements organizational vision of division (i.e., develops "big picture" focus).
- Develops division strategies and defines goals.
- Responsible for policy formulation and implementation associated with human health hazard and exposure to pesticides.
- Serves as representative/spokes person of pesticide programs with regard to human health issues and policy.
- Serves as second level manager to staff level personnel.
- Consults with and informs responsible Science Assessment Review and external peer review parties and senior scientists on policy issues.
- Supervises Branch Chiefs and ADDs.
- Division planning, priority setting, resource allocation and acquisition.
- Maintains contact with other division offices and external agencies
- Stays well informed with scientific issues
- Responsive to staff.

VII. PHYSICAL SPACE ALLOCATION

ABSTRACT

The Design Team recommends that the Division Director, Associate Director and Branch Chiefs have private offices. All other staff would have two persons per office. AARPs would be located in the bay areas. In the ideal setup, all members of a given Branch pair would be located in one area. Each Branch would have one meeting room. Correspondence and specialized files for all disciplines would be centrally located in a room equipped with a copy machine. The room would also have a file keeper. This would provide for better interdisciplinary communication and file security. The library would be expanded and there would be one large conference room per floor. **It is recommended that two similar functioning branches will be seated together with individual disciplines clustered within the two combines branches.**

A. HED AS IT IS NOW

The 20 offices on part of the 7th floor and the entire 8th floor accommodate 141 FTEs and 13 AARPs.

B. SPACE ALLOTTED TO HED.

The space allotted to the re-designed HED on the 7th, 8th and 10th floors is as follows:

The 7th Floor: 25 offices - Figure 1

As shown in figure 1, this space will accommodate 33 staff members, 4 Branch Chiefs and 2 team meeting rooms. AARPs will be located in the bay areas.

The 8th Floor: The entire floor - Figure 2

As shown in figure 2, this space will accommodate 106 staff members, 6 Branch Chiefs, 4 team meeting rooms and 1 conference room. In addition, this floor also has the "Caswell" room, a storage room, the Library and "probable future space" (near the mail room). AARPs will be located in the bay areas.

The 10th Floor: 12 offices - Figure 3

As shown in figure 3, this space will accommodate 17 staff members, 1 Branch Chief and 1 team meeting room. AARPs will be located in the bay areas.

C. OPTIONS FOR SEATING UNDER THE NEW STRUCTURE/FUNCTION OF HED.

Two seating options were considered by the team. Much of the HED staff wanted to sit together by discipline. Part of the reason for this preference was the desire not to move, being tired from packing up and moving too many times for the painting and carpeting, etc. In addition to the option of keeping each Branch together, and keeping the disciplines together, the team has developed two options and a recommendation which will allow disciplines to sit mostly together, but also keep branches together.

Option 1 - Figure 4

The two similar functioning branches will be seated together, with the individual disciplines clustered within the two combined branches (RR1 and RR2 together, RAB1 and RAB2 together, CEB1 and CEB2 together, TOX1 and TOX2 together).

Option 2 - Figure 5

The disciplines will sit together within one branch and the adjacent (second) branch will have the toxicologists from that branch sit adjacent to the toxicologists from the first branch. The chemists and Occupational/Residential exposure scientists from the second branch will be adjacent to the chemists and Occupational/Residential exposure scientists from the third branch, etc.

Pros

- compromise space plan between sitting solely by discipline and solely by branch
- closer interaction within a single discipline than if branch members were mixed up, to help ensure scientific integrity.
- promotes team interaction better than sitting strictly by discipline
- the 2 branch together model promotes similar handling of similar actions

Cons

- need to consider the possibility of the division being on 3 floors.
- there is still splitting of the scientific disciplines, making consistency more difficult.

Recommendation - The Design Team recommends option 1. The Transition Team will work with HED management to make the final seating arrangements.

D. CRITERIA FOR EFFECTIVE USE OF ALLOTTED SPACE

- The proposed recommendation, while keeping the like branches together also allows the disciplinary staff to sit together to encourage sharing of information.

- Two person occupancy per office for staff.

- One team meeting room per Branch will be ideal however, with the space allotted HED has 7 team meeting rooms and 1 conference room for 11 branches. Branch Chief offices may need to be used for some team meetings.

- Data must be removed from the files. Correspondence in files will be maintained. This will create more space for the Division, i.e., space where Times II files were located will create space for AARP and junior staff work stations.

- One central location of all disciplinary files, including chemical specific files and specialized files such as policy files, petition files, and cultural practice files. There should be a copy machine and an AARP file keeper located in this room. This will allow better communication as well as provide additional security for the files. (Note: Caswell File Room is needed until Caswell files are placed on electronic image disks with the Can-o-file.)

- Separate space for microfiche reader/printer, specialty equipment, e.g., can-o-file, Polaroid pallet, one-liner database, stand-alone PCs, etc. (Equipment that is not in use at all times).

- Division supply room that is locked is needed to house computer supplies, e.g., toner, cords, RAM, notebooks, etc.

- Keep Library, but expand it. (Note: There is not enough room in CM II to have an OPP Library.) Until the Division books can be moved into the library, maintain the library as it is, but provide a listing of reference materials and their present location to facilitate full use of division resources. Personal copies of books which individuals are willing to share could be included in this list.

- Under-utilized bay areas and other areas should be utilized or redesigned to enlarge present work stations or to build new offices for staff (i.e., Bay areas in RCAB TOX-I (828B) and SAB Bay.

- Provide room for Branch supplies.

- Branch staff should decide/agree where a person sits in a Branch area.

To accomplish this ideal design HED would need 2 floors in CM II. The reality is that the Division has approximately 1 1/4 floors, although additional space is being negotiated.

HED - 7TH FLOOR

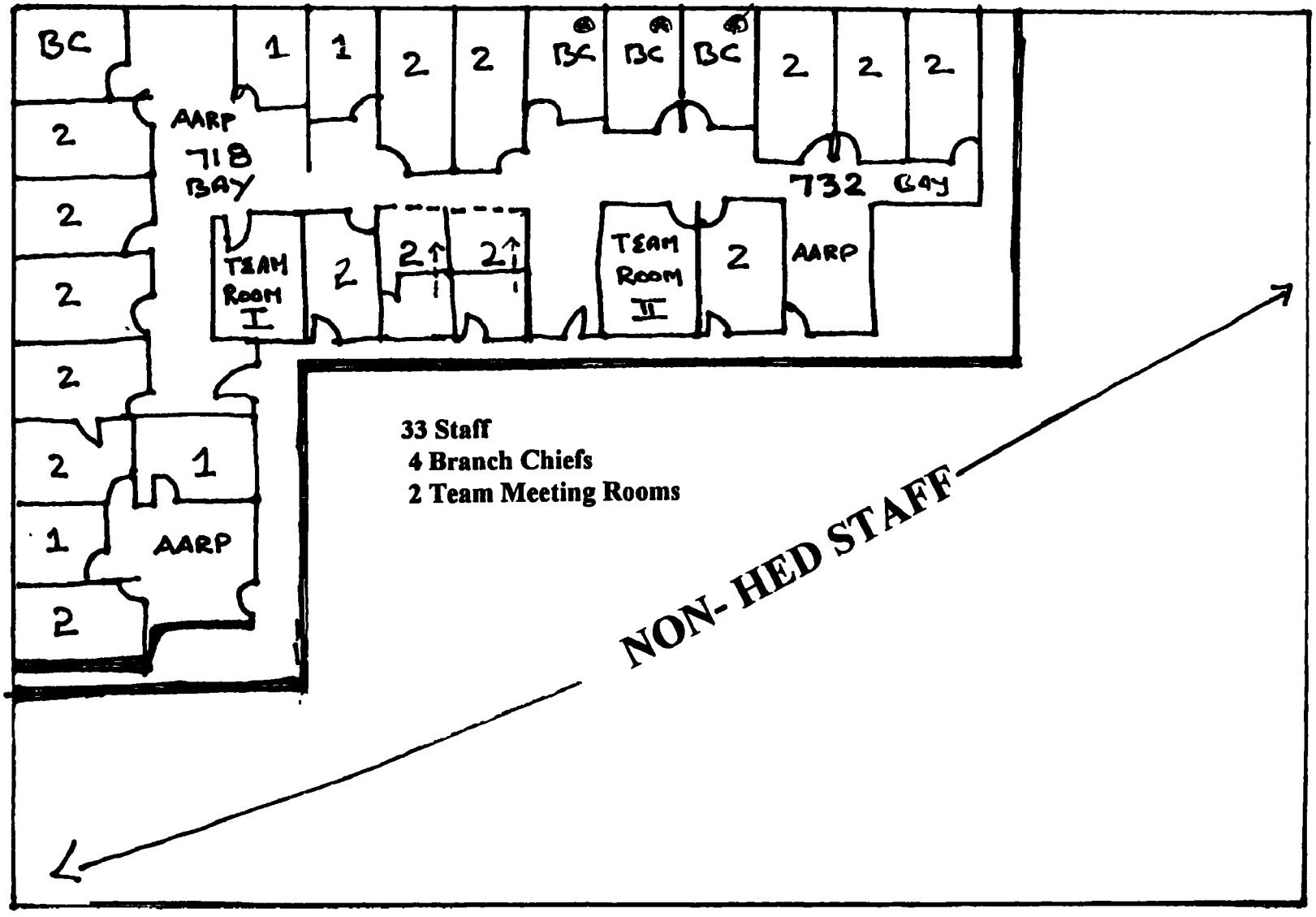
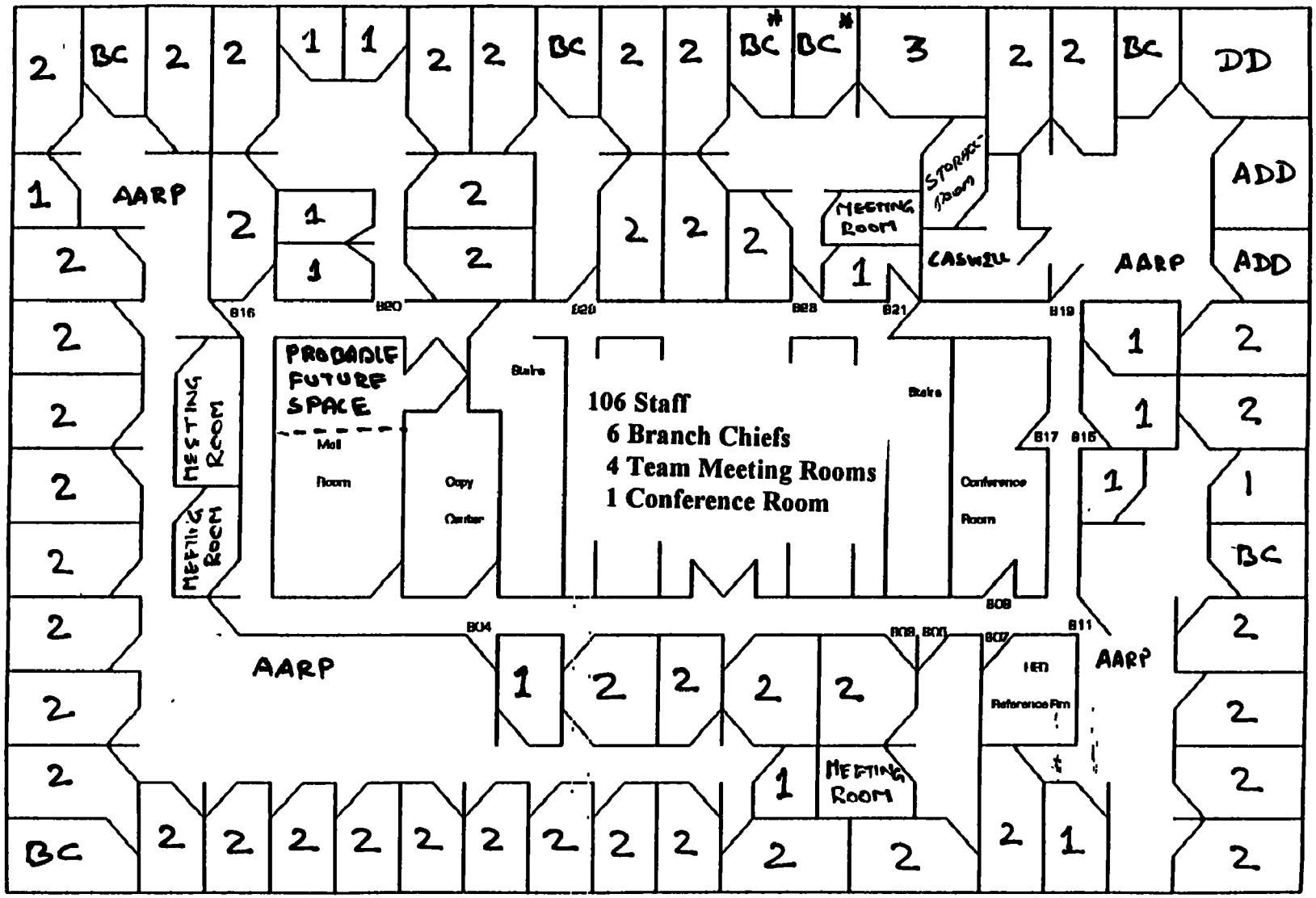


Figure 1

*** ONLY FOR VISUAL PRESENTATION..NOT PROPOSED SEATING ARRANGEMENTS**

HED - 8TH FLOOR



* ONLY FOR VISUAL PRESENTATION..NOT PROPOSED SEATING ARRANGEMENTS

Figure 2

HED - 10TH FLOOR

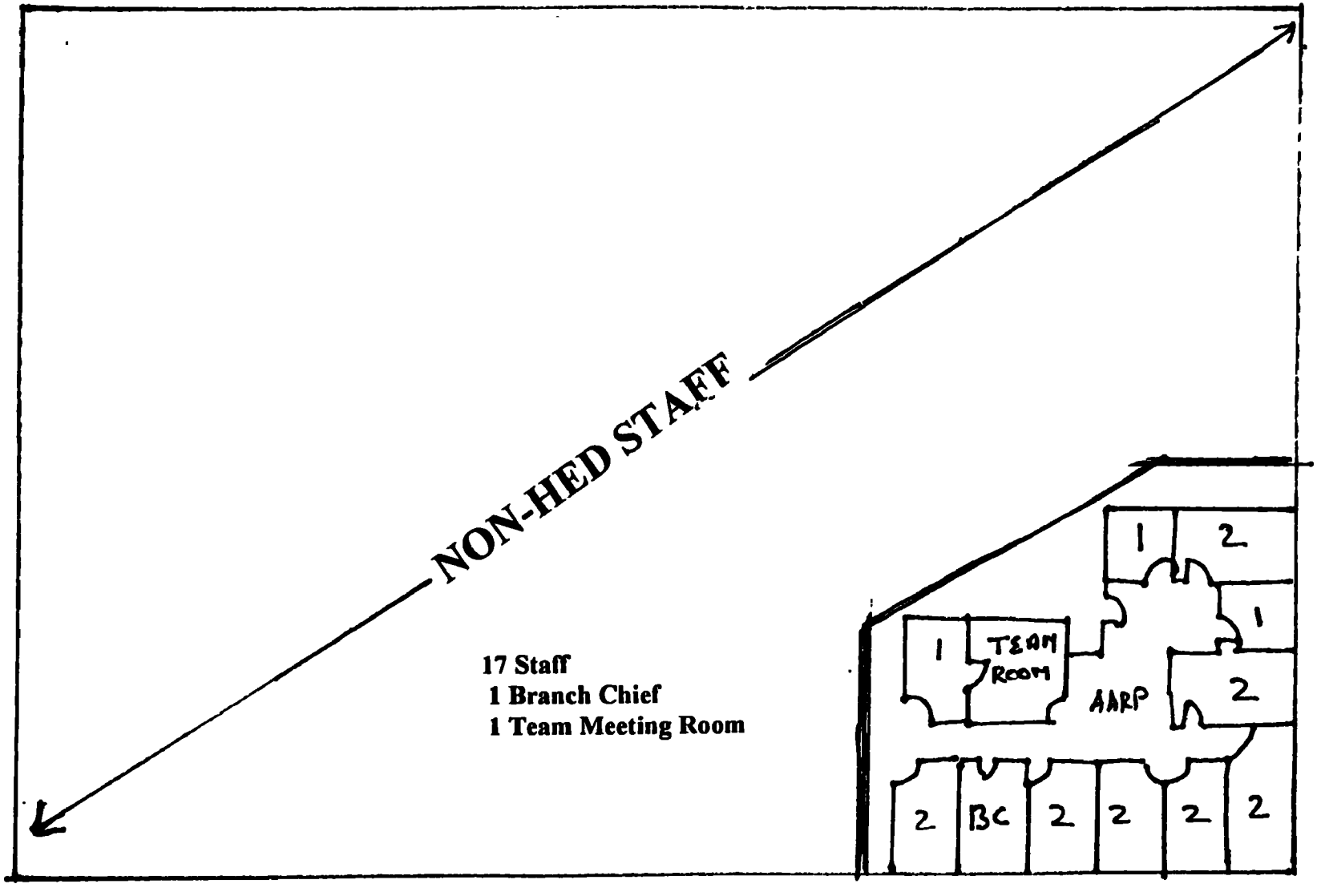
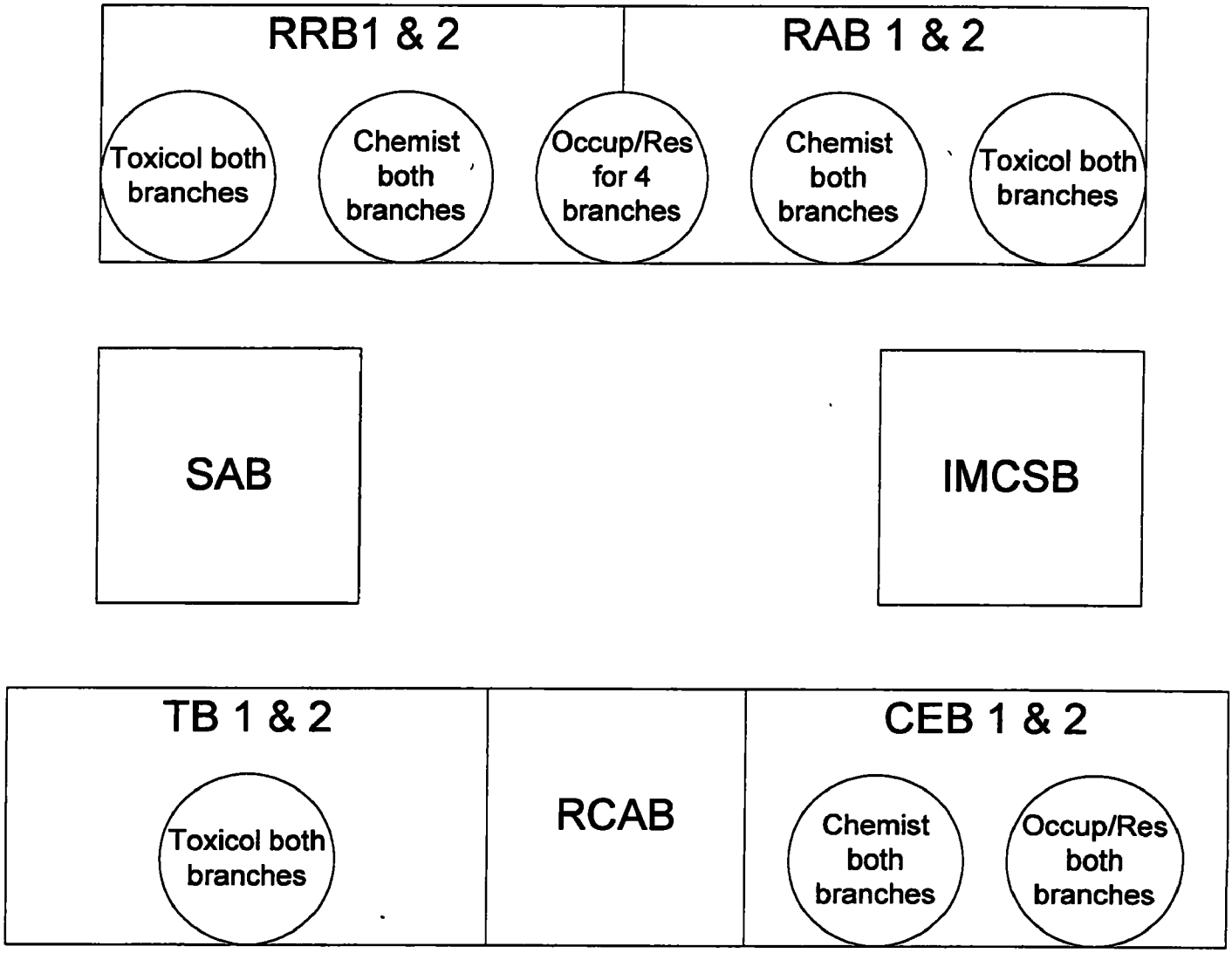


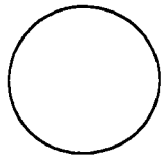
Figure 3

SEATING BY FUNCTION OF BRANCH WITH DISCIPLINE CLUSTERS

SPACE FIGURE 4



This represents relational seating, not based on actual physical space.
It can be modified as needed to accomodate for actual floor plans.

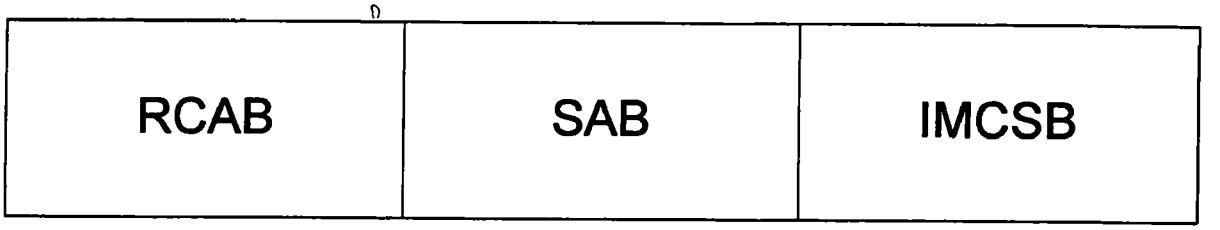


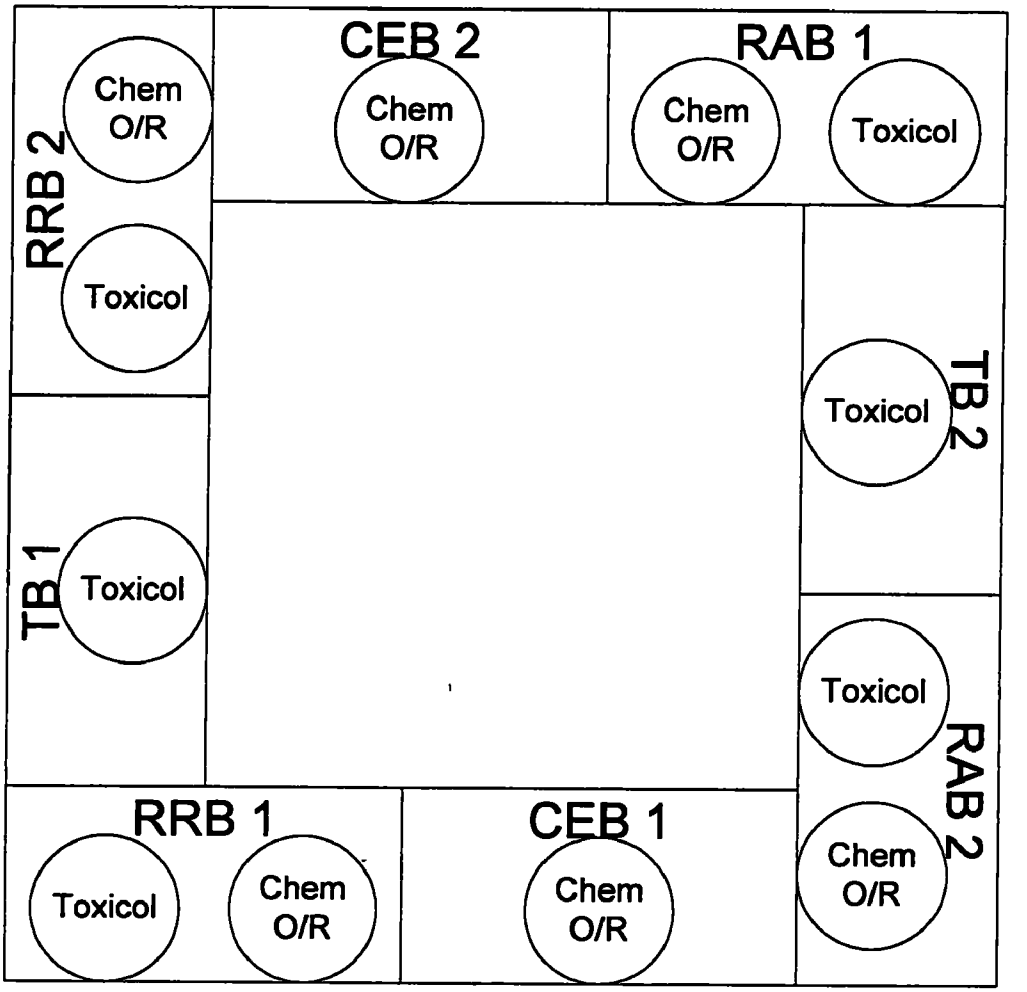
Seating location of people by discipline

Location of organizational unit

ALTERNATE SEATING BY BRANCH WITH ALTERNATING IDP AND SINGLE DISCIPLINE BRANCHES

SPACE FIGURE 5





This represents relational seating, not based on actual physical space.
It can be modified as needed to accomodate for actual floor plans.

IDP - Interdisciplinary Branch

Location of organizational unit

Seating location of people by discipline

VIII. HUMAN RESOURCES

ABSTRACT

An accurate method to measure performance leading to motivating staff is essential for HED to operate efficiently and effectively. **A performance assessment system is proposed which would include performance measurement at three levels: individual team members, team and Branch Chief.** An integrated team performance agreement and evaluation process would be used. This would entail performance agreements being negotiated between all major parties involved in an activity; and all of these parties would also contribute to or participate in the evaluation. Measures to motivate staff, training recommendations, development of agreeable work schedules and working conditions, support for a dual career track and criteria for good supervisors are also presented.

A. PERFORMANCE MANAGEMENT

How to measure performance and motivate staff was one of the issues identified early on in the Division's restructuring discussions. A performance assessment system was designed which included performance measures at three levels: individual team members, team, and Branch Chief. It was proposed that an integrated team performance agreement and evaluation process would be used. The discussion in this report highlights issues and concerns that will need to be resolved in Phase III implementation planning.

Integrated team performance management means that performance agreements are negotiated between all of the major parties involved in an activity; and all of these parties also contribute to or participate in the evaluation.

Benefits: The individual team member, team, and Branch Chief receives performance feedback not just from the supervisors and management but also from their peers (team members), subordinates, and customers or partners if appropriate. The 360 degree evaluation provides many benefits and promotes many of the Design Drivers. We believe that this type of performance program fosters the type of improvements we want to see in our Division:

- Goal and purpose driven
- Communication quality must improve
- Maintain and enhance science disciplines: consistency, integrity, scientific expertise
- Accountability
- Flexibility
- Clear definition of roles
- Meets Customer needs

1. Individual Performance

Individual Performance Agreement: The performance agreement is negotiated between the individual, the supervisor, and the individual's team(s). This ensures that the individual knows and agrees to that for which s/he is specifically accountable and what his/her contribution to the team and the program is expected. This also ensures that each team knows and agrees to each team member's role and responsibility.

Performance agreements should be written to reflect the actual work to be done. Performance agreements should have input and negotiation from the employee, or at least teams of employees. Employees should not be given a boiler plate standard to be signed without their input being solicited in the preparation of the standard.

The agreement should take into consideration all work activities which require a significant amount of the individual's time. This may include the work processes defined in the roles scheme of this document: data review, risk assessment, science assessment (renew committees), science policy, and administrative support.

Individual Performance Evaluation: The individual performance evaluation should be a 360 evaluation. The branch chief is responsible for the evaluation but should consider input from the individual, peers (branch team members), management, and customers. The purpose of a 360 evaluation is to obtain input from all people an individual works with so that the supervisor has an overall perspective of individuals performance. The evaluation should be used to acknowledge superior performance, improve an individuals performance and improve customer relationships. The details of how contributions are made or participation occurs could take many forms which must be examined by the Phase III Transition Team.

The evaluation system should be a fair and open process. The evaluation should occur only at the annual evaluation period, but performance discussions should occur two or three times during the year. At the time of the performance review, the individual performance on all team activities should be taken into consideration: branch teams, membership in SAC's, SARC's, OPP RED teams, policy development teams, etc. The relative amount of time spent on each team must be taken into consideration. It is therefore likely that the branch team should have the most input as compared to the other teams. When considering the input from the various teams the Branch Chief must consider the length of time the individual has been on the team as well as the length of time the other members have been on the team.

Each branch should decide on the process used for the individual team performance evaluation, team discussion or written evaluation. If it is a written evaluation it must be a open process. Factors which the team may want to consider to be include: -contributes to team discussion, regularly attends meetings, prepares for meetings, provides constructive input to work products, does not dominate team discussion or performance, does not hinder team interactions, and keeps other team members well informed.

Customer comments on an individual's performance should be addressed by the supervisor immediately, whether positive or negative. If the supervisor waits until the annual performance review to address the issues, the employee is not given a fair opportunity to respond to the comments, or make immediate modifications to his/her behavior.

A summary of the open discussion/written evaluation will be provided to the branch chief at the end of the performance year. The content of the summary should not come as a surprise to the individual because of the periodic evaluations throughout the year. The team input to the performance review will not be a major contributor to the overall score. It will most likely affect the overall score of individuals whose performance is border line to a higher rating levels.

There was concern about retribution on one team member by another or others. This issue was discussed at some length. The team felt that a single poor evaluation of a team member among a number of strong or positive evaluations by the other team members would need to be investigated by the Branch Chief. Team Leads will not be involved in performance management (see Chapter VI, *"Roles"*).

The staff must be trained on how to do these evaluations constructively and ineffective system could easily decrease morale, which is counterproductive to the reason for doing 360 evaluations: to improve the performance of the individual on the team and the performance of the team as a whole.

2. Team Performance

Performance Agreement: the performance agreement is to account for Team performance as a whole (e.g., how well does the team function, can it solve its own problems, does it meet its goals, is the team ensuring its own and members accountability) and is to be negotiated between the team, management, and its customers. This ensures that each partner is clear on their roles, responsibilities, and expectations of others. The purpose of this evaluation is to improve team function and customer service. **This is not an evaluation of the individual.**

Team Performance Evaluation: All parties participate or contribute to the evaluation. The Phase III Transition Team must set the details of the process. Refer to the suggestions for the Individual Performance Evaluation.

Customers must have input on the performance of HED. Comments should generally be directed to the branch or team since the ultimate work products, risk assessments, come from the team. Phase III Transition Team should work with the customers and branch chiefs to develop an appropriate method for evaluations (eg. Raosoft survey). Other HED committees such as the SAC's, SARC'S, and PSC should also be evaluated.

3. Implementation Suggestions from the Design Team on Performance

Agreements and Evaluations:

Components: 1) Self evaluation, peer evaluation, team evaluation, supervisor evaluation, 2) Management team discussion/decision, 3) approval by management, and 4) Supervisor/Individual discussion of final evaluation.

Process: Teams provide each member with written feedback/evaluation on a quarterly basis, initially and twice yearly after that. The purpose of the team evaluation is to improve the team process and improve customer service and satisfaction. The team evaluation would initially be done quarterly, so that mid-course corrections or encouragement can be made. The year end evaluation is provided to the supervisor for input on annual evaluations. Team evaluations should not be part of the individual's permanent record. How much weight is given to the team evaluation, supervisor evaluation, self evaluation, and any appropriate customer/partner evaluation would have to be decided.

Elements for the Performance Agreement for Scientists and Administrative Personnel:

Technical/Subject Matter Competence

Quality Work, with sound science, in a timely manner (assuming a realistic time frame).

Uses available Technological Tools effectively.

Communication: Communicates effectively, both orally and in writing, with other staff, customers, and the public.

Teamwork: Works well with others within and outside the team. Supports the team by doing own share. Takes initiative to share expertise.

Accountability: Meets customer needs and deadlines within resource limitations. Knows when to ask for more work, and when to ask for help.

Goal setting: Sets realistic goals and makes every effort to met deadlines. Committed to continuous improvement. Plans for growth.

Elements for Performance Agreement for Branch Chiefs

Technical/Subject Matter Competence and Managerial Aptitude:

Uses available Technological Tools effectively.

Recognizes quality work. Doesn't let politics interfere with sound science.

Communication: Communicates effectively, both orally and in writing, with staff, customers, and the public.

Teamwork: Works well with management team and supports the branch personnel by ensuring adequate resources for doing needed work. Exhibits professional courtesy to all staff. Understands individual circumstances (i.e., workload, outside pressures) and adjusts expectations accordingly. Committed to team concept of working.

Accountability: Makes decisions and sticks to them, but changes them when proven incorrect. Accepts responsibility for dealing with non-productive employees.

Goal setting: Sets realistic goals to meet customer needs and provides adequate resources for staff to meet deadlines. Innovative in problem solving. Understands the OPP vision, and what will impact staff.

Management/Leadership: Leads staff in learning the new way of working. Committed to continuous improvement. Provides meaningful, appropriate work for all staff. Exhibits right leadership at right time. Provides coaching, motivation as needed. Treats staff fairly and equitably. Directs work without micro-management. Works with the union as a partner. Supports staff recommendations when possible.

B. MOTIVATION RECOMMENDATIONS

1. How to get non-productive workers to work
   a) Team pressure, peer pressure
   b) Immediate counseling by the Branch Chief
   c) Letter to permanent file
   d) Reprimand and other measures

2. Encourage people to interact with those in other branches through more:

   a) Informal social events
   b) Group people together in different ways (different teams)
   c) Coffees (tea/soda) with Margaret

3. Grade equity for scientists

4. Variety in work assignments to prevent burnout.

   a) The team recommendation on assignment of chemicals should allow for greater variety of work assignments for staff.

b) The Policy Steering Committee (PSC) assigning projects should allow for greater distribution of special projects.

5. True Empowerment.

a) Have staff participation in decisions.
b) If management chooses to alter a science decision, the management must be accountable for explaining their rationale.
c) Management should support the risk assessment produced and act as a buffer to prevent risk management decisions from affecting the methodology used in the risk assessment.

6. Encourage professionalism, attendance at scientific meetings. Recommend that a division training person be appointed (at least 1/2 FTE located in Information Management and Contract Support Branch of HED)(IMCSB)). The training coordinator, in consultation with the Science Advisory Councils (SACs) should maintain information (announcements, etc.) on scientific meetings. **The following should be considered as options within budgetary considerations.**

a) Rewards for people who keep up to date in their science fields.

b) Pay dues for one professional society per person (e.g., American Chemical Society (ACS) for chemists; Society of Toxicology (SOT) for toxicologists, etc.), and encourage professional society committee work (e.g., give time).

c) Encourage publications in scientific journals, particularly for special project analyses.

d) Have a regular scientific seminar series, with staff encouraged to attend.

e) Send scientists to the lab periodically to train them in the latest research.

f) Sabbatical program - scientists and staff for outside related OPP mission related, scientific discipline activities. Classes and/or research at Universities, either locally or out of town.

7. More Rewards - cash awards, plaques, letters to file, etc.

a) Acknowledgement of good job.
b) Outstanding rating should go to those who really deserve it.
c) Awards available for individual achievements as well as team achievements
d) Give awards for good work, not just for special projects.
e) Peer Awards, recommended by peers.

8. Provide adequate resources, equipment and supplies to get the job done right.

C. TRAINING RECOMMENDATIONS

HED is a scientific organization and needs to maintain credibility in the scientific community by visibility and interaction with other scientists in professional scientific meetings, courses, etc.

1. Appoint a Training Coordinator. This would be a major factor in this individual's performance agreement, perhaps full time. The training coordinator should be in IMCSB, and should be at least 1/2 FTE.

2. The Branch Chiefs and SACs will recommend people for training and travel.

   a) Some training will be for all staff.
   b) Some training will be limited either in terms of space available or cost.
   c) Recommend staff input.

3. Everyone should have an Individual Development Plan (IDP).

4. **Mentoring Program**

The division should develop a mentoring program for new hires. Each new employee would be assigned a mentor who would be responsible for : 1) instructing the new employee on how to access scientific and administrative information; 2) providing advice on how to do the work (i.e. data reviews, risk assessments, preparing forms, procurement, etc); and 3) provide advice on interpretation of data and Agency policy. The Design team recommends that new hires in the inter-disciplinary branches be assigned a mentor from the appropriate disciplinary branch. This will help to foster communication across HED and facilitate introducing a greater pool of disciplinary experts for advice to the new employee than may be available to him/her within the assigned branch.

5. **Key Skills that need development**

This training should occur in 1997 and then be repeated as necessary. The Design team acknowledges that it will be difficult to address training needs of present staff and new hires while facing a considerable workload.

a. Teamwork/Personal Skills

1) Teamwork and team building

2) Communication skills: written, oral, and effective, efficient meetings

3) Time Management

4) Conflict Resolution

5) Constructive Criticism

b. Computer

1) Windows 3.1 and/or 95, Lotus 123, Lotus Notes, Crystal Ball, etc.

2) Literature searching

3) Accessing and finding useful information on the Internet.

4) Sharing computer files in different formats. Sending computer files via the internet.

c. Technical (Science/Regulatory)

1) Risk Assessment and Risk Characterization - includes preparation of assessments and characterization; use of probabilistic tools; effective communication of assessment and its inherent uncertainty.

2) Professional development in own field - ongoing need.

3) Sharing knowledge: Staff members have a lot of expertise which could be used to help train others. This expertise should be identified and then used for internal seminars.

4) Cross training - across disciplines within HED, risk management by RD/SRRD, and training for customer divisions on science issues. Present staff could present seminars for HED and others.

5) Big picture: how it all fits together, where HED fits into the OPP puzzle.

6) Training plan developed by SAC, including DRES, PHED, Incident Data analysis, Codex, Imports, etc.).

D. WORK SCHEDULES AND WORKING CONDITIONS

1. WORK CONDITIONS

Staff must have adequate tools to do the job needed, including computers, software, books, and other reference materials, adequate training, reasonable pressure to complete work within reasonable time frame.

2. WORK SCHEDULES

OPP offers flexitime, compressed work schedules, flexiplace as tools to improve employee productivity and morale. As HED moves to a team-base organization which require more meetings, these tools have to be used effectively to insure that employees are available for meeting when needed while still retaining the employees flexibility in working hours and locations. The design team has the following recommendation on effective use of these tools:

- Teams should coordinate compressed and flexiplace days so that all team members are present at the regularly scheduled meetings.

- Team members should not allow all member of the team to have same specific day off (eg. first Friday of the pay period) to ensure adequate coverage in the branch and availability to the customer to answer questions.

- Teams should have regularly scheduled meetings instead of changing meeting times on a weekly basis. This allows employees to have regular compressed/flexiplace days and allows others to schedule meetings around the time schedule.

Following is a summary of the advantages and disadvantages of the compressed work schedules and flexiplace.

a. Compressed schedule

Advantages

(1) helps employees manage time effectively, using less leave, by scheduling some needed activities on compressed day off.

(2) that day off every other week feels like free time, a great motivator.

Disadvantages

(1) having people with different compressed days off makes it more difficult to schedule meetings.

b. Flexiplace (telecommuting)

Advantages

(1) helps when employees facing long commute

(2) often less distractions than in the office

(3) should result in more productive employees, and there should be measures in place to ensure that sufficient productive work is occurring at the flexiplace site

(4) helps with coordinating the limited space, which faces the Division in the future. The Division will have additional employees with no additional space.

Disadvantages:

(1) People on flexiplace are less available (not just down the hall) and must be contacted by phone or e-mail.

(2) Some of the tools available in the office are not available in the flexiplace location. It is difficult to have all files and reference materials which could potentially be needed in the flexiplace location.

(3) The current system is easily abused, and not all managers and employees follow the rules.

(4) There may be more distractions at home such as housework, that interfere with work.

Tools needed to make flexiplace successful:

(1) There must be a written contract as per Agency policy.

(2) A decision is needed on whether the person and the job are amenable to flexiplace.

(a) Certain people cannot use flexiplace because of their work habits.

(b) Certain jobs are not amenable to flexiplace, such as jobs that require constant interaction with the public and staff.

(c) A computer which ideally is able to access the LAN is mandatory at the individual's home before flexiplace can begin.

(3) Employees should know whether flexiplace will work for them, but measures should be in place to ensure that productive work is happening (personal and Branch Chief accountability).

(a) Accountability should be required for both staff and their Branch Chiefs. This should be addressed in both the performance agreements.

(b) If a person is non-productive at the flexiplace location, the Branch Chief must address the issue immediately.

(4) Flexiplace phone numbers need to be available for people in the office to use. These numbers should be available from the clerical staff, the team leader, or branch chief. Currently, in many cases, this information is not readily available.

(5) Flexiplace schedules must be posted in all Branches. Individuals on flexiplace must put their schedule on CaLANdar.

(6) Flexiplace schedules should remain consistent. Individual changes to a flexiplace schedule must be done well in advance and on Calandar.

(7) Flexiplace schedule may need to be adjusted to accommodate needed meetings; i.e., the person must attend a scheduled meeting, regardless of flexiplace.

(8) The maximum number of days per week permitted for flexiplace depends on the job. Generally, three days per week would be a maximum. There may be some special situations, such as a person with special medical needs, where more than 3 days in a week may be allowed on a short term basis.

E. DUAL CAREER TRACK

HED has many talented scientists who would prefer to capitalize on their scientific skill, and may not be suited for a management track. A Dual Career Track would allow for professional growth, and maintenance of the various scientific disciplines.

We recommend that Margaret, Stephanie and Debbie work with the OPP's Director's office and OARM (Human Resources) to develop a realistic technical career ladder.

F. HUMAN RESOURCES SYSTEMS ALREADY IN PLACE

Human resource systems already in use by HED administrative staff are considered adequate and will not be discussed further in this document. These include systems for

- Budget (formulation, execution, accounting)
- Contracts, Grants, Co-Ops, IAGs
- Personnel (Processing, liaison to EPA Personnel and other divisions, time cards, performance contracts, time accounting, tracking special projects
- Facilities (Space, phones, voice mail, lights, LAN connections, moves, ADP support)

- Custodial (PC hardware and software)
- Security (CBI clearances, security briefings)

G. CRITERIA FOR GOOD SUPERVISORS:

Managerial aptitude: Willing to delegate. Buffers outside influences as appropriate. Team player. Supportive of staff. Generates Team Success. Likes people. Demonstrates empathy. Directs work without micro-management. Willing to learn from staff. Accepts responsibility for dealing with non-productive employees. Works in partnership with the union. Develops a sense of trust with staff. Supports staff recommendations, when possible.

Vision and Forward Thinking: Encourages innovation, creativity, risk-taking, experimentation and new technology applications. Encourages staff to learn how other organizations deal with issues similar to one's own. Sees "big picture." Learns from mistakes. Committed to continuous improvement.

Integrity: Demonstrates a high level of personal and professional honesty and integrity. Good work ethics. Professional courtesy (i.e., treat staff as the professionals they are). Use staff appropriately and effectively. Treats people fairly and equitably. Demonstrates understanding of staff needs. Gives amnesty.

Communication: Is able to communicate effectively, orally and in writing, in all directions, inside and outside the organization. Is a good listener. Acknowledges achievements, says thank-you.

Action/Results Orientation: Is able to make things happen, make decisions and achieve positive, demonstrable results within the scope or responsibilities. Actively builds consensus in solving problems while promoting innovation. Has a spine. Makes tough decisions. Not wishy-washy. Good at planning, scheduling, setting priorities, and meeting goals.

Resources Management: Assures organizational planning, budgeting, contracts management and financial accountability reflect the basic principles of doing the "Right Things Right" and conform to Agency and Federal regulations. Leads reforms in work processes to improve efficiency and effectiveness and makes decisions based on data and facts. Maximizes the Agency's return on resources. Distributes resources equitably.

Leadership: Develops, stimulates, coaches, empowers and facilitates employees to reach their full potential and be individually accountable for positive change. Champions work environments in which all members of the team look to be actively involved in defining and supporting Agency directions. Articulates and advocates the Agency's values and is an active external champion of EPA's mission.

Diversity: Creates an environment where diverse individuals play responsible and active roles by integrating people, ideas, and organizations. Fosters teamwork and builds collegiality by getting ideas and involvement from all employees in the organization. Understands individual circumstances (i.e., work load, outside pressures) and adjusts expectations accordingly.

Customer Focus: Is responsive to and achieves alignment and satisfaction with key customers, inside and outside the Agency. Understands that quality is customer driven. Doesn't forget internal customers.

IX. COMMUNICATION AND DECISION MAKING

ABSTRACT

HED's communication pathways and communication tools are essential for planning, developing, and completing the tasks required by the four core work processes. Portions of the following communication and decision making strategy parallel HED's workplan for bringing information/data in, circulating it to the appropriate staff, and tracking it through the organization as it gets assessed and transformed into completed products. Our communication systems will ensure the efficient and accurate movement (both internal and external to the organization) of information through formal and informal mechanisms, according to flexible operating procedures. These communication systems will extend between HED and other divisions at the DD, Branch Chief and Team levels. The systems will also allow for communication within the division vertically and horizontally. **HED accomplishes much of its risk assessment planning, QC/QA of data reviews, and hazard/exposure/risk assessment decisions in frequent, regularly scheduled meetings. Different meetings, however, have different purposes. In the reorganized HED, it will be essential to create and maintain communication pathways both vertically and horizontally to maintain scientific consistency within the organization.**

INTRODUCTION

In the new design, the flow of information will require careful planning to ensure that complete and accurate information gets to the appropriate individuals or teams, at the appropriate time such that effective risk assessment decisions can be made in a timely fashion. The flow of information within and through HED is essential to the success of our organization's mission. Communication is one of the major drivers for the proposed design. It will be the responsibility of every individual to develop and maintain appropriate, constructive relationships both within HED and between other divisions through effective communication.

A. FORMAL COMMUNICATION - INTERNAL

Written Communications.

To facilitate the quality of interactions between the branches in the new organization, each branch/team should develop Standard Operating Procedures (SOPs) for their work flow processes (i.e., including data reviews and risk assessment). There should also be SOPs for electronic filing. These SOPs should be simple and available on the T:drive for other members of the program to access (see PIRAT SOPs for example). Information on work planned, work in progress, and work completed can be quickly distributed to all staff via the T:Drive. Additional reports/schedules are:

Annual Report: Under the proposed system, oversight for this annual activity will reside in the Immediate Office (DD/ADDs) and Information Management and Contract Support Branch (IMCSB) will coordinate and facilitate development of the report.

Weekly Report (for OD): Under the proposed system this function will reside in the IMCSB. The Design Team proposes that staff report items to branch AARP for typing and sign-off by their respective Branch Chiefs. This will in turn be sent to the IMCSB for submission to OD.

Weekly Note to Staff by DD: Continuation of current CC:Mail note to all HED staff by DD/ADDs. This communication may be expanded slightly to mention or reference the existence of things of note for the division such as completed new chemical registration, REDs, SAP, SEPs, SOPs. The note should also include recent developments such as those associated with FQPA and Pesticide Program Dialogue Committee (PPDC).

Science Assessment Review (formerly Peer Review) Schedules and Documents - Stored on LAN and 1 Liners.

Schedules for REDs, new chemical registrations, etc, should be available on LAN and updated weekly by all the Branch Chiefs working as a team.

In addition to distribution of routine information, cc:mail can be an important tool for disseminating information (including electronic documents/files) to large numbers of people fast. Certain messages may not be in the form of formal memoranda; the "informal" use of cc:mail is also valuable for resolving small problems such as schedule changes, small changes in documents for concurrence, etc.

Meetings.

HED accomplishes much of its risk assessment planning, QC/QA of data reviews, and hazard/exposure/risk assessment decisions in frequent, regularly scheduled meetings. In the reorganized HED, it will be essential to create and maintain communication pathways both vertically (Team to BC, BC to DD/ADDs, etc.) and horizontally (Team-to-Team, Branch-to-Branch, etc.) to maintain scientific consistency within the organization. Different meetings have different purposes. Independent of whether the purpose is for planning, discussion, decision, data review, etc., a cultural change is necessary to improve meeting quality. Recommendations are:

Elements for Meaningful Meetings

- An agenda/briefing package is distributed in advance (for most meetings) indicating the meeting focus (decision vs. discussion)
- The appropriate compliment of people are present to address agenda topics
- All participants come prepared and stay focused on agenda items

- Information on decisions, discussions, follow-up actions are promptly transferred to all appropriate organizations/individuals

- Starts and ends on time

A matrix for meetings which should be frequently held in HED are presented in Table 1. A detailed description follow the table. These meetings are essential to the four core work processes and to the completion of risk assessments. The matrix identifies meeting participants and recommends communication pathways/methods to move information within and through the organization.

Table 1. Communication and Information Distribution Pathways (Internal and External) for Regular HED Meetings.

Regular HED Meetings (Suggested Frequency)	Participants	Purpose	Internal Communication Path	Recommended Method	External Communication Path
Management/ Prioritization (Weekly)	DD/ADDs/BCs Master Tracker Designated staff	Prioritize incoming work and discuss status/issues on HED projects in progress, as needed • Assess and balance workloads/resource commitments • Develop future schedules	Vertical to staff Horizontal between Risk Assessors	BC to staff and BC's LAN schedule Joint Branch Meetings	BC's schedule available to customer Divisions on LAN
Branch Prioritization (Weekly)	BC/BSS/TLs Staff with discretion of BC	Prioritize work and discuss status/issues on Branch projects in progress	Horizontal to BCs Vertical to Teams	Mgmt/priority meetings BC's LAN schedule	Horizontal between BCs at monthly interdivisional planning meetings • BC's LAN schedule
Teams (Once Weekly)	Staff assigned to dedicated IDTs/DRTs	Prioritize work and discuss/product/QC/QA individual data review and risk assessment documents	Vertical to BC/BSS Horizontal to branches sharing same chemicals	Branch Meetings Joint Branch Meetings BC's LAN schedule	Horizontal to OPP Reg/Rereg teams via cc:mail or phone and at OPP team meetings • BC's LAN schedule
Inter-technical Team (Every two weeks)	BSS (including AD/BPPD)	Discuss cross-branch/division issues on science and regulatory policy matters	Vertical to staff	Joint Branch Meetings • Minutes on U:Drive	Horizontal to AD/BPPD Between DDs as needed
Joint Branch (Every two weeks)	BC/BSS/TL/staff	Maintain consistency between parallel branches and transfer information from BSS inter-technical team meeting to staff	Horizontal to branches sharing chemicals	BSS Presentation at Quarterly All-Hands • Minutes on U:Drive	Between DDs as needed
SARCs (Weekly)	SARC Chairs, BSSs, staff, RA team reps, BPPD and AD (including DD/ADDs at RA Committee meetings)	Assess, identify, and document the dose and endpoint, RfD, cancer classification, metabolism, etc. for risk assessments • Review completed risk assessments for REDs/new chemical registrations	Lateral to RA Team	cc:mail draft minutes/memos; final docs on LAN Briefing as needed for SAC/PSC or DD/ADD or OD/AA to resolve difficult policy issues	Final RA document on T:Drive
SACs (As needed)	Disciplinary SAC members (Tox, Expo, Chem)	QC/QA of data as needed	Lateral to Teams	Joint Branch Meetings	Not needed
HED Management (Weekly)	DD/ADDs/BCs/TLs	Discuss program-related scheduling issues • Discuss agenda topics from OPP DD meetings	Vertical to Staff	Team Meetings	Not needed
All Hands for HED (Quarterly)	All Staff and Management	Division-wide meetings to assess how things are working in the new organization		Agenda and post-meeting discussion on cc:mail/u:drive	between DDs as needed

Regular HED Meetings (Suggested Frequency)	Participants	Purpose	Internal Communication Path	Recommended Method	External Communication Path
Intra-disciplinary Technical Discussions (Quarterly)	BSS, TLs, Staff including AD/BPPD	Ensure consistency within technical discipline	Vertical to DD/ADDs	Agenda and post-meeting discussion on cc:mail/u:drive	between DDs as needed

AA Assistant Administrator
AD Antimicrobial Division
ADD Associate Division Director
BC Branch Chief
BPPD Biopesticides and Pollution Prevention Division
BSS Branch Senior Scientist
DD Division Director
DRT Disciplinary Review Team
IDT Inter Disciplinary Team
OD Office Director
PSC Policy Steering Committee
RA Risk Assessment
SAC Science Advisory Council
SARC Science Assessment Review Committee
TL Team Leader

Description of the Meetings:

HED Management/Prioritization Meetings: **Weekly** - Branch Chiefs, IMCSB (master tracker) and designated staff meet with DD/ADDs to discuss priorities of incoming work and assess priorities of ongoing projects. Branch Chiefs should bring their current product schedules to these meetings and be prepared to discuss program-related scheduling issues.

Branch Meetings: **Weekly** - Each branch should meet to discuss workload, individual branch issues, etc. At the SAB and RCAB Branch meetings, the BSS would need to communicate the technical and policy issues raised in the Inter-Technical Team Meetings.

Joint Branch Meetings for Parallel Branches (e.g. RRB1/RRB2, RAB1/RAB2, TB1/TB2, and CEB1/CEB2): **Every two weeks** - The purpose of these meetings is to insure consistency between parallel branches and allow the BSSs to discuss with the branch staff the technical and policy issues raised in the Inter-Technical Team Meetings. This also provides a forum for the branch staff to inform the BSS of issues that need to be elevated. To insure consistency between RCAB and the interdisciplinary branches, RCAB would need to be represented at the Joint Branch Meetings. (See Figure 1.)

Team Meetings: at least **Once Weekly** (or from 1 to 3/per week, as needed) - Staff assigned to dedicated Interdisciplinary or to rotating Disciplinary teams will meet to prioritize work, to discuss/produce/QC/QA individual data review and risk assessment documents.

Inter-Technical Team Meeting: **Every two weeks** - A branch senior scientist (BSS) from each branch will meet every two weeks to discuss cross-branch issues and communicate major policy issues if necessary. They also need to communicate concerns/issues of the staff to upper management. An agenda will be required - rotating responsibility of the branches. AD and BPPD should be included. (See Figure 2.)

Science Assessment Review Committee Meetings - These include the Hazard ID, Cancer, Reproduction/Developmental, Metabolism, Mechanism of Toxicity and Risk Assessment Review Committees. Appropriate representatives from AD and BPPD should be included. It should be understood that decisions drafted at these meetings are not to be shared with Registrants prior to finalization of the documents.

SAC Meetings: **As needed** - Disciplinary SAC members (Tox, Expo, Chem) will meet to QC/QA of data in review.

HED Management Meeting: **Weekly** - Branch Chiefs and Team Leaders meet with DD/ADD to discuss agenda items from OPP DD meeting.

Quarterly Staff Meetings: Division-wide meetings for all staff and management. In the short-term, such meetings will provide a forum to review and discuss how well things are working in the reorganized HED.

Intradisciplinary Technical Discussion Sessions: **Quarterly** (or more frequently as training requires) - These sessions should be used to further consistency within the technical disciplines such as toxicology and exposure. These sessions may include seminars with speakers. Appropriate representatives from BPPD and AD should be invited.

It is a valid concern that HED staff and management spend a substantial portion of their time in meetings. It is also not only the time spent attending meetings but time required to prepare for meetings. To address this issue, please refer to the attached "A Month in the Life of HED Staff and Management". This linear calendar depicts what portion of the work week would be spent by an individual Team member/reviewer, Team Leader, Branch Senior Scientist, Branch Chief, and DD/ADD in the proposed meetings essential to our core work processes. A Team Leader will, on average, spend about 9 hours per week in meetings.

B. FORMAL COMMUNICATIONS - EXTERNAL

MEETINGS

Other divisions (EFED, AD and BPPD) should be included in the SARC meetings and Intradisciplinary Technical Discussion Sessions. It should be understood that decisions drafted at these meetings are not to be shared with Registrants prior to finalization of the documents.

Meetings for OPP Teams for REDs, Special Reviews, New Chemicals: Need to be held at the beginning of the process and frequently during the process. They should meet at the end to evaluate the risk management decision that was derived. There should be a detailed agenda prepared in advance and team members should come prepared to discuss these items. Minutes should be drafted and distributed electronically to all team members.

Pre RED or Registration Meeting with SRRD or RD and Appropriate Registrants: After data review but before the exposure assessment, the registrant would be invited to attend a meeting to discuss the direction in which HED is headed with regard to endpoint selection, assumptions about exposure, any questions concerning the upcoming assessments, questions about drinking water issues. By sharing the information early in the process, the opportunity exists to permit adjustment of the assessment while it is still in progress rather than waiting until the Risk Assessment is final and multiple rounds of rebuttals are triggered. Similarly, by including the lead Divisions in these discussions, fewer internal rounds of inquiry/clarification may be needed.

Inter-Divisional Planning Meetings: **Monthly** - Separate for Registration, Special Review and for Reregistration. The purpose of these meetings is to focus on the short range scheduled outputs for new chemical registrations, special reviews and reregistrations. The attendees would be Branch Chiefs from all divisions involved with these processes. As needed, the Risk Assessor and/or appropriate technical staff could be present to resolve major chemical specific risk assessment/risk management issues.

RD/SRRD Joint Management Meetings: **Monthly** - The purpose of these meetings is to review overall program-related issues. Attendees would be DDs, ADDs, and BCs as needed.

C. FEEDBACK SYSTEMS

A quarterly meeting between HED Branch Chiefs and representatives from EFED, BEAD, BPPD, AD, RD and SRRD to review REDs Special Review Projects and new chemical registrations issued in the last 3 months and discuss process improvements. This may be held at the Inter-Divisional Planning Meeting if time allows.

Customer Survey: The Branch Chiefs (as part of their new role) should design, implement and maintain a customer oriented survey (for all team members to complete) to insure that our internal needs as well as our customer's needs are being met. Limited examples include: were packages complete, were meetings appropriately held, was HED staff responsive to questions. This includes accessing HED's team as well as that of the Inter-Divisional Team.

Customer Service Representative: An individual will respond to the public and offices outside HED regarding question on status of projects, reviews, etc. within HED (e.g. HED answer person/representative).

The Design Team recommends that HED staff attend SRRD peer review meetings. This could be used as a training tool and would also give us insight as to how they view and assess HED's risk assessment documents.

D. DECISION-MAKING PROCESS

This section addresses how certain decisions get made and by what individuals/groups, and how decisions are communicated within HED and externally. A major aspect of empowerment is involvement in decision making. The Design Team recommends some ways to provide for greater staff involvement in the various aspects of decision-making in HED and to better communicate decisions once they are made. These are:

Decision Process	Participants	Staff Participation in Process	Recommended Communication Method	Recommendations to Management
Work Assignments - Data Review and Risk Assessments	Mgmt Team BC Team Staff Team SACs	IDB/DRB Teams prioritize and distribute work assigned to their respective Branch	BCs update and post schedules to the T:Drive weekly	Involve Teams in the development and implementation of a single Division level project scheduling system that can be customized by each Branch for their internal use. This system should also be accessible to our customers (RD/SRRD) and other divisions such as EFED, AD and BPPD.
Science Policy Decisions	Agency, AA, OPP, DD, ADDs, Staff, PSC, SACs	Staff volunteer/nominated to serve on workgroups	PSC responsible for maintenance of a policy directory on T:Drive	Announce the need for a workgroup • Allow staff to participate in selection of workgroup members • Ensure that workgroups keep staff informed on the progress/status of decisions/recommendations being developed
Science Assessments	SARCs, PSC, Staff	Exposure experts, Chemical Managers provide input at SARC meetings	Formal Memos • Meeting Minutes • SAB responsible for maintenance of SARC documents on the T:Drive	Membership to SARC should be made by management with a selection process involving the staff which also provide opportunity for individuals to volunteer membership Ensure that all schedules and final documents are available on LAN for all divisions •
Risk Assessment (RA) Decisions	RA Committee DD/ADDs Technical Staff	Technical staff provides input	Final RA Document stored on T:Drive by RCAB/IDBs	Ensure that Risk Assessment Documents reviewed by RA Committee are available on LAN for all divisions
Briefings for Risk Management Decisions	Agency, AA, OPP, DD, Technical Staff, PSC	Technical staff provides input	Briefing Paper • FR Notice • Weekly Reports • OPP Home Page	DD's Weekly Note to Staff should include mention of recent major Risk Management Decisions

E. INFORMAL COMMUNICATION TOOLS

Social Events: Purely social function can promote better communication between individuals and develop stronger relationships. This is consistent with the required cultural change necessary with the restructured HED. Examples of these activities include the annual Winter holiday party and the semi-annual Division Picnics. Project teams such as chemical specific teams are encouraged to get together for mini-celebrations of accomplishments. Additionally, organized sporting events and recreational activities would be another way for individuals to become closer with one another on a voluntary basis.

Building Interpersonal Skills: The Division should participate in division wide training programs such as Myers-Brigg, Zenger Miller, criticism and conflict resolution, sensitivity training, team building, courses.

Performance Evaluation Training: If the Division adopts a performance evaluation system that includes input from staff as well as management it is important to train people how to evaluate their fellow employees.

Margaret's Coffees: It is recommended that these informal gatherings be continued. Getting-to-know you sessions such as these have successfully allowed congenial interactions between Margaret and all staff.

F. ELECTRONIC AND PHONE COMMUNICATIONS

HED's electronic communication devises are fundamental to efficient and effective interoffice distribution of information and scheduling. The communication pathways recommended above rely heavily on utilization of **phones (with voice mail), cc:mail and CaLANdar** by all of HED. **The use of these tools should be incorporated into performance agreements.** Listed below are general guidelines for use of these systems to optimize communications.

1. cc:Mail: On a daily basis, we deal with an ever increasing number of cc:mail messages. It will be necessary for us to manage and optimize the value of cc:mail messages.

cc:Mail should be checked at least once each day, more if possible. It is recommended that staff on flexiplace be required to check their, **cc:mail** at least daily.

Use cc:mail to:

- disseminate information to large numbers of people fast
- forward an electronic copy of a completed document concurrently with the completed paper copy

- resolve small changes in documents for concurrence.
- Do not use cc:mail to make work assignments.

2. **CaLANdar:** This device gets us where we need to be, when we need to be there!

It is recommended that staff on flexiplace be required to check their, **CaLANdar** at least twice daily.

Recommendations on CaLANdar use:

- Each person must check CaLANdar at least twice daily (once in the morning and again before leaving for the day).
- All appointments must be put on CaLANdar.
- All leave time, compressed days off, and flexiplace days must be on CaLANdar.
- When scheduling a meeting, if there is less than 24 hours notice of the meeting, contact each person expected to attend by phone or in person.
- Meetings must show the location of the meeting and sufficient information about the meeting for participants to know why they were invited and how they should prepare.
- Do not use CaLANdar to deliver new work assignments.

3. Telephone Communication Tools

One concern of the Office Director is that Branch and Division office telephones be answered throughout the day from 8 am to 4:30 PM. To accomplish this, each branch will need one AARP. Additionally, there will be times that the AARP is not in the office, either on leave or performing duties elsewhere in the office, such as xeroxing or filing. A system needs to be worked out within each Branch to have complete telephone coverage throughout the day. One method would be to forward the calls to another number. OPP telephones, including the new ISDN phones can be forwarded to any number within the local telephone system (any number which does not require dialing 9 first). The Branch calls could be forwarded to another branch AARP, or a schedule could be worked out in which the Branch personnel are required to provide telephone coverage. For individuals on flexiplace, EPA phones cannot be forwarded automatically to that individual's home phone; however, forwarding individual calls to an off-site number can be done by anyone in the office.

It is recommended that staff on flexiplace be required to check their voice mail at least twice daily. To enable staff on flexiplace and others to check voice mail and access the LAN remotely when it would require a long distance phone call, an 1-800 number could be established for calling into the voice mail system, or telephone credit cards could be issued to those individuals, with the proviso that they be used only to access voice mail and the LAN. An additional possibility for accessing the LAN would be access through the internet. Many individuals on flexiplace have personal Internet accounts, which could be used. Alternatively, the Agency could provide Internet e-mail accounts for those individuals.

CLIP OUT BOX OF ESSENTIAL ELEMENTS FOR COMMUNICATION

Elements for Meaningful Meetings

- An agenda/briefing package distributed in advance (for most meetings) indicating the meeting focus (decision vs. discussion).
- The appropriate people are invited/present to address agenda topics.
- All participants come prepared and stay focused on agenda items.
- Information on decisions, discussions, follow-up actions are promptly transferred to all appropriate organizations/individuals.
- Starts and ends on time.

Elements for cc:mail Communications

- Read/scan all messages daily.
- Follow-up on messages requesting a response.
- Send messages to all appropriate people.
- Put relevant information in the subject.
- Keep message brief and to the point.

Elements for CaLANdar

- Check CaLANdar twice daily: when you log on and when you log off of the LAN.
- Title meetings accurately and give meeting location.
- Provide enough information (use cc:mail if necessary) so attendees arrive prepared.
- Allow at least 24 hours warning of impending meetings.
- Put all meetings, flexiplace, leave and compressed days on CaLANdar.
- Respond to all meeting requests (Y or N) **don't** delete or ignore.

Elements for Phone Usage

- Each branch needs complete phone coverage from 8-4:30 PM
- This is achieved by an AARP or designated alternate
- New ISDN phones can be forwarded within local phone system
- Use voice mail and check for messages frequently
- Respond to all voice mail messages

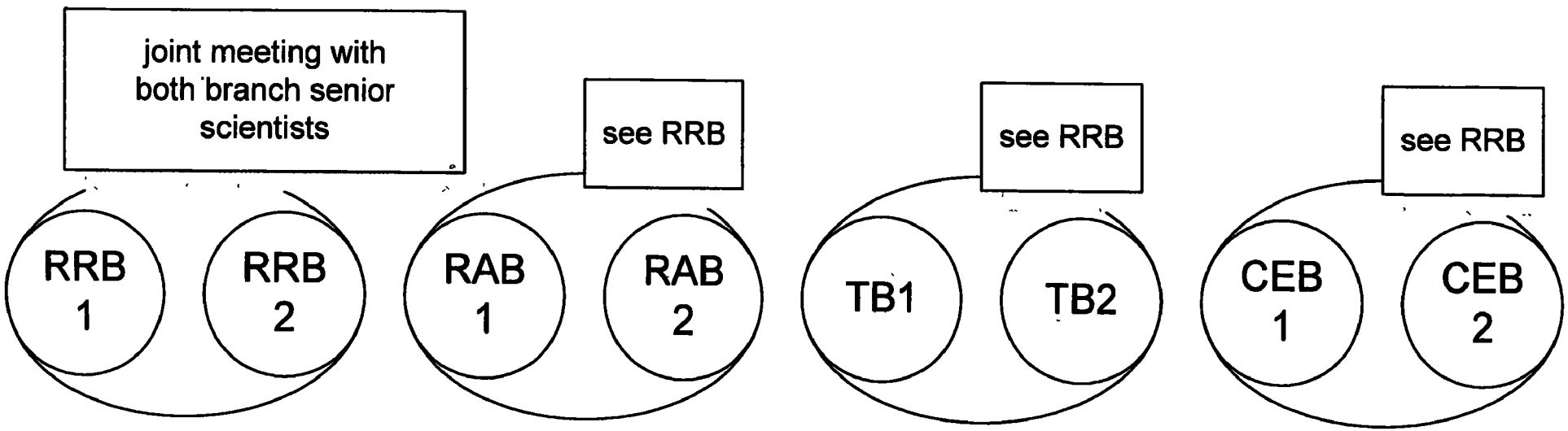
A Month in the Life of HED Staff and Management: Communication, Discussion, and Decision making meetings.

Date	Day	Staff	Team Leader	Branch Sr. Sci.	Branch Chief	DD/ADDs
1	Mon	1-3p IDT/DRT	10-11:30a Mgmt 1-3p IDT/DRT		10-11:30a Mgmt/Prioritize	10-11:30a Mgmt/Prioritize
2	Tue	11-12a (RA) Risk Assessment comm. *1-2 HED REDTeam*	11-12a RA comm. *1-2 HED REDTeam*	9-10a Intertech 11-12a RA comm.	11-12a RA comm.	9-10a Intertech 11-12a RA comm
3	Wed	9-10a Branch *10-12Cancer comm*	9-10a Branch	9-10a Branch *10-12Cancer comm*	9-10a Branch	12n TL Brn Bag
4	Thu	10-12a Hazard ID comm. 1-3p IDT/DRT	10-12a Hazard ID comm 1-3p IDT/DRT	10-12a Hazard ID comm.	9-11a Reg, SR, REDs Planning	
5	Fri					
8	Mon	1-3p IDT/DRT	10-11:30a Mgmt 1-3p IDT/DRT	*9-11a Registrant*	10-11:30a Mgmt/Prioritize	10-11:30a Mgmt/Prioritize
9	Tue	11-12a RA comm.	11-12a RA comm.	11-12a RA comm.	11-12a RA comm.	11-12a RA comm.
10	Wed	9-10a Parallel Br	9-10a Parallel Br	9-10a Parallel Br	9-10a Parallel Br	
11	Thu	10-12a Hazard ID comm. 1-3p IDT/DRT	10-12a Hazard ID comm. 1-3p IDT/DRT	10-12a Hazard ID comm.		
12	Fri					
15	Mon	*10-11a Metab com* 1-3p IDT/DRT	10-11:30a Mgmt 1-3p IDT/DRT	*10-11a Metabolism comm.*	10-11:30a Mgmt/Prioritize	10-11:30a Mgmt/Prioritize
16	Tue	11-12a RA comm.	11-12a RA comm.	9-10a Intertech 11-12a RA comm.	11-12a RA comm.	9-10a Intertech 11-12a RA comm.
17	Wed	9-10a Branch	9-10a Branch	9-10a Branch	9-10a Branch	
18	Thu	1-3p IDT/DRT 10-12a Hazard ID comm.	1-3p IDT/DRT	10-12a Hazard ID comm.		
19	Fri					
22	Mon	1-3p IDT/DRT	10-11:30a Mgmt 1-3p IDT/DRT		10-11:30a Mgmt/Prioritize	10-11:30a Mgmt/Prioritize
23	Tue	11-12a RA comm.	11-12a RA comm.	11-12a RA comm.	11-12a RA comm.	11-12a RA comm.
24	Wed	9-10a Parallel Br	9-10a Parallel Br	9-10a Parallel Br	9-10a Parallel Br	
25	Thu	1-3p IDT/DRT 10-12a Hazard ID comm.	1-3p IDT/DRT	10-12a Hazard ID comm.		
26	Fri					
29	Mon	1-3p IDT/DRT	10-11:30a Mgmt 1-3p IDT/DRT		10-11:30a Mgmt/Prioritize	10-11:30a Mgmt/Prioritize
30	Tue	11-12a RA comm.	11-12a RA comm.	9-10a Intertech 11-12a RA comm.	11-12a RA comm.	11-12a RA comm.
31	Wed	9-10a Branch	9-10a Branch	9-10a Branch	9-10a Branch	

Note: SARC meetings (other than Hazard ID Assessment Review Committee), quarterly meetings, and meetings with registrants, internal/external meetings not routinely scheduled on a monthly basis, are designated by *italics*.

JOINT PARALLEL BRANCH MEETINGS

COMMUNICATIONS FIGURE 1

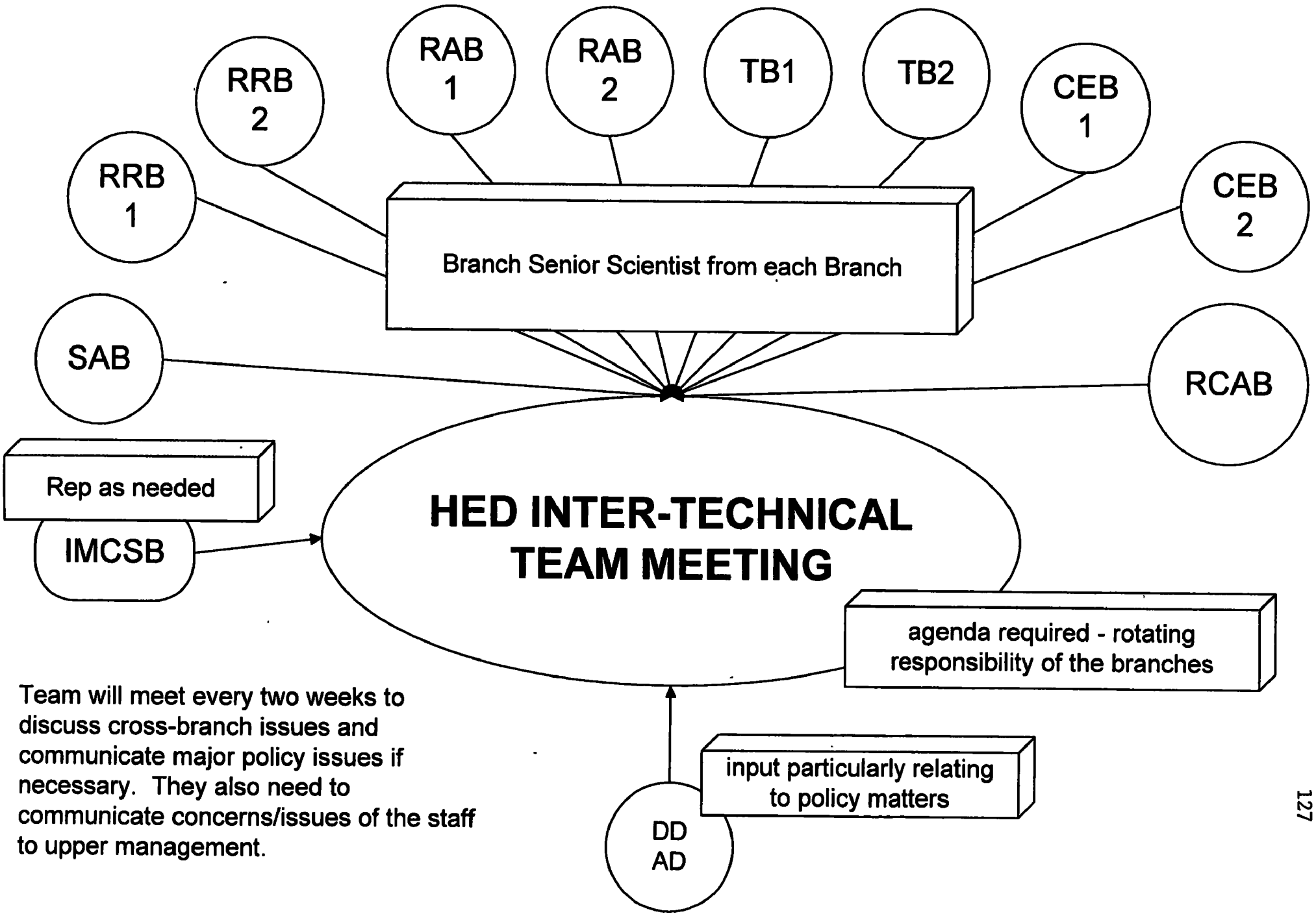


Characteristics - These joint meetings are for parallel branches, as noted above.

Purpose - Insure consistency between parallel branches and allow the Branch Senior Scientists (BSS) to discuss with the branch staff the technical and policy issues raised in the Inter-Technical Team Meetings. This also provides a forum for the branch staff to inform the BSS of issues that need to be elevated. To insure consistency between RCAB and the interdisciplinary branches, RCAB would need to be represented at the Joint B ranch Meetings.

HED INTER-TECHNICAL TEAM MEETING

COMMUNICATIONS FIGURE 2



Team will meet every two weeks to discuss cross-branch issues and communicate major policy issues if necessary. They also need to communicate concerns/issues of the staff to upper management.

X. PLANNING, GOALSETTING, BUDGET, WORK ASSIGNMENTS (Tracking, contract, admin work processes, and SOPs)

ABSTRACT

The purpose of planning is to enable our organization to move forward cohesively and be productive and efficient. It is essential that the plan we have in place sets goals and develops systems to ensure that strategic planning and budgeting occur in an organized manner. Planning needs to be proactive rather than reactive taking into account past history and allowing for contingencies and changing needs. HED staff at all levels as well as HED customers need to be involved in the planning process. In order to plan, HED needs a means to track its activities. **Two important tracking/scheduling systems in the new organization are: gatekeeper for all actions coming into and out of HED from other Divisions (i.e., RD and SRRD); and a central master scheduling system headed by the coordination decision team (consisting of the HED Branch Chiefs).** Effective contract management is also needed for the division to plan appropriately to handle its workload. In house contract management includes the Project Officer (PO, residing in IMCSB) and the Work Assignment Manager (WAM) (duties divided between administrative (residing in IMCSB) and technical (residing in the respective disciplinary branches)). Secondary review of contract deliverables and checking for quality assurance is performed by the person assigned to the chemical and is done in a timely fashion.

INTRODUCTION

The purpose of planning is to empower our organization to move forward cohesively and be productive and efficient. The plan needs to establish goals and establish a process that can proceed in an organized manner. In order to plan, HED needs a means to track its activities. Two important tracking/scheduling systems in the new organization are: the gatekeeper (for all actions coming into and out of HED from other Divisions), and a central master scheduling system. Effective contract management is also needed for the division to plan appropriately to handle its workload.

A. PLANNING

The purpose of planning is to enable our organization to move forward cohesively and be productive and efficient. It is essential that the plan we have in place sets goals and develops systems to ensure that strategic planning and budgeting occur in an organized manner. The planning process (short and long term) should be proactive instead of reactive thereby reducing "fire-fighting". More HED/customer negotiations; coordination with EFED, BEAD and other support divisions, RD and SRRD together, etc. is needed. Plans should be based on past history and they should include contingencies and flexibility for changing needs (i.e., new laws and policies, reorganization, crises, physical changes like renovations, and other disruptions of normal work and goals). HED Branch Chiefs and their customers must be involved in the planning process. The following information needs to be taken into consideration in order to develop fixed, realistic and shared goals.

1. The Plan supports HED's Design Drivers (as described earlier)

2. Annual Plan: Includes resources for training, travel, procurements, contract support, awards, etc.

   - TAIS data (and other historical data)
   - Performance Agreements
   - Award Planning
   - Work Plans (fiscal year only)
   - Contract Support

3. Long-term Planning

   - See annual
   - Guidelines/harmonization
   - Policy Development
   - FQPA
   - Congressional Projects (i.e., FIFRA)
   - Development - update and upgrade tools (i.e., Automated Data Processing (ADP) - systems)
   - Procedures: SOPs, SEPs, etc.

B. HED TRACKING/SCHEDULING SYSTEMS

The HED tracking/scheduling systems include the **gatekeeper** for all actions coming into and out of HED from other Divisions (i.e., RD and SRRD); and a **central Master Scheduling System**. The Design Team proposed a central Master Scheduling System for the Division which would: 1) aid in determining which chemical goes where based on the chemical distribution plan; 2) serve as the master division schedule for all actions and projects for registration, reregistration, special review and other projects and 3) include progress in the review process (i.e., when the chemical is scheduled for a SARC or SAP) and reasons for deviations from previous schedules. Data for this schedule would be supplied by the individual Branch Chiefs.

C. CONTRACT ADMINISTRATION

Contracts are used in HED to assist in fact-finding, preparations of the Data Evaluation Record (DER), Reregistration Eligibility Decision document, reorganizing and planning support, etc. The management of these contracts involves a series of roles.

These duties can be divided many ways to accommodate the role of contracting. Some roles, unmentioned (pre-award roles) are restricted to the Project Officer (PO) while other roles are restricted to the Work Assignment Manager (WAM). Two types of WAM are proposed; an Administrative WAM (AWAM) to handle the administrative matters and a

Scientific WAM (SWAM) to deal with technical aspects of the work assignments. The Project Officer (PO) is responsible for the contract. However, in conjunction with the PO and WAMs, the Information Management and Contract Support Branch (IMCSB) is responsible for budget negotiations, overseeing all Contracts, Grants, Co-op agreements, Inter Agency Agreements (IAGs), etc., including finding vehicles such as those mentioned to support new or old tasks performed by the Division. Secondary review of contract deliverables and checking for quality assurance is performed by the person assigned to the chemical and is done in a timely fashion. The process HED will use for contract administration is presented in figure 2. Detailed duties and responsibility of contract administration are as follows:

Project Officer (PO):

Each contract will have a PO (liaison between the Contract Officer (CO) and contractor) within the Division - located within the Branches. POs are legally responsible for contract administration. The PO is responsible for the following activities:

- Assure all SWAMs and AWAMs have been certified in Contracts Administration
- Follow-on Procurements or New Procurements:
  - Work with the CO, SWAM, AWAM and division management in the preparation and execution of the Request for Proposal (RFP).
  - Chairperson for the Technical Evaluation Panel (TEP) - This is the panel that grades and ranks contractor proposals received in response to the RFPs in the award process.
- Liaison between CO and Contractor - contractor administrator.

Scientific Work Assignment Manager (SWAM):

SWAMs will work with the Project Officers and the Administrative WAMs to administer HED extramural activities. One SWAM will be assigned to each contract in HED and is responsible for the following activities:

- Develop requirements, formats, guidelines, skill mix for Work Assignment/Task Orders to handle workload.
- Schedule priorities, establish/monitor due dates.
- Estimate technical hours for work assignments/task orders.
- Prepare requests, including data assembly, for processing by Administrative WAM (IMCSB) to and from contractor.

- Monitor work progress; give technical direction; identifying delays, determining needed changes and suspensions; and providing assistance whenever it is necessary for the completion and acceptance of the product or service.

- Assist in monthly voucher certification in conjunction with AWAM and PO.

Administrative Work Assignment Manager (AWAM):

AWAMs will work with the Project Officers and the Scientific WAMs to administer HED extramural activities. One AWAM assigned to the IMCSB will be responsible for the following activities:

- Processing of Work Assignment/Task Orders to and from the Contractors once requests, including the data assembly packages, are received from the SWAM.

- Develop and write purchase requests, including specifications and work statements.

- Budget tasks within funding levels of contracts in order to guarantee contract coverage in future months/years.

- Exercise options for follow-on years

- Develop controls (database, performance summary sheet, etc.).

- Develop specific project plans, including financial status.

- Monthly voucher certification in conjunction with SWAM and PO.

- Assist PO and SWAMs in fiscal year budget formulation and execution.

Characteristics of This System:

1. AWAM/PO handle all budget negotiations but, also shares other responsibilities with SWAM.

2. Technical direction given from the science branch - SWAM.

3. Fewer FTEs used - one AWAM per division to handle TOX, Occupational/Residential exposure, and CHEM - one SWAM per contract.

4. Total resource requirements used for contract management of the division - approximately three FTEs total; percentage of five FTEs and one full-time FTEs.

5. Responsibility for extramural support lies in IMCSB.

6. SWAM - Science branches are aware of chemical schedules.

7. Scientific Branch doesn't have the responsible of shipping and packaging of data.

8. Scientific Branch doesn't have the responsible for tracking burn rates or hourly rates.

9. Flexible - Team approach.

10. PO - one point of contact for the contracting officer, SWAM, AWAM.

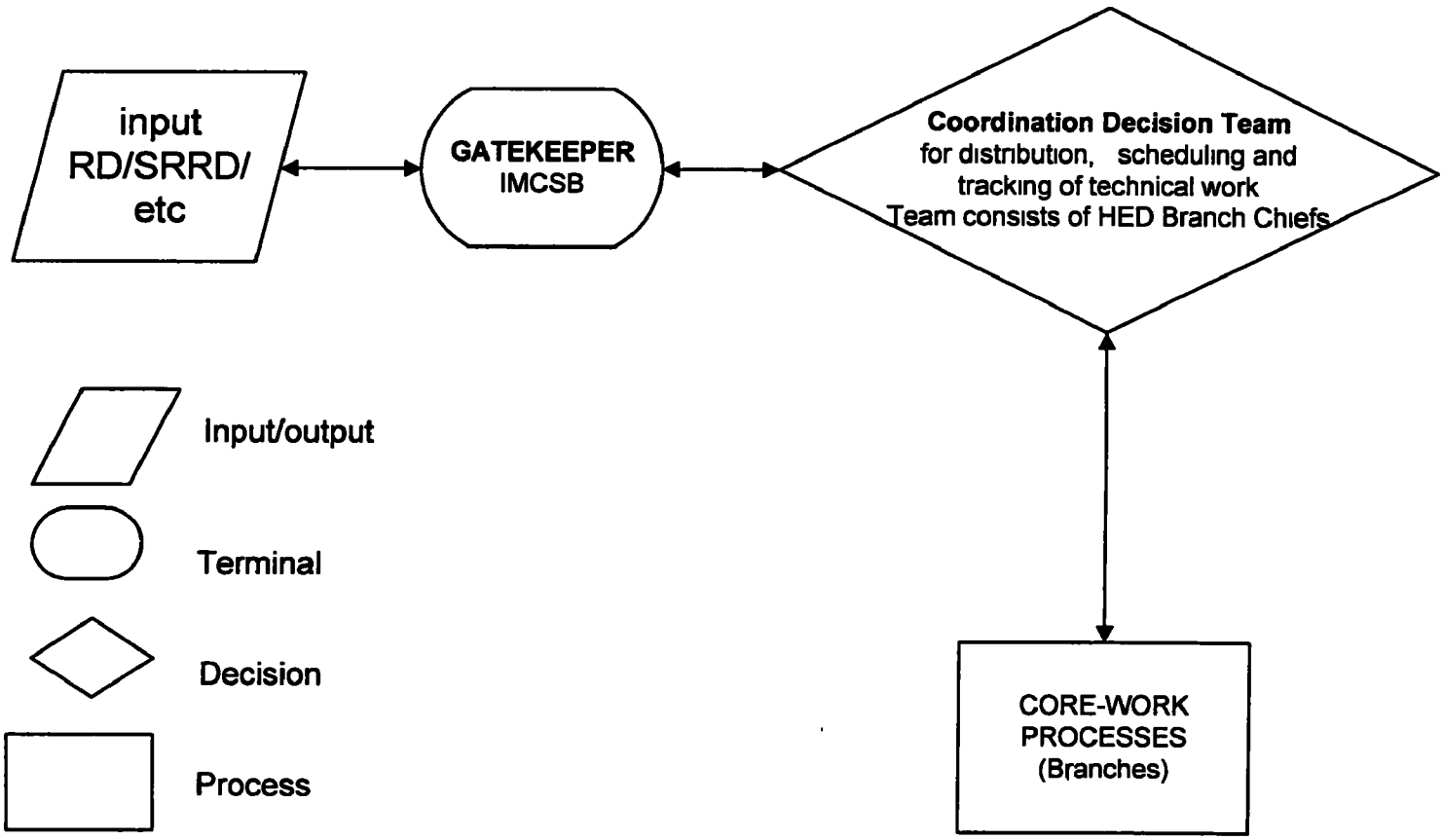
11. SWAM - one point of contact for the contractor/reviewer - science issues.

12. AWAM - one point of contact for the contractor/SWAM/reviewer - administrative issues.

HED MASTER SCHEDULING SYSTEM

PLANNING - Figure 1

PURPOSE OF COORDINATION FUNCTION: determine which chemical goes where based on chemical distribution plan; create the master division scheduling (includes Registration, Reregistration, Special Review and other actions/projects) and tracking of projects; schedule would include progress and reasons for deviations from previous schedule. (data supplied from the individual branches)

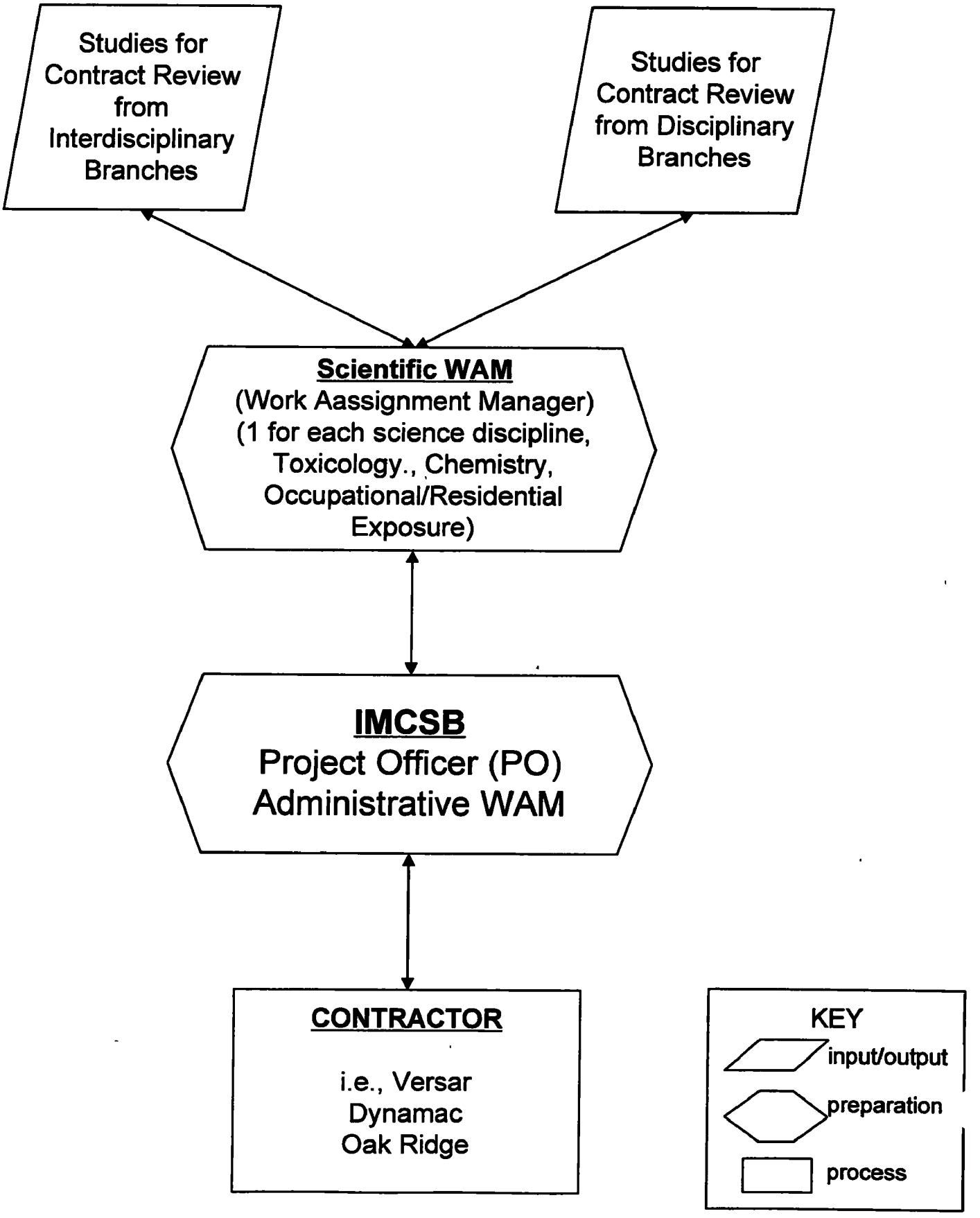


Characteristics of team

1. representation from all existing branches
2. shared coordination responsibility
3. consistency across division
4. interdisciplinary skill mix
5. central resource for location of chemical/project/action
6. customer appreciation of one central master schedule
7. flexibility
8. members are the Branch Chiefs from each branch

CONTRACT ADMINISTRATION WORKFLOW

PLANNING - Figure 2



XI. TOOLS AND TECHNOLOGY

ABSTRACT

The Design Team tried to capture the tools that HED currently have and identify those that we anticipate needing. We have recommended directions in which we think OPP/HED should go in developing tools. As risk assessments become more complex and interdisciplinary teams are implemented, it will be critical for HED to manage and share data to maintain consistency and scientific integrity. We considered a variety of topics including basic day-to-day tools used at the desk top level, procedures for filing and maintenance of data, standardization across the Division, Division-level project management tracking/scheduling systems and access of our customers to HED documents and decisions.

The Team's Major Recommendations to Management are: 1) Standardize data review formats across the Division, 2) Standardize fonts across the division, 3) Adopt new IRSD environments ASAP, 4) Make use of ADP tools part of CJEs, 5) Develop the Lotus Notes document repository project fully, 6) **Maintain key division data bases in the core disciplinary branches, i.e., CEBs for PHED, DRES, and NPRD, and TOXs for ISIS,** 7) Hire epidemiologists, statisticians, and data base experts, 8) HED should support strengthening of IRSD computer staff, 9) **Reviewers should be asked immediately to save all electronic data review records for future storage to LAN, 10) Hire one or more Division computer specialists,** 11) The Electronic Data Submission project should be prioritized and completed, 12) **SOPs are needed for all division processes,** and 13) Other recommendations are embedded in the document.

INTRODUCTION

The Design Team tried to capture the tools that we have and identify those that we anticipate needing. We have recommended directions in which we think OPP/HED should go in developing tools. As risk assessments become more complex and interdisciplinary teams are implemented, it will be critical for HED to manage and share data to maintain consistency and scientific integrity. We considered a variety of topics including basic day-to-day tools used at the desk top level, procedures for filing and maintenance of data, standardization across the division, and division-level project management tracking/scheduling systems.

A. TRACKING ACTIONS/SCHEDULING PROJECTS THROUGH HED

Action Tracking: Currently Pesticide Program Area (PPA) actions assigned to HED from RD/SRRD come into RCAB where they are logged into the PRATS system and distributed to the appropriate receiving Branches. The Information Resource Service Division of OPP (IRSD) has indicated the existing Pesticide Regulatory Action Tracking System (PRATS) system will continue without major modifications through FY97 and well into FY98 at which time PRATS, Chemical Review Management System (CRMS), and Pesticide Data Management System (PDMS) will be moved to ORACLE. **The new system should be developed with input from the client divisions, including HED. Someone within HED should be designated to work as a contact to IRSD for this project to ensure that actions entered are recoverable by many routes including Guideline, MRID, crop and use site, and PC code. The system should be designed in such a way that it acts as a review**

index as well as a tracking system. We recommend that IMCSB assume responsibility for logging RD and SRRD actions into PRATS.

Project Scheduling: HED needs an efficient way to monitor the progress of complex projects such as risk assessments for REDs, new chemical registrations, etc. and identify contact persons within HED. Because many elements of a health risk assessment are closely related and sequential, it is necessary to have a system whereby the events of the risk assessment process are known to staff and management. Fast turn-around projects such as Graybeards, Section 18s, and 24cs, may not need detailed process tracking at the Division level. Branch workloads also need to be monitored to maintain balanced distribution of work and to facilitate prioritization of work during the weekly HED prioritization meeting.

HED risk assessments and other projects could be monitored using off-the-shelf project management software. Possible software packages that have been identified include Manage Pro and MicroSoft Project. HED should select the most appropriate tool and develop a project scheduling system to be used by all branches. The internal scheduling across the division would then be consistent, and would eliminate redundancies, inadequacies and proliferation of branch lists. Further, such a tool would facilitate planning and scheduling future REDs, special reviews and registration actions. We recommend that **IMCSB maintain the HED project management scheduling system with input provided by the Branch Chiefs.**

B. RECORDS MANAGEMENT - DATA/INFORMATION ARCHIVAL

Documents that need to be filed include: science reviews, records of communication (phone calls), waivers, results of Graybeards, protocol reviews, congressional inquiries, policy documents, branch SOPs. The Design Team is recommending that Branches be required to write SOPs. For a detailed discussion on this subject refer to Chapter IX, *"COMMUNICATIONS AND DECISION MAKING"*. Other documents which are routinely needed by HED staff include policy documents and reference documents, such as guidelines.

1. Electronic

Currently, HED stores science reviews and other documents on DCOPP5\VOL1 in the T:Drive in WordPerfect. For the immediate future, this process should be continued. Reviews and other documents should be stored by discipline in the following HED subdirectories: POLICY, CHEM, TOX, OR (Occupational/Residential), SAB (external peer reviews), RA (Risk Assessments), and SOPs (see above recommendation). The date of the memo (or sign-off date) should be included in the electronic file. There are several ways to accomplish this. One would be to include the date electronically at the top of the memo, as was recommended by the Science Review Documentation Workgroup. Another way would be to include the sign-off date at the bottom of the memo as is currently done by TOX. Another way would be to include a concurrence line at the bottom of the memo as is currently done by Chemistry.

This LAN repository of documents will serve as a basis for future archival in Lotus Notes. An upgraded document archiving system is currently under development in Lotus Notes. The Lotus Notes archive will permit detailed indexing of studies, with the ability to automatically assess completed science reviews, and Science Analysis Review Committee (SARC) documents by guideline from a CRMS-like report. As such, it will partially automate the evaluation of existing data bases for chemicals in preparation for REDs and Tolerance Reassessment. It will also permit generation of a toxicology profile. Data currently being introduced into the MicroSoft Access one-liners system can be directly transferred into Lotus Notes to populate the indexing fields in the database. Consolidation of these systems will reduce redundancies in effort.

Information in the Lotus Notes data base will be accessible on the desktop for use by HED and our customers (RD, SRRD, EFED) who currently find it difficult to locate information on the T:Drive. (The current T:Drive files are searchable in WP6 by full text searching after an index is created.) Currently, the T:Drive is only accessible to those with rights to DCOPP5. Lotus Notes storage will also permit incorporation of older documents which are currently only available in paper or microfiche media. An SOP must be developed to determine whether a comprehensive set of documents has been imaged, or to identify those that are missing. IRSD has offered to help HED search through product jackets, PM files and other sources to locate missing documents. The Design Team has approached IRSD to evaluate the utility of the Canofile for imaging paper files for incorporation into Lotus Notes, if the TIFF files produced by the Canofile can be easily exported. Once imaged, text versions can be generated in a batch file by Optical Character Recognition (OCR) to permit future fuzzy text searching. This tool will be particularly useful in organizing data for future Common Mechanism and Aggregate Exposure assessments.

The Canofile should also be used to store office files, such as personnel records, procurements and large collections of documents held by reviewers. CD-ROM collections of policy documents could also be made available to new reviewers by this process.

Division-level gatekeeper(s) should be established for electronic filing of disciplinary science reviews and other documents. This task appears to be appropriate for IMCSB. Having a single entry point will help to ensure that documents are entered in a consistent manner. **An SOP for this process should be developed**. Until the backlog of information on the T:Drive is incorporated into Lotus Notes, the T:Drive and Lotus Notes should be maintained in parallel. By that time, the software and hardware needed for full implementation of the Lotus Notes archiving pilot should be available for all HED staff and the switch over can be completed.

To meet the FQPA directive that the Agency consider international harmonization on pesticide residues, it becomes more important to have access to data from CODEX, Canadian, and Mexican pesticide tolerance systems. IRSD has indicated there are plans to include CODEX Maximum Residue Limits (MRLs) in the **Tolerance Index System (TIS) system which is currently being redeveloped in Oracle.** This project was de-emphasized by the

OPP Office Director for FY97. **HED should indicate it as a priority for FY98, as this tool was indicated as needed in the divisional survey.** Reviews of CODEX are available within HED and should be scanned and made electronically available. In the interim, many MRLs and international tolerances are available on the Internet from Canada.

HED staff should be informed of information currently available on the LAN such as access to 40 CFR, 21 CFR, FR Notices and PR Notices in Lotus Notes and other information available through Agency LAN Services. A survey of what other information is available should be conducted and a list distributed to HED staff, with instructions on how to access the information. These instructions should continue to be available electronically.

The 6-digit PC code should be used for Chemical-specific files. The PC Code (also referred to as the Shaughnessy code) does not generally change. The common name may change during the course of development of the chemical. Use of Caswell numbers (also called the Tox Chem numbers) and Chemical Abstract Numbers (CAS) was discussed, but these numbers are less available and less well known by OPP Staff. An SOP addressing filing locations for chemical mixtures, and for chemicals such as 2,4-D which have multiple salts and esters, and for cross referencing chemical names to the PC Code must be developed. An alternate process will need to be identified to file inerts (possibly using some modification of the 9-digit code that RD currently uses), and for chemicals which do not yet have a PC Code, such as some unregistered chemicals.

Confidential Business Information (CBI) needs to be available to HED for product chemistry reviews. Because of issues relating to CBI, Agency memoranda containing CBI will have to be maintained on a stand-alone computer for the time being.

The policy directory needs to be maintained. This could be the responsibility of the Policy Steering Committee (PSC) who will have the major responsibility for policy development.

The DCOPP5\VOL1 U:Drive serves as team work space for shared products. It should be restructured to include files by discipline to mirror the T:Drive, to be used for filing completed reviews of unregistered chemicals (FIFRA sensitive, but not CBI information). The U: drive will also include needed team work areas, to be set up as needed by the teams. Since multiple branches may be working on a given chemical at any one time, "read" rights will be needed across branches.

2. Paper

Paper files should be centralized (in one central file room) and maintained by discipline. Consideration was given as to whether there should be one file per chemical (with all disciplines included) or one file per chemical filed under the discipline. The driving factor for the design team's recommendation was the difference in the degree of archiving which has already been done on the existing paper files in the different disciplines. The TOX files are

currently being microfiched. Some of the chemistry files are microfiched, but the microfiched copies are not complete. None of the OREB files have been microfiched. None of the RCAB (Risk Assessment) files have been microfiched. Considering the different amounts of archiving which have been done on the various files, it was felt that keeping the disciplines separate was best for the time being. As discussed above for electronic files, the files should be maintained by PC Code, with a cross-reference to the chemical name and CAS number maintained in the file room.

The special files, including the chemistry petition files, the cultural practices files currently maintained by chemistry, the AgCensus volumes currently kept in OREB, the literature references kept by OREB, and other similar files will need to be available to everyone. So these files will need to be kept in a central location.

One individual from each branch (perhaps an AARP) should be responsible for placing paper copies into the files. Steps should be taken to prevent removal of paper and fiche copies from the file room to safeguard against erosion of these files.

C. STANDARDIZATION OF TOOLS

1. Review Formats

Formats of data reviews should be standardized across the Division. This will be especially critical with the existence of disciplines in 6 or more branches. Standardized formats, and the use of the WordPerfect Document Summary, will help to ensure consistency in content and evaluation procedures across branches. It will reduce the possibility of missed issues or materials by reminding reviewers what information needs to be available in a review. This step should be readily accomplished by adopting the review templates currently used by HED contractor support. This can easily be accomplished using Templates for WP6.1.

Similarly, **a standard font should be adopted by HED.** This will reduce time wasted in rework by coordinators and risk assessors attempting to fold together documents developed by multiple reviewers, freeing up time to focus on production of the end product (risk assessment and characterization). The selection of a standard font should be done in conjunction with other divisions within OPP to ensure that a similar issue of reformatting does not occur between divisions.

2. Computer Hardware and Software

Software used within HED should be standardized. **HED should adopt IRSD's new environment as soon as possible.** This environment will consist of a Windows 3.1 platform, with upgrade to Windows '95 in the future. Software and hardware will soon be available to make this step feasible. This will prevent the need for generating multiple versions of documents to accommodate users of differing versions of WordPerfect or other software.

This problem exists not only internally, but also with our contractors who work in WP6.1 and have to convert backwards to be compatible with us. Lotus Notes should be available for all users to permit access to OPP, California and Canada Web sites. IRSD has obtained the hardware available to permit this upgrade once it is installed. The new OPP environment will contain Lotus 1,2,3 Version V, Visual dBASE, and WP6.1. Only a limited number of Visual dBASE licenses will be available, as this software is now only available through individual user licenses, and not as a site license. HED will need to determine how many licenses are actually needed. Excel will be needed to run Crystal Ball, but will not be available on the LAN.

HED should standardize on WordPerfect 6.1 and press SRRD to adopt WP 6.1 as the standard for final RED production to encourage standardization and upgrading across OPP. It should be noted that WP 6.1 is already the Agency Standard. Although many HED staff members are happy with the word processing capabilities of WordPerfect 5.1, including many members of the design team, the Agency Standard is WordPerfect 6.1, and any documents transmitted to the Assistant Administrator must be in WordPerfect 6.1. There will be a short learning curve to learn the new software, however, once HED staff see the capabilities of WordPerfect 6.1, they may be less reluctant to switch. These capabilities include:

- easier copying from one document to another and from other types of files, such as spreadsheets and databases; and the ability to have 9 documents open at the same time
- easier to share documents in different formats, such as Microsoft Word documents used by most of Corporate America.
- easier to switch from one program to another, as might be needed to check information needed for use in your document.
- additional features of the updated program

HED should identify **Project Management Software for HED project scheduling** as described above and make this software available to each Branch.

Immediate hardware needs that have been identified include access to CD ROMs and increased scanning capabilities. HED should follow the Agency's lead and standardize on IBM compatibles. This will reduce difficulties encountered in converting documents generated on diverse systems. In addition, where shortfalls on availability of adequate Pcs (i.e., **486s or Pentiums with at least 32 Mb RAM**) are identified, equipment **should be obtained**. Implementation of a number of suggestions in this document will not be possible if adequate hardware, training and management buy-in are not available to **all HED staff**.

D. OPP CRITICAL TOOLS NEEDS

Some of the tools identified as needed for improved efficiency and function are most appropriately dealt with at the office level rather than the division level or have multi divisional ramifications. Margaret should be encouraged to elevate the issues to the OD.

1. **Literature searching capabilities,** a possible IMCSB function, will be essential to implementation of FQPA to assist in obtaining non-guideline mechanistic data, epidemiological data and exposure data/information. Use of the Library of Congress InterAgency Agreement (IAG) held by both HED and EFED and divisional access to Dialog are currently available. However, OPP should have on staff, technical information specialists who are familiar with data bases and skilled in developing focussed, well designed searches. In addition, the results of literature searches should be saved and catalogued to prevent repetition of work. The team recommendation is to have one person in IMCSB conduct the literature searches. This recommendation does not preclude the possibility that some branches will have a large need for literature searching and have their own person available to conduct the searches. But to have 11 people trained to conduct literature searches, and then to have them do enough searches so that training isn't forgotten might be difficult.

2. **On-site library.** In the same vein, **OPP should have an on-site library.** We suspect that this need for reference materials and access to journals is shared by multiple divisions. OPP should take the initiative to establish an Office wide library to prevent redundancies that would occur if each division attempted to establish its own library. Space would also be saved if one centralized facility were developed rather than several small units. This, in conjunction with the literature searching capability appears to be a likely task to be assumed by Information Services Branch (ISB)/IRSD.

3. **Standard Vocabularies.** OPP should complete initiatives that were previously started to **standardize OPP vocabularies** and determine who will maintain theses vocabularies on the LAN. This step would help reduce the potential for ambiguities in the contents and applicability of regulatory actions and FR notices. It would be useful both to OPP staff and our regulated community. These vocabularies could then be placed on the OPP Web page as a service to our regulated communities.

Vocabularies which have been identified as needing standardization and for which work is currently underway are:

IRSD Chemical names - common names ANSI names
IRSD Use sites
HED Commodities, Raw Agricultural Commodities (RACs)

4. **On-line Scheduling for Projects.** Publication of Office wide scheduling on the LAN would be helpful in planning workload and allocating resources for all OPP divisions. Schedules that would be helpful include:

SRRD Tolerance reassessment schedule
SRRD RED schedules (SRRD should develop a tracking/scheduling system that can be accessed and customized by each successive group working on a RED)
RD Registration Action Priorities
Other projects which cross division lines
Internal Division or Branch Projects

The scheduling software should allow each branch to customize reports and add their own comments and dates.

5. Physical/Chemical Property Database. A database should be established and accessible on the LAN and on the Internet. The database should include the Physical and Chemical property data for Pesticide technical chemicals, organized by guideline number, along with a reference to the source of the data (MRID). The database is needed for HED and RD to ensure that data are available, to eliminate duplication of Product Chemistry reviews by RD and HED, and for Occupational and Residential Exposure assessments. The data are needed for EFED reference use, and for emergencies (spills, etc.).

6. Re-emphasis of the Electronic Data Submission projects should occur. Availability of data electronically would reduce the need for retyping of portions of study reports such as materials and methods, and prevent the need for re-keying data entries needed for incorporation into probabilistic analyses and other statistical assessments. Data (database or spreadsheet format) and reports (word processing or ASCII text files), along with summary tables (spreadsheet or word processing table format) should be available in an electronic format useful to OPP scientists. Use of some of the principles outlined in the Doherty proposal. For a detailed discussion on this subject refer to Chapter II, *"CORE WORK PROCESS - DATA REVIEW"* This proposal would be useful in implementing this step as long as those portions of text directly copied are labeled as such, and it is clearly stated that data evaluation will be conducted by OPP and not the registrants.

Electronic data submission is feasible, but the process for accepting electronic submissions is not completely worked out. Equipment for producing CD-ROMs if commercially available at reasonable cost (< $1000). OPP computers are expected to have CD-ROM drives in the near future, enabling the reviewers to read data submitted on CD-ROM. The electronic submission of data will not be mandatory, but rather encouraged. Some of the registrants will not have the capability to provide submissions on CD-ROM. The registrants have a number of concerns regarding the electronic submission of data, including their desire that the files they submit will not be changed, and the fact that most of the registrants use Microsoft Word and other Microsoft software, rather than WordPerfect. Submission by CD-ROM will provide unchangeable files. The exact formats for the submission will still need to be worked out. IRSD (PMSD) has been moving forward with a plan to implement the CADDY system for electronic submission, which is being developed for the European Community primarily to reduce paper. The CADDY format includes graphics files in the TIFF format for all of the pages of the submission. CADDY does allow

additional files to be included on the CD-ROM, but this portion of the system does not seem to be emphasized by IRSD. The emphasis seems to be on how to assign the MRID numbers to the submission so that the files are named by MRID number as has being done by PMSD since June 1996 when they stopped microfiching the submissions and began putting them on CD-ROM.

7. Other Database Needs. Electronic databases should be available to all division staff who need them. If additional databases are identified to which HED staff need access, the Division Computer Specialist and the Branch Chief should be informed, so that the need for the database can be evaluated and prioritized.

8. Toll-Free telephone access to the LAN and Voice Mail. Toll-free telephone numbers should be established for voice mail and ONLAN to accommodate employees that occasionally or routinely work from home or other flexiplace locations or need access while on travel. An alternative would be telephone credit cards issued to employees much like the American Express cards issued for travel.

E. RISK ASSESSMENT TOOLS

As part of its activities, the Design Team attempted to catalog those tools which currently reside in HED (or are imminent). SOPs are needed for the use of these tools which are listed below. SOPs are also needed for all parts of the Risk Assessment process.

1. Hazard Assessment Tools

- SAR - ISIS (this is a likely tool to serve as a repository for initial and final decisions about chemical groupings for tolerance reassessment (TRA)). Structures in appropriate electronic format should be provided by the registrants.
- TOX 1-liner data base in MicroSoft Access

2. Dietary Exposure Assessment Tools

- DRES. The DRES database will be updated and maintained by Chemistry and Exposure Branch I. Individual assessments by DRES will be conducted in the six branches performing exposure assessments. It will be their responsibility to forward the results and the resulting chemical specific data files to CEB I. The design team recommends that the Branches conducting exposure assessments assign two people in their branch to perform the DRES analyses. This recommendation is based on the experiences of the PIRAT team, who found that a certain amount of proficiency was required to perform the analyses accurately and efficiently. DRES has a number of intricacies which require practice to maintain. An SOP is needed for conducting DRES analyses, and for capturing and archiving the resulting data files.
- DRES runs - capture to dBase III files

- EFED surface and drinking water raw data
- NPRD National Pesticide Residue Database: FDA/USDA/State Monitoring Data are currently available and used within. These data are intended to be introduced into the NPRD when it is funded, to simplify searching of the monitoring databases. Data base experts will be needed to design the data base and assist in its use.

3. Occupational/Residential Exposure Assessment Tools

Physical/Chemical Properties (other than EFGWB 1-liners)

Several Occupational/Residential exposure tools which are unique to this discipline consist of data sources designed to provide epidemiologic data. Those currently used consist of Poisoning Incident Databases. They are:

- Incident Data System includes 6a2 reports from registrants and voluntary reports from the public. On the LAN.

- National Pesticide Telecommunications Network contains voluntary reports from the Public. This is maintained for EPA by Oregon State University.

- California Pesticide Illness Surveillance Program which generates for EPA tailored reports for REDs and Special Reviews. This may be available on the Internet. California is one of (now) 12 states requiring doctors to report illnesses caused by pesticides. However only reports from CA and WA states are reliable.

- American Association of Poison Control Centers generates reports based on 100,000 exposures per year. Currently generating a report for chlorpyrifos.

- NIOSH and potentially the National Center for Environmental Health are developing with EPA, individual state program for pesticide incident monitoring.

<u>Other Occupational/Residential tools anticipated to be used in the future are:</u>

- National Electronic Injury Surveillance System which will generate statistical samples of emergency room incidents to be run by the US Consumer Product Safety Commission.

- National Hospital Discharge Center will generate statistical samples of incidents will be run by the National Center for Health Statistics.

- Pesticide Handlers Exposure Data base (PHED) 2.0 will be completed by (best case) year end. Work to do includes QC/QA of data entry (not done in original) plus addition of 5 - 6 new studies. Comparison of the results from versions 1.1 to 2.0 will be needed to validate version 2.0. New manuals will be needed.

The PHED database will be maintained by Chemistry and Exposure Branch II. Individual PHED assessments will be conducted in the six branches performing exposure assessments. It will be the responsibility of each branch to forward copies of all PHED assessments to CEB II so that consistent PHED records can be maintained. It is recommended that the Branches conducting exposure assessments assign two people to perform PHED analyses. This recommendation is based on the experiences of the PIRAT, who found that proficiency was required to perform the analyses accurately and efficiently. PHED has a number of intricacies which requires practice to maintain. An SOP for conducting PHED analyses does exist but should be more detailed for ease of use in the new organization. A detailed SOP will be essential in maintaining accuracy and consistency in exposure assessments among the branches. Insuring this consistency will be the responsibility of the PHED staff in CEB II.

The Agency relies heavily on this database to conduct occupational exposure assessments for REDS, Section 18s, 24Cs, and Section 3 actions. It is recommended that the PHED surrogate exposure guide be one of the tools used in estimating exposure for REDS, Section 18s, and 24Cs. These actions require either a significant quantity of PHED analyses (as in the RED process) or are of a rapid turnaround nature (Section 18s, 24cs). The surrogate exposure guide provides the PHED user with **basic** exposure estimates for pesticide handler scenarios. Each exposure estimate is accompanied by the applicable PHED run and references the field studies the runs are based on. It is essential that users of this table be familiar with these runs and additionally consult the individual studies used in each handler scenario. The use of this table will result in more timely, consistent and defensible assessments. The guide **should not** be used for Section 3's as a more refined/custom run is recommended. Development of these customized runs will require a high degree of proficiency with the database in order to insure accurate results.

It is additionally recommended that CEB2 develop two PHED managers, one emphasizing the internal responsibilities of the database while the other accommodate the external needs associated with the project. Both PHED managers should be proficient in each area in order to effectively QC/QA each others work and provide back-up when one leaves the Division or goes on vacation. Internal database responsibilities include: 1) maintenance of PHED consistency within the Agency through the chairing of workgroups, individual contact, and maintenance of PHED records, 2) assessment of registrant PHED submissions, and 3) providing guidance and training both within and outside of the Agency. External database responsibilities include: 1) interfacing with the PHED Task Force consisting of representatives of Cal-EPA, Health Canada, industry, and increasingly OECD, 2) extensive QC/QA of the new DRAFT version (PHED 2.0), 3) generation of reference manuals, 4) encouragement of new study submission to the database and 5) addressing NAFTA issues.

Reentry Databases to be developed by the Agricultural Reentry Task Force (ARTF) members may be similar to PHED. This database will be only available to Cal EPA, Health Canada, EPA, and members of ARTF. This is a data compensation issue. The

data base will consist of generic transfer factors representing worker reentry exposure, to be cited by members only. The database to be developed by the Outdoor Residential Exposure Task Force (ORETF), will include Lawn Care Operator (LCO) and Homeowner mixer/loader/applicator exposure (similar to PHED) and transfer factors for various exposure patters (like kid on lawns). This is for residential turfgrass applications only, not indoors.

4. **Risk Assessment Tools**

Crystal Ball, @Risk - tools for probabilistic analyses

5. **Analytical Tools** that will be necessary to analyze the contents of these data bases are:

- Microsoft's ACCESS
- dBase III (soon, dBase V)
- Systat and EPIinfo, these generate plots, graphs etc.
- Grateful Med to perform literature searches on Medline, Toxline, and others.
- Center for Disease Control (CDC) Wonder for accessing CDC experts and has national statistics for deaths due to pesticides.
- CDC EPIMAP which is a statistical program for mapping health indicators.
- SAS

F. TRANSITION RECOMMENDATIONS (summary of major recommendations from above)

A number of steps have been identified that will help with the transition to the new HED environment. **Branches should be directed to clean up PRATS prior to reassignments.** IRSD plans to do blanket transfers to reassign work as needed. However, logging out all old, completed actions and actions never received in HED will reduce the burden and increase efficiency.

1. **An SOP is needed to capture older electronic files from reviewers.** These older files can be directly entered into the electronic data bases but should be flagged to indicate that they have not been through the gate keeper.

2. **Reviewers should be encouraged NOT to destroy or discard their electronic or paper files** - these may be the only existing records for those actions..

3. **An SOP is needed to identify missing documents**, by comparing lists of documents which should exist with those that do exist, for both paper and electronic documents.

4. **The Branch Chiefs should** meet to devise a method for tracking/scheduling projects while the master scheduling system is being developed.

G. RECOMMENDATIONS TO MANAGEMENT (summary of major recommendations from above)

1. **Standardize data review formats.** This will make electronic data filing easier and prevent reduce likelihood of omissions because of systematic reporting of results and facilitate training of new staff and ensuring consistency between branches.

2. **Standardize fonts across the division.** This will reduce the time required to integrate hazard and exposure assessments into a risk assessment and free staff to focus more on the production of risk assessments. This should be coordinated with RD and SRRD. If the Office chooses a standard font, then this font should be used in the Division.

3. **Adopt new IRSD environments ASAP.** This step will make tools more accessible to staff, enhance standardization with other parts of the Agency, and allow HED staff to use new features provided by software they develop. It will also facilitate communication with other agencies and allow access to Agency Web pages and the information available by that route.

4. **Make use of ADP tools part of CJEs.** Communication with staff will be enhanced. Prioritizing work and scheduling meetings will be easier if all staff use CaLANdar and cc:Mail, at minimum.

5. **Develop the Lotus Notes document repository project fully.** With spreading of disciplines across 6 branches at minimum, sharing of information and organization of data will become increasingly important. In order to ensure consistency and completeness and timeliness of reviews/risk assessment products by different organizations, it will be essential to have access to existing data reviews, and other risk assessments which have been conducted on a single chemical. In addition, this tool will permit HED and our lead divisions to readily assess the status of reviews for staging of future REDs and Tolerance Reassessment activities.

6. **Data base maintenance.** Data bases which are key to preparing risk assessments (PHED, DRES, ISIS, NPRD) will require maintenance, development and enhancement. The most likely places to do this are the core disciplinary branches, i.e., **CEBs for PHED, DRES and NPRD; and TOXs for ISIS.**

7. **Hire epidemiologists, statisticians, and data base experts.** As risk assessments become more complex (e.g., introduction of probabilistic analyses, use of diverse data bases with varying designs), it will be essential to increase the sophistication of the staff available to generate internal assessments and review those submitted by the regulated community. HED needs additional staff with expertise to produce or evaluate statistically complex risk assessments, and to evaluate epidemiological data.

8. HED should support strengthening of IRSD computer staff. HED will be making increasing demands upon this staff to provide resources and technical support. The existence of adequate, technically competent IRSD staff will be critical to efficient functioning of HED in a highly automated environment.

9. Reviewers should be asked immediately to save all data review records for future storage to LAN. In some instances, no formal copy of a review exists. In others, access to electronic copies will save time and money in data entry. These material may be lost in the upcoming reorganization if steps are not immediately taken to preserve them.

10. If IRSD develops an application for HED, and the maintenance is left to HED, we will need a **computer specialist** to maintain the data base and serve as a **liaison to IRSD and contractor support.** This may not be a full time effort, but will need someone who is computer literate.

11. The Electronic Data Submission project should be prioritized and completed to allow introduction of the greater efficiencies that it will introduce into the review process.

12. SOPs are needed for all processes, including:

- DERs and Data Reviews
- Graybeard, including tracking and write-up. Some graybeards currently come through PRATS, while others don't.
- Waivers
- Protocols
- Phone calls, including when a write-up is needed and the format to be used
- All Science Assessment Review Committee documents (formerly called Peer Review)
- Gatekeeping, including paper and electronic filing.

13. Other recommendations are embedded in the sections above. **These should also be adopted.**

XII. CULTURE

ABSTRACT

Culture establishes the norms of an organization and is reflected in its people's behavior. An organization's culture is complex and is based on shared assumptions and beliefs of the people within an organization. Significant changes in HED's organizational culture is needed since the Division is altering its structure towards a flattened organization. Core values, people's attitudes and behavior are critical factors shaping the culture of an organization. These core values include: team work, mutual respect and trust, empowerment and involvement as well as taking responsibility for actions. Also included are consideration of customer orientation, balancing HED goals with customers' needs, free flow of ideas and information as well as cooperation across the organizational unit's boundaries. The culture should provide for an open process, and push down decisions to the lowest possible level of the organization. Strategies to implement cultural changes include, the development of standards for conduct of business, management buy in and leading by example, encouraging peers to display positive behaviors and training and rewarding staff for those championing positive conduct in line with HED's core values

INTRODUCTION

Culture is the norms of an organization; in other words the "way we do business in an organization". An organization's culture is complex and is based on shared assumptions and beliefs of the people within an organization; these assumptions and beliefs are sometimes taken for granted. An organization's culture is reflected in people's behavior and is also a product of group experience in a defined group (organization) with some history.

The current culture of HED is very hierarchical. Clear divisions in the organization are evident along disciplinary lines. Little interaction occurs across branch boundaries. Information flow down the organization chain of command is limited and spotty, leading to feelings of isolation and disenfranchisement by the staff. Decision-making is very heavily invested in the current branch chief and division director levels. Interactions with our customers have been erratic, and often confrontational, leaving neither side feeling that they have been adequately served. As part of its reinvention process, the Design Team has identified cultural changes that will be needed to implement the new team structure in a flattened organization.

A. CORE VALUES, PEOPLE'S ATTITUDES AND BEHAVIOR

The **core values, people's attitudes and behavior** shape the culture of an organization. The design as presented here will help HED move toward a new organizational culture and cultural awareness. Alteration into a new structure will be completely implemented **ONLY IF** there is a modification of people's behavior and attitudes. We have identified the following major core values, attitudes and behaviors as the goals toward which the new HED should be moving:

1. **Team work** should be the basic building block of the new HED.

2. All HED staff and management should accord each other **mutual respect** regardless of role/position. This attitude should be practiced in HED and when interacting with people of other Agency offices.

3. Staff should be **empowered and involved** whenever appropriate, in all levels of processes and decision-making.

4. Staff and management should be **accountable and responsible** for their decisions and actions.

5. HED should develop a **customer orientation**, bearing in mind that customers may be internal (HED), external (other Agency units), or ultimately outside EPA.

6. HED's **goals and needs should be balanced** with those of our external customers. HED should develop a partnership with our sister divisions, seeking to find ways to optimize attainment of OPP long-term goals. Achieving a balance between the interests of HED and our sister divisions will benefit both parties in the long term.

7. **Broad organizational goals** should take precedence over personal or an individual organizational unit gain. HED should strive to balance high levels of personal performance and recognition with divisional performance.

8. Interbranch projects should **not** be **limited by the lines on the organizational chart**. Staff with unique talents should be made available within the constraints of their work load to participated in actions and projects which are centered in other branches. This will help to optimize the use of HED resources (i.e., staff) and encourage team spirit across the Division. Staff should be encouraged to take the initiative to solve problems and find ways to enhance and use their skills, while assuming responsibility for completing their assigned tasks.

9. HED business should be conducted as an **open process**. This will allow a greater level of acceptance and buy-in of decisions.

10. **Decisions** should be made at the lowest possible level of the organization.

B. CHANGE IN BEHAVIOR

The major focus of improving organizational culture is a **change in behavior**, both at an individual and organizational level. This will be accomplished by addressing organizational culture through the use of the design drivers for HED as listed below.

1. **Communication**
- Encourage feedback from management, staff and customers to address continuous renewal and improvement.
- Support training for working and interacting as a team.

2. **Maintenance and enhancement of scientific disciplines and excellence**
- Encourage mutual respect among staff at all levels.
- Do not optimize personal gain at expense of organizational gain.
- Create environment of accountability and responsibility.
- Outputs should be useful for regulatory decisions.

3. **Staff empowerment**
- Encourage interbranch interaction and activity.
- Create an environment of team work.
- Keep staff participating in regulatory decision making process.
- Allow people to talk and express their comments and views.
- Maintain high level of professional behavior; develop standard of conduct. This will allow encouragement of staff at all levels and interaction at a team level. In addition seek to reduce negative behavior that could impede the team's ability to functions.
- Every decision does not require a meeting.
- Create an environment of flexibility with other branches in HED.
- Interbranch cooperation and sharing of staff should be encouraged (ability to work/interact beyond individual branches to meet needs of task).

4. **HED goals/purpose linked to OPP mission**
- Think of OPP not as a small unit but as a larger organization.

5. **Management/leadership**
- Management must enforce and support behavior to make sure these new cultural practices are implemented.
- Make sure people work with a group and product is completed.
- Performance review: create greater external review during performance review process; make sure implementation of cultural values are part of performance appraisal.
- Implement cultural change by rewarding for implementation of design drivers and appropriate behavior.
- Maintain core values from management and peers.
- Develop process for rewarding the team.
- Branch Chief should act more as a facilitator compared to a manager

6. **Customer relationship**
- The organization should have a customer orientation (internal, external and public).

C. CULTURAL CHANGE

Cultural change will require encouragement if it is to occur. A number of steps can be taken to help ensure that HED staff and management move in the direction of an organization exhibiting the **basic core values, behaviors and design drivers** as listed above. Those steps considered most critical to a successful cultural change in the new HED are:

1. **Develop ground rules for conduct of business.** A basic set of ground rules will establish standards for profession behavior which may enhance in uniting members of teams. Common courtesy toward other HED and OPP staff should be the goal. The standards should encourage behaviors which demonstrate respect for individuals and their sensibilities. They may also encourage more complete participation of the more reticent individuals by allowing them to feel more comfortable in a group setting, and demonstrating that their ideas are both wanted and valued.

2. **Management** must adopt the core values plus behavioral ground rules and **lead by example.**

3. Individuals reflecting the core values in their work practices should be **recognized and rewarded.**

4. The ground rules should be **displayed, reinforced and continually evaluated for appropriateness.**

5. Staff should discourage their peers from exhibiting inappropriate behaviors in their coworkers as they arise and remind them of the core values and ground rules, thereby applying **peer pressure** to enable and maintain cultural change

6. **Training on working in a team environment, facilitation and conflict resolution** should be provided to the staff to provide them with valuable tools that will be needed to successfully adapt to the new work environment.

7. **All opinions should be recognized and considered,** regardless of rank or position. Decisions will be made by appropriate team members in the context of the task and situation.

APPENDIX A. SUMMARY OF BOUNDARIES DISCUSSION

ABSTRACT

The HED Design Team discussed boundaries in the current organization of HED as viewed by HED staff, our division's management, RD, and SRRD as well as what was in a "Customer Survey Summary" which was prepared by the Implementation Team. The discussions focused on where each boundary should be and what the relationships are between HED and its customers at the boundaries. The HED Design Team determined that boundaries are generally established by roles (risk assessment/risk management, expertise/job skills, disciplinary/interdisciplinary, etc), resources (allocation and coordination), and policy (science policy/legal mandates).

The boundary established by roles is generally in the right place, and everyone is responsible for maintaining it. However, HED/customer relationships associated with the roles boundary need improvement because of perceived mutual distrust, lack of shared goals, and the absence of a shared understanding of the workload. The Design Team concluded that relationships could be improved by involving HED staff/customer staff in resolving technical issues with less involvement of managers, clarifying risk assessment and risk management roles, better communication, involving customer staff as observers in HED processes, increasing participation of HED staff in customer-requested meetings, and encouraging timeliness, consistency, flexibility, and clarity in HED responses to customer requests.

The resource boundary consists of scheduling, prioritization, staffing, facilities and budget, and the Division Directors must agree on resolving issues in these areas with staff involvement. Although there have been recent improvements, the HED/customer relationships associated with this boundary could be improved further by coordination of tracking and certain information systems (e.g., CRMS, PDMS, PRATS, LUIS, etc.). Relationships could also be improved by better integration of tracking between customers as well as between HED and other risk assessment divisions (EFED, BPPD, AD, etc.), broadening the support capabilities of information systems to suit customers and HED's needs, HED and customers use the same scheduling and prioritizing systems, and increased use of compromise when resources are limited.

The policy boundary is the least clearly defined of the three boundaries and it was considered with respect to constraints on the time available to complete certain tasks (e.g., statutory due dates). Again, better communication between HED and other divisions regarding policy issues was mentioned as a suggested improvement in relationships associated with this boundary. Other recommendations for improving relationships at the policy boundary included: all the divisions in OPP should work together on policies associated with FQPA, and there is a need for training on how each person's job fits into the overall mission of OPP.

INTRODUCTION

The Design Team was divided into subgroups to consider boundaries in the current organization of HED as viewed by HED staff, our division's management, RD, and SRRD. These points of view are also indicated in a document entitled "Customer Survey Summary" which was previously prepared by the Implementation Team.

In describing the boundaries indicated by the four perspectives, each subgroup addressed the following:

- Are the current boundaries in the right place?
  - If not, should they be changed, and
  - Why?

- Characterize HED/customer relationships.
  - What should the relationship be?
  - Who should work out the relationships, and
  - WHY?

Although the discussions within each subgroup were more specific, this is a summary of the main ideas as presented on flip charts during the February 12 discussions with details from the Customer Survey document as appropriate. The four subgroups identified the following general boundaries:

- Roles (risk assessment/risk management, expertise/job skills, disciplinary/interdisciplinary, etc)
- Resources (allocation and coordination)
- Policy (science policy and legal mandates such as FQPA)

A. ROLES

The HED management, RD and SRRD subgroups concluded that the boundary defined by risk assessment/risk management roles is in the right place, i.e., HED assesses risk and RD and SRRD manage risk. Responsibilities in these roles were divided as follows:

- risk managers provide information needed for risk assessments

- HED staff or teams review information provided by risk managers and conduct risk assessments

- risk managers use HED assessments to support their decisions

The HED/customer relationship, according to the SRRD subgroup needs improvement because of mutual distrust, lack of common goals (e.g., "Make the risk go away!" vs. conservative risk assessments), and the absence of a shared understanding of the workload ($RED_a \neq RED_b \neq ...$, x FTEs do not include x RED rebuttals + mitigation work).

The HED management, RD and SRRD subgroups agreed that overall HED/customer relationships could be improved if:

(1) risk managers provided timely delivery of complete information packages for assessment,

(2) the staff has sufficient information and expertise to explain HED assessments,

(3) there are clear definition of the roles and responsibilities in risk assessment and risk management (rules) (also includes relationships with other divisions assessing risk such as EFED, BPPD, and AD), and risk managers do not attempt to circumvent or intrude on the risk assessment process, and

(4) HED assessments (i.e., REDs for reregistration, tolerance recommendations for registration, and special reviews) are accepted as delivered with the understanding that they may be limited by the information provided up front and/or the time allowed for completion of the assessment.

The customer survey pointed out:

- some parts of HED are flexible and quick to respond (e.g., Chemistry, PIRAT, etc.), while other parts of the division require debate of issues (e.g., Toxicology, certain Peer Review Committees, etc.).

- issues should be resolved more frequently at the staff level since management is usually not familiar enough with the issues to resolve technical problems effectively.

- the concept of "chemical ownership" is a means of effective service and communication is valued highly by HED's customers.

- HED's customers must understand enough of the science to explain HED's conclusions to interested parties, especially those with limited technical or non-technical backgrounds.

The customer survey indicated what is expected by customers in HED's products as well as specific suggestions on improving the existing HED/customer relationships. With regard to HED's products, the survey suggested the following:

(1) Each review should begin with an executive summary of the data under consideration including the following:

- clear explanations for scientific conclusions;

- a list of issues addressed by the review (i.e., bottom lines);

- a clear statement about whether testing guidelines have been satisfied;

- lists of technical deficiencies and ways unacceptable studies can be upgraded to satisfy guidelines; and

- a clear explanation for accepting a study that does not fully satisfy testing guidelines but is used to support a scientific conclusion;

With regard to process and services in HED, the survey recommended:

- Involve customers' staff as observers in Peer Review Committee meetings (NOTE: the proposed design refers to these as Science Assessment Review Committees) dealing with their chemicals.

- HED staff should take time to participate in RED team meetings

- comprehensive literature reviews are needed prior to completion of HED risk assessments to prepare for rebuttals.

- standard formats for data reviews, hazard and exposure assessments, risk characterizations, risk assessments, and cover letters that would fit customer needs with little or no reworking. These formats would make information easier to find for everyone.

- explanations of the logic for selection of endpoints, RfDs, cancer classification, etc.

- explain the assumptions and logic used for exposure estimates selected to support risk characterizations. The standardized worker exposure assessment in RED chapters does not always provide enough insight.

- More communication before the HED products are completed (i.e., studies should be reviewed to better anticipate a need for more information before a risk assessment is started, risk mitigation options should be considered before a risk assessment is considered complete, etc.).

B. RESOURCES

From the division management perspective, the resource boundary consists of scheduling, prioritization, staffing and budget. The staff may have some input, but the Division Directors must agree on resolving issues in these four areas. The HED/customer relationship could be improved if planning is more realistic and less reactive.

The RD subgroup and the customer survey noted recent improvements in the HED/customer relationship (e.g., PIRAT, and "graybeard" committee). However, problems with work flow were raised (i.e., chemical ownership, proper routing of work to the right people, and customer competition for priorities).

The HED staff perspective indicated that the resource boundary is not always in the right place, especially in the following areas:

- Information resources (CRMS ≠ PDMS ≠ PRAT; access is in the wrong place, i.e., RD/SRRD → PDMS → HED/EFED)

- Scheduling (good when SRRD/RD and HED [RCAB] use the same centralized system)

- Expertise and job skills (there is not enough staff for the amount and type of workload)

- Management/staff relations (management support is uneven, accountability is misplaced, responsibilities are not clearly defined, empowerment?)

- Administrative support (excellent but limited)

The staff subgroup suggested the following improvements to HED/customer relationships at the resources boundary:

- Better input from science needs, CMRS, PDMS, and PRAT systems should be linked, and access/input should be changed from RD/SRRD → PDMS → HED/EFED to RD/SRRD ↔ PDMS ↔ HED/EFED.

- Make sure RD, SRRD, and HED are suing the same centralized system for scheduling and prioritization, improve electronic tracking programs.

- Learn to say "no" (propose alternatives) and accept "no" (compromise).

- Increase administrative support (contracts, systems, budget, personnel).

The HED staff subgroup concluded that implementing these suggestions would improve staff morale and efficiency and reduce the backlog of work in the division.

The following comments were made in the customer survey regarding HED's handling of priorities:

- need firm commitments to dates for a final review, even if it is in the distant future, (There are an unnecessary number of postponements right now.)

- coordinate Peer Review process (see note earlier in this section) with respect to completion dates for reviews.

- synchronize HED's project tracking/scheduling systems with those of the customer (e.g., CRMS, PRAT, etc.)

- limited resources and current priority system interferes with resolution of post-RED issues.

- a point person to contact for a quick response to a question on a review or an explanation for why an upcoming due date will be missed without sending it through a formal tracking system.

- HED does not respond well to actions on safer chemicals, Special Reviews, minor uses, protocol questions, correspondences, and other short miscellaneous actions because its workload is dominated by reregistration activity.

C. POLICY

The HED management subgroup considered this boundary briefly, but there was only a mention of the relationship between HED and EFED regarding drinking water standards. The RD subgroup mentioned legal constraints on the time available to complete certain tasks (statutory due dates on Section 18s, tolerances, etc.). Again, there was little comment other than to suggest better communication between HED and RD regarding those issues.

The customer survey included the following points about policy issues:

- need to integrate drinking water assessments with groundwater and surface water assessments of EFED.

- should be working on FQPA issues together with other divisions in OPP.

- If OREB identifies a high exposure earlier in the registration or reregistration process, the registrant would have time to develop data and/or meet with OREB prior to registration.

- There needs to be overall training done on the "big picture." Where does each person's job fit into the big picture.

APPENDIX B. GLOSSARY

6a2	Adverse data on a pesticide, which are required to be reported to EPA under Section 6(a)(2) of FIFRA.
AARP	Contract Staff hired through the American Association of Retired Persons. Primarily clerical staff are hired.
Access	A relational database program produced by Microsoft.
ACS	American Chemical Society, a professional society for chemists and chemical engineers
Action Tracking	Tracking of work assignments
AD	Antimicrobials Division of OPP
ADD	Associate Division Director.
ADP	Automated Data Processing (computer equipment)
ai	Pesticide Active Ingredient
ARTF	Agricultural Reentry Task Force, which is producing reentry data for use in occupational exposure assessments.
ASCII	American National Standard Code for Information Interchange. DOS text.
ATSDR	Agency for toxic Substances and Disease Registry
AWAM	Administrative Work Assignment Manager for Contract. Forwards and accepts work assignments to/from contractor. Handles administrative details of the contract.
BC	Branch Chief
Bean sheet	A work assignment order, currently produced by the PRATS System
BPPD	Biological and Pollution Prevention Division of OPP
BSS	Branch Senior Scientist

CaLANdar	Calendar scheduling program used on the LAN.
Canofile	A proprietary database system which scans documents into TIFF format and catalogs the documents.
CBI	Confidential Business Information.
cc:Mail	e-mail program used on the LAN
CCPR	CODEX Committee on Pesticide Residues
CD-ROM	Compact Disk - Read Only Memory.
CDC	Centers for Disease Control
CEB1 and 2	Chemistry and Exposure Branches
CHEM SAC	Chemistry Science Advisory Council
CJE	Critical Job Element. A term used in the Performance Agreement.
CO	Contracting Officer for contract.
CODEX	International Organization, under the auspices of the United Nations, which establishes food standards, such as pesticide MRLs, for the protection of the consumer, and promotion of fair international food trade practices.
Compressed Schedule	Also know as CWS (Compressed Work Schedule), 5-4-9 plan, AWS (alternate work schedule). Allows 5 work days one week in the pay period, and 4 work days in the other week in the pay period, where 8 of the work days are 9 hours and one work day is 8 hours, with one day off per pay period (compressed day off).
CRMS	Chemical Review Management System.
Crystal Ball	A computer software program which combines multiple distributions for Monte Carlo Analysis.
DA	Designated Agent. Processes time cards. Receives pay statements
DD	Division Director.
DER	Data Evaluation Record. Review of a pesticide study.

Dialog	An on-line computer service, containing a number of databases for searching, such as literature searching.
DQC	Discipline Quality Control
DRES	Dietary Risk Evaluation System.
DRP	Data Review Processes
EC	European Community. A European Economic and Political oriented organization, related to the European Union (EU).
e-mail	Electronic mail.
EXPO SAC	Occupational/Residential Exposure Science Advisory Council
FAO	Food and Agriculture Organization of the United Nations
FFDCA	Federal Food, Drug, and Cosmetic Act, under which pesticide tolerances are set
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
Flexiplace	Also known as telecommuting. Allows some work days at an alternate work site, often the employee's home.
Flexitime	A flexible work schedule which allows the setting of daily work hours, so that arrival times can be from 6:30 am to 9:30 am, with corresponding departure times.
FOI, FOIA	Freedom of Information, Freedom of Information Act. A process by which government collected information is released to the public.
FQPA	Food Quality Protection Act, 1996, which amended FIFRA and FFDCA
FR	Federal Register, published daily.
FTE	Full time equivalent. Generally used to mean one person-year.
Gatekeeper	A single point for documents leaving the Division. Ensures that all proper procedures have been followed before a document is released (signed paper copy, electronic copy, "Bean sheet", ...)

Grateful Med	A free service which performs literature searches of Medline, Toxline, and others
Graybeard	A system using experienced reviewers, where decisions can be made quickly about the real need for data
Hazard ID	Hazard Identification (as in Assessment Review Committee)
HED	Health Effects Division of OPP
IAG	Inter Agency Agreement
IDB	Interdisciplinary Branch
IFMS	Integrated Financial Management System
IMCSB	Information Management and Contract Support Branch
Inert	A component of a pesticide product which is not the active ingredient.
IRSD	Information Resource Services Division of OPP
ISDN	Integrated Services Digital Network. A new type of telephone line, which is digital, and allows data and voice communication on the same phone line.
ISIS	A group of computer programs which are capable of drawing chemical structures and using structure activity relationships (SAR). (Formerly ChemBase and related products)
JMPR	Joint Meeting on Pesticide Residues, a United Nations sponsored organization, which provides scientific analyses for pesticide residues and estimates MRLs, deliberated by CODEX
LAN	Local Area Network.
LCO	Lawn Care Operator
Lotus Notes	A groupware/database product, which includes Internet access
MRID	Master Record Identification (Number). Used to catalog data
MRL	Maximum Residue Limit. Term used in other countries to mean the same as US Tolerance.

MSD	Margaret, Stephanie, Debbie (the current DD and ADDs for HED)
MSS	Master Scheduling System
NPRD	National Pesticide Residue Database. A database which is planned to contain monitoring data from a number of sources, including FDA, USDA, and the States.
NPTN	National Pesticide Telecommunications Network, which is maintained for the EPA by Oregon State University.
NTIS	National Technical Information Service. Distributes Government Documents
OCR	Optical Character Recognition. A computer software program which "reads" a graphics file and produces ASCII text from the graphics file, which can then be saved as a word processing file.
OECD	Organization of Economic Cooperation and Development, which is involved in harmonization of health guidelines, such as toxicology, product chemistry, and in the future, residue chemistry, in cooperation with FAO, WHO, and the EC
OPP	Office of Pesticide Programs of EPA
OR	Occupational/Residential
Oracle	A relational database program produced by Oracle Corporation
ORD	EPA's Office of Research and Development
ORETF	Outdoor Residential Exposure Task Force, which is producing exposure data for outdoor residential sites. No indoor residential sites will be covered by this task force.
PC Code	A six digit code for pesticide chemicals assigned by EPA. Also known as the Shaughnessy Number, after John Shaughnessy, who designed the PC Code system.
PHED	Pesticide Handlers Exposure Database
PIRAT	Pilot Interdisciplinary Risk Assessment Team.
PO	Project Officer (for a contract)

PPA	Planned Program Activity. Used in Budget process.
PPDC	Pesticide Program Dialog Committee
PRATS	Pesticide Review Action Tracking System
PSC	Policy Steering Committee
QA	Quality Assurance
QC	Quality Control
RA	Risk Assessment
RAB	Registration Action Branch
RCAB	Risk Characterization and Analysis Branch
RED	Reregistration Eligibility Document
RfD	Reference Dose
RFP	Request for Proposal for contracts
SAB	Science Analysis Branch
SAB	Science Advisory Board of the EPA
SAC	Science Advisory Council. There will be one SAC for each discipline (Tox, Residue Chemistry, and Occupational/Residential Exposure)
SAP	Science Advisory Panel of OPP
SAR	Structure Activity Relationship. A method of assessing the likelihood of toxic effects based on similarities in chemical structure.
SARC	Science Assessment Review Committee (formerly known as Peer Review).
SAS	Statistical Analysis Software
Section 18	Emergency Exemption submitted under Section 18 of FIFRA

Section 24(C)	A Special Local Need for a pesticide, registered under Section 24(C) of FIFRA
SEP	Standard Evaluation Procedure
SOP	Standard Operating Procedure
SOT	Society of Toxicology, a professional society for toxicologists
SWAM	Scientific Work Assignment Manager for Contract. Consulted by the contractor on science issues.
TAIS	Time Accounting Information System. Currently used to track work done by PPA categories.
TEP	Technical Evaluation Panel. Evaluates proposals submitted for contracts.
TES	Toxicological Endpoint Selection
TIFF	Tagged Image File Format. A bit mapped format for graphics files
TL	Team Leader
Tolerance	Maximum legal amount of a pesticide which can be present in a food commodity
TOX 1-liner	A summary of toxicological data
TOX SAC	Toxicology Science Advisory Council
TQC	Team Quality Control
TRA	Tolerance Reassessment
WAM	Work Assignment Manager (for a contract)
WHO	World Health Organization of the United Nations
WPS	Worker Protection Standards.

APPENDIX C. FUTURE CONSIDERATIONS

A. THE HED SPLIT

The Design Team was asked to address the following questions: 1) is the division too big, 2) can the structure absorb additional staff or 3) would the division need to divide.

The Design Team concluded, that given the present structure of HED with a Director and 2 Associate Directors, the division could absorb 2 more branches should there be a need in the future to take 30 additional staff. Since the division is entering into a critical stage with re-organization, re-staffing, etc., this would not be an ideal time to split the division. The proposed changes will require some stability and continuity. In addition, the division has to stay as one to test the structure and the systems proposed under the new design.

B. CREATION OF A SCIENCE INFORMATION MANAGEMENT BRANCH

1. Introduction

The staff, during the working sessions, requested clarification as to where science information management functions reside. The functions currently assigned (in the re-design) to IMCSB are too many and too diverse considering the other responsibilities of this branch. In addition, many other science information functions are currently (in the re-design) assigned to SAB. The Design Team evaluated the overlap between the science information management functions in IMCSB and SAB.

2. Current Re-Design

Under the current design, SAB is responsible for some of the science information management functions which include external peer review, maintenance of the IRIS and the 1-liner data bases, and maintenance of files supporting the Science Assessment Review Committees (SARCs). On the other hand, IMCSB, under the re-design, is responsible for "logging" actions from RD/SRRD into and out of PRATS, maintaining the Master Scheduling System, conducting literature searches and providing LAN support. In addition, IMCSB is also responsible for general divisional operations including human resources, contracts management, facilities, coordination of training, budgeting, planning, and other activities.

3. Proposal for Consideration

In order to address the concerns raised above, the Design Team recommends that when HED needs to add additional branches due to increased personnel, the Division may wish to consider consolidating the science information functions within a single branch. The proposed Science Information Management Branch (SIMB) would have the following functions:

Literature search
Library support
1-Liner data base maintenance
IRIS database maintenance
SARC database maintenance
PHED database maintenance
DRES database maintenance
ISIS
Lotus Notes Records Repository
Master Scheduling System
Planning, scheduling and coordination of SARCs

Thus the science information management functions are maintained in one branch providing our customers a central focal point of contact.

C. CREATION OF AN ADMINISTRATIVE AND CONTRACT SUPPORT BRANCH

The separation of the science information management functions from IMCSB would leave this branch (possibly renamed - Administrative and Contract Support Branch (ACSB)) with the following administrative functions:

System Administration (LAN, computer support)
Program Support
Contract Support
Strategic Planning
Accounts / Finance / Budget
Human Resources
Travel & Training
Facilities management

D. PROS AND CONS OF THE PROPOSED MODIFICATIONS

1. ADVANATAGES - Creation of SIMB collects into one branch the science information and database management needs of HED. This step would permit the more efficient utilization of staff recommended to be hired for information and database management. In addition, SIMB would be able to focus on information and database management issues because these would be central to branch function. Information and database needs will increase in the new environment because of the cross cutting disciplinary issues and greater dependence on models and probabilistic analysis. These issues will be further magnified as new hires swell the Division to its full complement over the next several months. The smaller size of ACSB will make it more manageable and more focussed on operations management and budget.

2. DISADVANTAGES - Recently completed staff assignments were based upon the current HED branch functional statements. In order to accomplish these modifications, the branch assignment of the staff currently in the SAB would have to be determined. The Design Team was undecided on the best "location" for the statisticians currently in SAB. Three possibilities were discussed: 1) all statisticians in SIMB, 2) all statisticians in RCAB, or 3) distribute statisticians across other branches. The remaining staff could possibly be reassigned to the existing interdisciplinary/ disciplinary branches or other alternatives investigated.

E. SUMMARY

It is the opinion of the Design Team that the re-design plan is flexible enough so that the division can absorb a reasonable increase in staff without being divided into two divisions. The proposed changes to IMCSB and SAB are more efficient, better address current and future HED support needs and address the design drivers to a greater extent than the current SAB / IMCSB branch combination. **However, these proposed modifications can not be accommodated at the present time and therefore should be considered when the HED structure is modified due to the impending new hires.**

APPENDIX D. COMMENTS AND QUESTIONS BY STAFF AND RESPONSES TO THESE COMMENTS

I. INTRODUCTION

The Design Team appreciates the responses from HED staff regarding the draft Design Team Document. Thanks for your complements on the team - the details - the document. This appendix summarizes the comments, concerns and questions raised by the HED staff during the working sessions and/or direct inputs to the Design Team members and the Design Team's responses to the issues raised. The final document includes any applicable changes as a result of analyzing these issues.

ELEMENTS IN THE RE-DESIGN THAT WERE LIKED BY THE STAFF

GENERAL ON THE DESIGN

- The design is very creative and reflects a lot of hard work.
- People on the design obviously worked very hard.
- Excellent job in the time given.
- For a new employee, it was the first document which defines what HED does!
- That the plan is detailed and not superficial.
- Nice road map
- All major issues were addressed in the document
- The level of thought and detail in the document
- The design should facilitate the production of a single quality product in HED
- Delineates issues
- Now have two ways of arriving at same product. What we have been doing, what we will be doing.
- Complete plan which addresses all aspects of HEDs work given the constraints
- A very open process
- Spells out clearly the various processes of HED
- It provides opportunities to learn other disciplines.
- Fairness in division with regard to distribution of work
- Liked the idea of interdisciplinary teams and -based management.
- There is flexibility in work assignments
- The design facilitates the work of the interdisciplinary branches.
- Opportunities to work in teams with different disciplines.
- Provides more opportunities to do varied work.
- Can interact with other disciplines within your own branch (IDB)
- Provides opportunity to interact with other disciplines outside the branch
- Encourages discipline mix and provides opportunity to do new work
- Increases understanding of the work processes.
- Overall work process and flow of work
- Thorough: Good use of flow charts to depict process

QC/QA PROCESS

- Meritorious effort to maintain scientific consistency.
- Participation by staff in the HED deliberative process is a positive change in HED.
- Combining RfD and TES is a good idea.
- Combining TES and RfD and creation of Risk Ass.CMM.
- Like the combination of RfD and TES
- Consolidation of RfD and TES, and the new SARCs common mechanism and risk assessment.
- Liked combining RfD and TES - it saves time
- Recognizes need and importance of consistency
- More "peer" in peer review.
- Pleased that tox will become more involved in the metabolism committee
- QC/QA addressed by SACs and SARCS

- The SACs will promote consistency and the variety of work.
- Concern about multiple layers of review but thought it necessary given the structure constraint.
- The process for consistency - the SACs and the SARCs
- Like SACs and SARCs provided they have a stable membership base.
- SACs and SARCs will ensure consistency
- The process develops and maintains consistency
- Like idea of cleaning up the QC/QA process (moving it from the existing RfD) committee
- Risk Assessment Review Committee should ensure the consistency of risk assessments, which are changing rapidly as a result of FQPA.

STRUCTURE/WORK PROCESS

- Proposed structure changes leadership roles
- Empowerment of staff
- Earnest effort to empower everyone.
- Increases staff involvement.
- Greater personal empowerment.
- Empowers staff in decision making.
- Increases the learning process and empowers learning in interdisciplinary areas
- Opportunity to work in both disciplinary and interdisciplinary environment.
- Like the idea of mentoring program - but it needs to be explained more thoroughly in the document
- The flow charts in the document helped to explain the core processes

BRANCH ASSIGNMENT OF CHEMICALS

- Branch ownership of chemicals by chemical class is a good idea.
- Branch assignment of chemicals (variety of work, class - common mechanism)
- Like the option that was selected for branch assignment of chemicals.
- Branch assignment of chemicals should allow for greater variety of work.
- The approach should facilitate expansion of knowledge
- Like option C for branch assignment of chemicals

RISK ASSESSMENT

- The intended production of a single risk assessment document is a good idea.
- Like the contact with industry in the middle of the process

COMMUNICATION

- The emphasis on increased communication and regular information meetings to enhance communication is very good.
- Emphasis on communication.
- Regular meetings (formal and informal).
- Like the emphasis on communication.

- Improves communication
- Recommendations for the use of communication tools.
- Creation of teams, SACs, and SARCs will improve communication and interaction

HUMAN RESOURCES

- Human resources section made to feel appreciated
- Training effort - (inter/intra, but should not be limited by the committee, i.e.the training proposals were good but consideration of fairness should not create a straightjacket were people who have received training cannot get additional training until all have had some.)
- Increases training and attendance of professional meetings.
- Cross training.
- More training opportunities.
- Pleased with more opportunities for training and the attempts to make training more equitable, and that we will have a training coordination function.
- Training coordinator
- PSC input on training and travel.
- Division paying for professional dues.
- Liked that the document recognizes that lack of advancement opportunities reduces morale.

TOOLS & TECHNOLOGY

- More access to lit searches.

CUSTOMER RELATIONSHIP

- Should improve customer relationships.
- Customer needs focus.
- Liked the customer service rep.
- The customer service representative position.

CULTURE

- Liked the presumption in the work of the design that everyone would buy in. Liked the design team's own commitment in and confidence in the changes. Liked that they took initiative to create things that had not existed before.

II. A. DATA REVIEW PROCESS

The Draft document discussed the need for consistency in study or data reviews under the revised division structure because of the loss of section heads and dilution of the disciplines across six branches. To address this major concern, the Design Team recommended a QC/QA process for the study/data reviews that would involve one or more of but NOT ALL of the following steps: 1) QC/QA review; 2) review by the Branch Senior Scientist (BSS); 3) the Science Advisory Council (SAC); and/or 4) the Science Assessment Review Committees (SARCs). The "criteria" for which one of these steps would apply depended on the "type of review" (i.e, pipeline reviews, short actions that include Section 18, 24 (c) amended use, etc., and large actions that include REDs, new chemicals, EUPs, tolerance requests, etc.).

STAFF COMMENTS: The staff was not clear on the QC/QA process described in the re-design (i.e., what step is needed, when it is needed and for what type of action) and were very much concerned on the roles of the, BSS, the SACs and the SARCs in the data review and QC/QA process. Concerns raised by several staff members included: introduced too many layers of review (i.e., review -- BSS -- SAC -- SARC); slow down the review process; may create a "bottle neck"; lessens empowerment; is there a need for a BSS if there is a SAC?; how will the BSS handle reviews outside of his/her discipline; why do we need a BSS if there is a SAC; will there be one BSS for each discipline in a branch?; what is the criteria for sending a review to the SAC; and could just a review by SAC be sufficient?. In summary, the staff envisioned "too many layers" and wanted the data and the QC/QA process to be "streamlined".

DESIGN TEAM'S RESPONSE: To address this concern, the Design Team re-evaluated the data review process and streamlined this process including the QC/QA process as follows:

In performing " QC/QA", the teams in a Branch will check the "data reviews" for:

- Accuracy of data transcription
- Validity of the methods used
- Review and evaluation of "science"
- Interpretation of study reports
- Scientific accuracy
- Results support the conclusions
- Application of disciplinary science policy

In performing QC/QA, the Branch Senior Scientist (BSS) will be check the "final product" (as opposed to the data reviews) for:

- Assure risk assessment policy
- Application of HED/OPP/Agency policies

The revised QC/QA process for the different type of actions along with the signature authority is presented in Figure 1.

Pipeline Studies (from RD, SRRD): For pipeline studies that do not require a Risk Assessment (RA), following the primary review by the Lead Reviewer, the team will perform

a QC/QA check. The Reviewer/Team will sign off on the study review as appropriate. The completed action will then be submitted to the BSS for his/her review. If the BSS is not an expert in that particular field, then the BSS will consult with the member of the SAC in that discipline who is member of that Branch and/or a senior specialist in that field, either within the Branch or outside the Branch (when the BSS deems this is appropriate). The pipeline study reviews are not routinely evaluated by the SAC because they will be submitted to the SAC when that study becomes a part of the complete data package at a later date (when it is ready for risk assessment). The Memorandum for that review will be signed by the Lead Reviewer and the BSS.

Short Actions (e.g., Section 18, 24(c), amended use): For these short actions that require Risk Assessment (RA), following the primary review of data, the Lead Reviewer will prepare the RA in consultation *(ad hoc)* with the appropriate SARC (e.g., Hazard ID Committee) and obtain the appropriate endpoints necessary for risk assessments. The SARC is consulted on an *ad hoc* basis to avoid a "formal" meeting which might cause a delay in the review process. The RA product will then undergo a QC/QA review and a review by the BSS. If the product also contains a review of data and the BSS is not an expert in that particular field, then the BSS will consult with the member of the SAC in that discipline who is a member of that Branch and/or a senior specialist in that field, either within the Branch or outside the Branch. Following this step, the RA product will be reviewed by the Risk Assessment Review Committee (RARC). RARC will have to develop SOPs for short turn-around actions such as section 18s.The Memorandum for this "product" will be signed by the Lead Reviewer/Team and the BSS.

Major Actions (e.g., new chemicals, REDs, tolerance requests): For all major actions that require RA, the data reviews and RED Chapters will be submitted to the team for QC/QA and then to the appropriate SAC for their review and then for assessment by the appropriate SARC(s). Following review by the SARC(s), the Lead Reviewer will prepare the RA incorporating the decisions/ recommendations of the SARC(s). The RA product will then be reviewed by the team for a QC/QA check and then by the BSS. The RA will be submitted for review by the Risk Assessment Review Committee. The study reviews will be signed by the Lead Reviewer and the Team. The disciplinary chapters will be signed-by the Lead Reviewer and the BSS. The Risk Assessment document will be signed by the Risk Assessor and the BSS.

Branch Senior Scientist (BSS): The Design Team believes that the BSS is a value added position who will play a major role in the immediate future (6-9 months). The role, however, may change over time as the Division/Branches/teams becomes more proficient in functioning under the new design.

Science Advisory Council (SAC):

The Design Team recommended the creation of a Science Advisory Council (SAC) for each discipline. These SACs will be composed of scientists by discipline from each Branch and one person in each of these SACs will serve as the Chair of the respective SAC. The SACs recommended were:

Toxicology SAC (TOX SAC)	Occupational/Residential Exposure SAC (EXPO SAC)	Chemistry SAC (CHEM SAC)
6 Toxicologists	6 Exposure Specialists	6 chemists

The Design Team also believes that the SACs, although apparently an added layer, are absolutely necessary because data reviews are produced by scientists in specific disciplines spread among six different branches. Study evaluations must be reviewed by a centralized group to evaluate the interpretation of results, assumptions used, science and regulatory policies and recommendations made across these six branches. However, it is emphasized that NOT all reviews are routinely reviewed by the SACs. Of the smaller actions only issues that raise "scientific" or "policy" concerns are submitted to the SACs.

STAFF COMMENT: The HED staff were concerned as to the function, staffing and mechanism of the SACs.

RESPONSE OF THE DESIGN TEAM:

Function of SAC: The primary function of the SAC will be to maximize consistency and scientific accuracy across chemicals. SACs provide empowerment since the staffing of the SACs will be made up of staff scientists, it moves the secondary and tertiary reviews out of management, and it eliminates the need for review by the Branch Chief. With the scientific disciplines spread over several branches within HED, SACs will provide consistency in science - policy - interpretation which may include:

- checking for adequacy of the reviews (e.g. DERs)
- evaluating the adequacy of the study (i.e., it met the Guideline requirement)
- review and evaluation of science (i.e., interpretation of study results)
- examination of the appropriateness of end points selected in toxicology studies
- evaluation of the appropriateness of the NOELs/LOELs established
- examination of the assumptions used in disciplinary (risk) assessments
- review of appropriate exposure data (transfer factors, use of dermal absorption and clothing penetration, etc.)
- assessment of residue chemistry factors (incorporation of percent crop treated, composition of livestock diet, etc.)
- Address "Graybeard" issues

The TOX SAC, for example, will perform quality control of the toxicology data package (DERs) that will be presented to the Hazard ID Committee which will enable this Committee to concentrated on identifying hazards for both acute and chronic exposure via all routes of and save time by separating the out the quality control function from this Committee. In addition, the SACs will be available for *ad hoc* consultation, address policy issues and communicate policy decisions across the branches.

Staffing of SAC: The Design Team is making the following recommendations for staffing of the SACs:

- SACs will be staffed with scientists by discipline from each Branch.
- Staffing should be accomplished by Division Management (i.e., MSD and the Branch Chiefs) during the Phase III of Implementation Planning (Transition Team).
- There should be a staggered rotation with term limit of two (2) years.
- Members of the SAC must elect the Chairperson who would be a member of the Policy Steering Committee.

Process of SAC: The process of the SACs will be as follows:

- The "product" (i.e., reviews) will be submitted to the SAC for review.
- SAC will review the product in an "informal" manner.
- SAC will not hold regular meetings; meetings will occur as needed.
- SAC will informally interact with the team that requests the reviews.
- SAC will meet with the reviewer to discuss and resolve the issues if and when needed.
- SAC will consult with disciplinary experts as needed.
- SAC will maintain a log on the issues raised/resolved/recommended resolutions.
- The Chair of SAC will communicate the conclusions/decisions of the SAC to the /Branch/SARC (as appropriate) and this information will be made available on the LAN.
- SAC member will back up the reviewer who will be presenting to the appropriate SARC. This will enable the SAC representative to "enlighten" the SARC if and when there are questions regarding on the data base and/or the QC/QA process.
- The Chair of the SAC will be responsible for the planning, scheduling, coordinating, and operations of the SAC.
- SAC is a decision making body and will be the final arbiter of issues concerning data interpretation for disciplinary reviews.

STAFF COMMENT: Need to develop SOP's for risk assessments, SACs and SARCs.

DESIGN TEAM'S RESPONSE: The Design Team has recommended that SOPs are needed for all parts of the Risk Assessment process (Pages 107 -110 in the Draft).

STAFF COMMENT: The Design Team, in reference to the Doherty's "electronic" submission of data, recommended that the new method should be tested in a pilot program and modified necessary. In reference to this, one staff member commented that this has already been conducted and that Marion Copley should be contacted for details. Another staff member commented that the Doherty proposal causes added work for the reviewers with little value added while yet another member commented that this proposal may actually use more time than it saves.

DESIGN TEAM'S RESPONSE: The Transition Team will maintain contact with appropriate staff as suggested and will also evaluate the other two comments.

II. B. SCIENCE ASSESSMENT REVIEW PROCESS

The Design Team recommended a Science Assessment Review process (previously the peer review process) consisting of six Science Assessment Review Committees (SARCs) each with specific functions and process. The six SARCs are: Hazard ID Assessment Review Committee; Cancer Assessment Review Committee; Reproduction and Developmental Toxicity Assessment Review Committee; Metabolism Assessment Review Committee; Mechanism of Toxicity Assessment Review Committee; and Risk Assessment Review Committee.

STAFF COMMENT: The HED staff had some concerns about the names, staffing, composition and mechanism of these committees.

1) Names of the SARCs: Three concerns were raised in association with the names of the SARC. The first, raised by several staff members was not using the term "peer review" for these Committees is a concern because the term "peer" is a widely accepted term by our customers and not using this term in these committees may create a impression of a lack of peer review in HED. The second was the use of .CMM for the abbreviation of the Committees which sounds like a computer file name. The third was the use of the abbreviation Risk Ass. for the Risk Assessment Review Committee.

DESIGN TEAM'S RESPONSE: The Design Team evaluated these concerns and concluded that: 1) the SARC is a "decision making body" composed of experts in the field as opposed to "peer review" and therefore, the name "Science Assessment" is appropriate and does reflect the function of these Committees, namely assessment of the science. Under the current structure "peer" review is actually performed by the members during the QC/QA process and/or by the SAC and that the SARCs will not be involved in "peer" review *per se* but rather will assess the scientific decisions in these reviews. The Design Team recommends that OPP issue a press release announcing these changes in HED's peer review process (i.e., names and functions of each of the SARCs); 2) the staffing of the SARCs should be based on the following qualifications:

- Independent of their current position (management or staff/branch location)
- Must be technically competent in discipline
- Must have credibility with peers and management
- Must be able to look at the "big picture"
- Must be able to hone in on critical technical details
- Must be a player will work in a group
- Must be a problem solver
- Staffing will be decided by Division Management (i.e., MSD and the Branch Chiefs) with an opportunity for individuals to volunteer for membership.

The Design Team removed reference to computer jargon relating to committee names.

2) Composition of SARC: The Design Team has determined that the composition of the SARC should be based on the following factors:

- Need scientific background appropriate to the SARC discipline
- Mixed seniority, independent of grade
- Membership not limited to HED (include AD, BPPD, EFED) or OPP
- Must have good writing skills (to prepare the final document)
- Appropriate skill mix will be decide by Management (MSD & BCs)
- Staggered rotation, every two (2) years (as personnel resources allow)

STAFF COMMENTS: Specific concerns raised by staff members in their written response to the Design Team on four of these committees are discussed below with the Design Team's responses.

1) Hazard ID Assessment Committee: Several staff members commented that it was a good idea to combine the functions of the present RfD and TES committees under this one committee and that they like this proposal.

However, one staff member raised the following issues in written comments to the Design Team. The written comments stated that "the proposed changes to the (RfD) Committee appear to stem from the inadequate knowledge about the whole process and the other might be the result of personal ambition of a few members of the redesign". This staff member also stated: not to change the name or alter the function of RfD Committee (i.e., call committee by their function names); not to alter the function of the RfD Committee (i.e., QC/QA of science review and DERs can not be done at the branch level); not duplicate its function (i.e., QC/QA done by TOX.SAC will be a waste since it will be repeated by this Committee); why create a new system when we already have a most efficient and excellent system (i.e., do not fix it if it is not broken); not alter the RfD Committee structure (i.e., membership should be based on expertise and not elected positions) and data base for RfD and TES are different and they are not being rehashed (as stated in the document). Another staff member, also raised the concern about the name change and how it will affect our customers (within and outside OPP). It was noted that the TES was changed from its original name "Less Than Life Time" recently and now HED is again changing the names of these Committees.

DESIGN TEAM'S RESPONSE: It was concluded that: the recommendation to combine the RfD and TES Committees are valid based on the rationale discussed in Chapter II.B (Page 18 of the Draft). In summary the rationale were: the process is streamlined (no rehash of the data base); enable one group of scientists to identify hazards for dietary (acute, chronic and drinking water) and non-dietary (occupational/residential) exposures; make evaluation of aggregate risk more consistent (i.e., identify hazards for multiple routes (oral, inhalation and dermal) and multiple sources (dietary/occupational)); address the kids sensitivity issues (i.e., for all routes (oral/dermal/inhalation) and source (drinking water /dietary/ occupational/ residential); results in a single document that will provide hazards identified for the various risk assessments (i.e., eliminate generation of two separate documents).

The comments for change in the name of this Committee (as expressed by both staff members) will be handled by the press release from OPP. In conclusion, the fact that majority of the staff liked and agreed with the Design Team's recommendation (combine RfD and TES) confirms that this is indeed a good approach. The Design Team does not agree with the other comments by that staff member because: 1) the Design Team had thorough

knowledge of the whole process and there were no "personal ambitions" by any team members; 2) the data base is the same for RfD and TES and these Committees not only rehash the data but the TES Committee often has to have the decisions made by the RfD to assess chronic non-dietary exposure scenarios; 3) the name Hazard ID is appropriate since the primary function of this Committee will be hazard identification; 4) the QC/QA function must be removed from this Committee so as to concentrate on hazard identification as well as to ascertain consistency across the branches on scientific issues, policies and recommendations; 5) QC/QA done by the TOX SAC is at the division level and NOT at branch level and will not be repeated by this Committee; 6) the Chair of the Hazard ID Committee will have the responsibility to ensure that the decision made by the TOX SAC on the quality of the data base will be followed.

2) Cancer Assessment Review Committee: The Design Team indicated that improvements are needed in coordination and scheduling of this Committee meetings. A written comment stated that "planning, coordinating and scheduling CPR meeting is a time-consuming and difficult job, which requires cooperation from both toxicology branches and statisticians. RCAB has been ably performing and should maintain this function since they maintain liaisons with SRRD, RD and other Agency offices and are attuned to the overall priorities".

DESIGN TEAM'S RESPONSE: The Design Team has concluded that the function of the RCAB under the re-designed structure will be significantly different from the existing function of the RCAB: 1) under the new structure RCAB will NOT be planning, scheduling and coordinating for the Science Assessment Review process; 2) the four interdisciplinary branches will be responsible for their own risk assessment process; and 3) RCAB will be involved in performing risk assessments only for the disciplinary branches. In summary, under the re-design, 5 branches (4 interdisciplinary + RCAB) will have to interact with the SARCs as opposed to 1 branch (RCAB) as it is now. Therefore, it is imperative that the Chair of the SARCs must be responsible for the planning, coordinating, scheduling, and conducting of Committee meetings.

3) Mechanism of Toxicity Assessment Review Committee: One staff member raised the concern that "as we start to receive mechanistic data on our chemicals, there will be data which some of us will not have the backgrounds to fully understand". The Registrants send in data that the toxicologists either do not understand and therefore do not adequately explain which causes the Committee to ignore the submitted data. The staff member further pointed out that in the past the toxicologists "have been put into the position of representing the Registrant to the Committee on one hand and then representing the Committee to the Registrant on the other". Therefore, it was suggested that there should be a "provision (particularly for mechanistic data) that the Registrants may send a representative who could come in and present the data directly to the Mechanism of Toxicity Assessment Review Committee".

DESIGN TEAM'S RESPONSE: The Design Team agreed with the staff member that not all the toxicologists have the necessary background in this area, a SOP must be developed as soon as this Committee is formed, and that the Registrant should be allowed to present mechanistic data to the staff. The Design Team does not agree with the staff member, however, that the Registrants be allowed to present the data "directly to this Committee"

because this will set a precedent and the Registrants will ask that they be given the same "access" to the other Committees. When the registrant presents mechanistic data, the individual reviewer should be supported by division experts.

STAFF COMMENT: Another staff member indicated a serious concern for having the SARC for Mechanism of Toxicity so late in the process in Figure 1 in Chapter II. B. The member stated that common mechanism should be identified ASAP for all chemicals, including new chemicals, "otherwise we could review the entire chemical before we realize we cannot conduct cumulative and aggregate risks because of common mechanism issues". Also, for new chemicals, since the registrants are providing risk assessments, monte carlos, endpoint identifications, common mechanism information, etc., these information are available up front to make a determination as to whether the chemical should even be accepted and reviewed by the Agency.

DESIGN TEAM'S RESPONSE: The location of the Mechanism of Toxicity Assessment Review Committee in Figure 1 is not according to the "order" of the Committees. Since this is a "newly" created committee it was placed after all the "existing" committees and does not indicate either the "order" or the "importance' of this Committee. Also, this has been defined in the final document. The Design Team shares the same concerns as to when in the risk assessment process the common mechanistic data be assessed. Often, the "need" for common mechanism assessment will not be known until all data reviews are completed and therefore this cannot be done ASAP as suggested by the staff member. On the other hand, being aware of the common mechanism early in the risk assessment process will enable a more efficient risk (aggregate and cumulative) assessment as suggested by the staff member. Therefore, the reviewers should be cognizant of possible issues surrounding common mechanism that may arise during the review process. Thus, the issue is not ignored but monitored by the reviewer early in the review process. The Design Team recognizes that this and recommends that the Transition Team should work with HED management to form this Committee as soon as possible to address these issues and this Committee should develop a SOP.

4) Risk Assessment Review Committee:

STAFF COMMENT: One staff member questioned whether HED will really have any influence on risk assessments by AD and BPPD to promote consistency.

DESIGN TEAM'S RESPONSE: The Design Team determined that this matter will be discussed during the Dan Barolo/Division Directors briefing and the Transition Team will work with HED's management (MSD and BCs) to develop a mechanism for consistency in risk assessments to work with other divisions in OPP.

II. C. RISK ASSESSMENT PROCESS

STAFF COMMENT: The Design Team recommended that in their review of a data package for REDs and new chemicals, a "clean-up" meeting be held with the Registrants prior to the preparation of the disciplinary risk assessment chapters for the REDs. One staff member commented that SRRD generally takes the lead on both measures at the beginning of the process and at the end and that by including this clean-up meeting HED was taking too much responsibility which is "approaching stepping on toes".

DESIGN TEAM'S RESPONSE: The intent of this "clean-up" meeting with the Registrant is get their input (on exposure assessment, risk assessment and assumptions used, etc.) earlier in the process than at the present time. SRRD will still take the lead to assist HED in this process.

STAFF COMMENT: Tox endpoints need to be identified first before OREB (type rev) should be conducted for a given chemical. Remember, data are not required for any occupational type exposure until the tox. endpoints are identified. In the Figure, occupational/residential data review occurs before the tox. endpoints are identified. This has always been an issue in HED, which has pretty much finally been resolved.

DESIGN TEAM'S RESPONSE: The Design Team acknowledges that not all data reviews are conducted simultaneously as indicated in the Figure 1 of Chapter IIC. There is no suggestion that this process be modified at this present time.

STAFF COMMENT: Are the exposure assessors at the hazid.com there to say - No chronic residential assessment is expected, so don't bother to select an endpoint? The committee should select all the endpoints for all the scenarios. Otherwise, a year later a new use that has a chronic residential scenario means a revisit to select a new endpoint. The exposure assessor should use endpoints in the document selecting for the assessment as required by the exposure from the use-pattern.

DESIGN TEAM'S RESPONSE: The Committee does select endpoints for all scenarios. The exposure assessors are needed to provide insight for the existing use patterns (i.e., inhalation vs. dermal) as well as provide input as required by this committee.

STAFF COMMENTS: In response to the Design Team's recommendation that the Registrant submit their risk assessment, several staff member raised their concerns that this may cause too much reliance on the Registrants judgement and cause less critical data review by HED, may lead getting into the rebuttal phase too early in the process, may create a need to rebut every difference and that Office of Solid Waste and Emergency Response had a bad experience when they initiated a similar step in their Superfund program.

DESIGN TEAM'S RESPONSE: A risk assessment conducted by the Registrant would consist of the use data generated and marketing information they routinely gather. It forces them to review their database and confront the issues early on. Currently, the Registrants are brought in at the end of the process, rebut the risk assessment and we end up rebutting and defending every aspect of our risk assessment. Often, we agree with their conclusions and

change the risk assessment resulting in unnecessary work. In other words, the rebutting of every detail is already happening, the Design Team believes it should happen earlier in the risk assessment process. The risk assessment provided by the Registrants will provide a mechanism for them to give information and advise the Agency of what they believe are the appropriate data (exposure, endpoints, assumptions, etc.). Their risk assessment will NOT replace HED's risk assessments. HED will have to reassess the value of registrant's submission of risk assessments after we have had some experience using them and readjust our review process as necessary to avoid the problems experienced by OSWER/Superfund.

STAFF COMMENT: Several member raised their concerns that a mechanism is needed to get inputs from EFED (on drinking water) and BEAD (on use information) as well as other divisions as recommended by the Design Team, since such a mechanism does not exist in the present organization structure. Another member suggested that interactions/harmonization with other divisions and other offices should be formalized to make sure that the process occurs.

DESIGN TEAM'S RESPONSE: The Design Team has determined that HED's needs from other divisions will be discussed during the Division Directors briefings and the Transition Team will work with HED's management (MSD and BCs) as well as the PSC to develop a mechanism to work with other divisions in OPP as well as other offices in the Agency.

IV. BRANCH DEFINITION AND WORK PROCESS

A. STRUCTURE FOR DATA REVIEW PROCESS

1. Interdisciplinary Branches

STAFF COMMENT: The Design Team recommended the PIRAT model as the basic structure for the interdisciplinary branches with two multi disciplinary teams consisting of hazard, exposure and risk assessors in each. One staff member commented that the multi disciplinary approach is based on an inappropriate PIRAT model which only handles small actions.

DESIGN'S RESPONSE: The Design Team recommended the PIRAT model after its evaluation of the advantages and disadvantages of two models: a disciplinary model and an interdisciplinary model (given the constraints of the structure that were given to the design team). While the disciplinary model was best suited for Data Reviews, the interdisciplinary (PIRAT) model was best suited for the Risk Assessment (RA) process. Since RA is the major product and focus of HED's customers, the Design Team recommended the PIRAT model. In addition, the PIRAT model satisfied all the Design Drivers; having a mixture of scientists in various disciplines with experience, expertise and knowledge will increase communication, empower the staff, give flexibility to management, which in turn will enable the branches to meet their goals and purpose and have a better customer relationship (Page 36 of the Draft).

STAFF COMMENTS: Sending overflow work to disciplinary branches could make the interdisciplinary branches appear to shine while the disciplinary branches end up being the "dumping ground" for work that the interdisciplinary branches can not do or do not want to do. -- The disciplinary branches should not be working for the interdisciplinary branches. Interdisciplinary branches do all the REDs while the disciplinary branches may get the "goodies" special projects, etc. -- Need to address equitability of work load, and specifically avoid features which will make reviewers overloaded or branch chiefs juggling too many customers. (dumping of registration actions on disciplinary branches.)

DESIGN TEAM'S RESPONSE: The distribution of work to all branches will be based on priorities and current work load. The priorities will be determined at the weekly prioritization meetings. It is the responsibility of the management (MSD and BC's) to ensure that work is distributed equally across the branches ensuring equity in work load and they will analyze the work load spread across the branches as part of their annual planning. The Master Schedule System is the tool to identify work loads. In addition, there is no need for the staff in the disciplinary branches to feel that their branch is a "dumping ground" because if a interdisciplinary branch can not complete the full action, then the entire action (not some parts of it) will be handled by the disciplinary branches through RCAB. Thus, the disciplinary branches will also have their turn to work on complete data packages.

STAFF COMMENT: "Shouldn't the ONLY difference between the disciplinary vs interdisciplinary roles be to serves as risk assessors? I noticed all the contract management, PHED, maintaining data bases....a lot of EXTRA (pain in the neck) stuff (but extremely important) is the responsibility of the discipline branches.... I vehemently disagree with the

disciplines being asked in this way to support so heavily these teams because that is EXACTLY what it is. It is the support work that can be so demanding, difficult and least appreciated".

DESIGN TEAM'S RESPONSE: The disciplinary branches are responsible for the DRES (Chemistry and Exposure Branch I) PHED (Chemistry and Exposure Branch II) and ISIS (Toxicology Branch I) databases because these branches have the concentration of expertise in needed disciplines to maintain and support these data bases as well as train additional staff to learn to use these data bases. The SWAMs are located in the disciplinary branches because 1) the system is consistent with the existing structure and it works, 2) contract workload can not be split or spread out across six branches 3) both the Project Officer as well as the Contractors need a single point of contact, and 4) it reduces the number of SWAMs; (i.e, 1 SWAM/discipline/contract in two disciplinary branches vs. 1 SWAM in each of the branches; 2 SWAM vs. 6 SWAM). The intent of the design is to encourage efficient HED output. The performance of support activities is critical to the function of any organization and should not be viewed as demeaning.

STAFF COMMENT: Since only the interdisciplinary branches have the risk assessment function, it is implied that individuals assigned to "disciplinary" branches are not sufficiently skilled to perform risk assessments.

DESIGN TEAM'S RESPONSE: The "function" of the branch has nothing to do with the "capability" of the member of the branch. Risk assessors are assigned to the interdisciplinary branches since they are "self-contained" branches and will perform their own risk assessments while the disciplinary branches, although they will focus on hazard and exposure analyzes, will still play a significant role in the overall risk assessment process. They will also be free to evaluate unusually complex disciplinary assessments that would otherwise slow down the risk assessment team.

STAFF COMMENT: The re-design does not accommodate the production, transfer, and completion of (return) of "BEANS". Tracking of "BEANS" is awfully loose and clarification is needed as to how will break up of the package be coordinated.

DESIGN TEAM'S RESPONSE: The Design Team has determined that the ultimate production-transfer-completion of the "BEANS" is the responsibility of the Branch Chiefs. Since one of the responsibility of the Team Leader is to ensure that work is distributed and tracked within the team, he/she will help the Branch Chief in the "overall" tracking of the work in a Branch. The weekly meeting should be used for monitoring this process. If a data package that is submitted to one of the interdisciplinary branches needs to be "broken down" and sent elsewhere (contracts, etc.), the Team Leader will be responsible for the coordination of that effort by working closely with their counterparts in the other branch(s), that is, providing input or with the SWAM in the case of contract support. If a data package that is submitted to the disciplinary branches needs to be "broken down", then RCAB will be responsible for the production, transfer, coordination and completion of the data package since they will be working closely with the disciplinary branches.

STAFF COMMENT: Format for reviews in the re-design should be based on the documents produced by the PIRAT (i.e, use the PIRAT documents as the model).

DESIGN TEAM'S RESPONSE: The format for reviews should be standardized across the division is recommended by the Design Team and will be addressed by the Transition Team.

STAFF COMMENT: How are internal work requests initiated and monitored? (e.g., a request for a DRES run or statistical analysis).

DESIGN TEAM'S RESPONSE: The lead reviewer/scientist assigned to the task should initiate and monitor the internal work requests such as a DRES run, statistical analysis, contract support, etc. in cooperation with the Team Leader.

STAFF COMMENT: New hires should not go to the interdisciplinary branches (IDBs) as they do not have enough colleagues to train the new hires.

DESIGN TEAM'S RESPONSE: The IDBs should be fully capable for training the new hires since there are 4-5 scientists in these branches in each discipline (toxicology, chemistry, exposure). However, if the IDB is in need of special and/or additional training for the new hires, they could obtain this from the disciplinary branches. The Design Team did recommend that the disciplinary branches will serve as the "home base" for training the new hires, "keeping-up" with the state of the art of science, and professional advancement of the staff.

STAFF COMMENT: The final risk assessment document should go through IMCSB as is done for all other documents (Figure 5).

DESIGN TEAM'S RESPONSE: Figure 5 corrected was to reflect this..

B. STRUCTURE OF SCIENCE ASSESSMENT REVIEW PROCESS

1. Science Analysis Branch (SAB)

STAFF COMMENT: Lack of discussion of location of IRIS and external peer review and need to specify the location of the one-liner database.

DESIGN TEAM'S RESPONSE: The SAB, as it is currently now, will be responsible for the IRIS, external peer review, and the 1-Liners and SARC databases.

STAFF COMMENT: If special projects are done by the Policy Steering Committee (PSC) what is SAB going to do because they do special projects now?

DESIGN TEAM'S RESPONSE: As stated in the document (page 28), the PSC will only evaluate the scope of the special projects, determined the resources needed to accomplish the task and identify the HED (i.e., HED personnel) as well as other relevant members to complete the task. The PSC *per se* will not do the special projects. The projects will still be performed by the appropriate HED staff from all branches including SAB.

STAFF COMMENT: There is a need to clearly define the role of statisticians in SAB as to why we have them, why we need them, what type of statistical support we need, and how they will interact with scientists in the other branches, the SACs, and the SARCs in the risk assessment process.

DESIGN TEAM'S RESPONSE: The Design Team evaluated this and determined that the statisticians can interact with the various branches in several ways including: 1) help hazard assessors (toxicologists) to characterize hazard; 2) work with exposure assessors in Monte Carlo assessment; 3) be brought into teams doing risk assessments (early on in the process during team meetings) to provide statistical support and participate proactively; 4) interact with the toxicologists, pathologists and the Chair of the Cancer Assessment Review Committee (during the scope-out-meeting) to develop appropriate risk characterization methodologies; 5) provide this support for PHED, DRES and other systems requiring statistical support; 6) assist hazard, exposure and risk assessors on an *ad hoc* basis; and interact proactively with the SACs and SARCs.

STAFF COMMENT: Peer review processes did not allow for staffing in SAB.

DESIGN TEAM'S RESPONSE: The SARCs will have a chair and exec. secretary. While the exec.secretary will reside in SAB the chair may not. SAB has no other role regarding the SARCs.

D. STRUCTURE FOR RISK ASSESSMENT PROCESS

STAFF COMMENT: Need management involvement in scheduling and risk assessment products not currently in the plan.

DESIGN TEAM'S RESPONSE: Risk Assessment (RA) is part of the process, the schedule of which will determined at the weekly HED prioritization meeting. In addition, the Team Leader and the team will be involved in the planning, scheduling and coordination of the final product.

STAFF COMMENT: Need to clearly defined the procedures to get information on water from EFED and on residential exposure and common mechanism to complete risk assessments.

DESIGN TEAM'S RESPONSE: HED management and the Transition Team will work with their counterparts in EFED and other divisions in developing a process to get data from these divisions. Data on occupational exposure will be provided by the exposure scientists in the interdisciplinary branches since the risk assessment is a self-contained process for these branches and by exposure scientists in the disciplinary branches to RCAB that will be preparing the risk assessments. Data on common mechanism will be made available as early as possible in the risk assessment process, both to the appropriate teams and SARC (Mechanism of Toxicity Assessment Review Committee). SOPs should be developed as soon as possible for these procedures.

STAFF COMMENT: At which point in the risk assessment process is a request for statistical analysis triggered?

DESIGN TEAM'S RESPONSE: The need for statistical analysis of data can be triggered any time during the risk assessment process (i.e, primary, QC/QA, BSS, SAC, and SARC reviews, and/or scope-out meeting), during PHED and DRES runs, and development of risk characterizations.

E. STRUCTURE FOR POLICY/DEVELOPMENT AND SPECIAL PROJECTS

STAFF COMMENT: No mention of endocrine disruptors which will soon be a requirement of FQPA.

DESIGN TEAM'S RESPONSE: The design is flexible to accommodate new requirements. The PSC will be the driving force behind this.

V. BRANCH/OPERATIONS

STAFF COMMENTS: There were several comments which implied that the branch team operations description was too detailed and would not allow branch or team flexibility. One commenter appreciated the branch flexibility.

DESIGN TEAM'S RESPONSE: The Design Team did go into considerable detail on the operations which should be consistent across the division to gain consistency of division products. Within this general structure, each branch and team should have considerable flexibility to develop their own SOPs which should be tailored to the type of actions and the skill mix.

STAFF COMMENTS: Describe in more detail the team peer review process already in place in chemistry branches and PIRAT.

DESIGN TEAM'S RESPONSE: The SOP for this process will be developed by the respective branches. Staff can approach these current teams to get guidance if desired.

STAFF COMMENT: For reviews of new chemicals, screen toxicity studies and pick out those that will drive risk assessment (RA) to be reviewed first. Review those studies to get RA started, then other toxicity studies can be reviewed while RA is being completed.

DESIGN TEAM'S RESPONSE: It is beyond the scope of the Design Team to specify order of study review. Each branch should have the flexibility to develop their own SOPs for prioritizing study review for the most efficient operations. In addition, the decisions on work load will be determined by the during the meeting which will take place prior to initiation of a "task".

STAFF COMMENT: Need scientific support for reviewers when presenting to SARCs or outside peer reviews, registrants, etc. If the Branch Chief and the BSS are from a different discipline from that of the reviewer, where is the reviewer going to going get his/her scientific support? Right now it is being provided by the Section Head/BC.

DESIGN TEAM'S RESPONSE: The reviewer can draw support from the SAC member in his/her branch as well as experts in the disciplines during presentation of the data to the SARC and/or the outside peer review and registrants. Additional support can also be obtained from the Chairs of the SARCs and scientists from the other branches. The interaction between the scientists should be "boundary-less".

STAFF COMMENT: Need to make it clear in the design that it's okay for reviewers to informally cross Branch boundaries to get input on science/policy prior to BSS review, especially if the nature of the data in not in the BSS' area of expertise. There should be considerable flexibility at the branch level.

DESIGN TEAM'S RESPONSE: The re-design does provide considerable flexibility at the branch level and the interaction between the scientists in various branches should be "boundary -less". As stated earlier, following the primary review by the Lead Reviewer, the

Team will perform a QC/QA check. The review will then be submitted to the BSS for his/her review. If the BSS is not an expert in that particular field, then the BSS will consult with the member of the SAC in that discipline who is member of that Branch and/or a senior specialist in that field, either within the Branch or outside the Branch.

VI. ROLES AND RESPONSIBILITIES

Several concerns were raised on the lack of definition of "leadership" with focus on a possible conflict of interest between Division Director (DD), Associate Division Director (ADD), Branch Chiefs (BC), Branch Senior Scientists (BSS) and Team Leaders (TL). While BC is responsible for keeping reasonable work allocations for their staff, they are also under pressure from the senior level to achieve occasionally unreasonable goals. Therefore, the staff may not actually have fair and balanced workload, as the design appears to intend). The staff also wanted "definitions" for DD, ADD, BC, BSS and TL.

1. DIVISION DIRECTOR

STAFF COMMENT: Define the role of DD

DESIGN TEAM'S RESPONSE: The role of DD is defined as follows:

- Establishes and implements organizational vision of division (i.e., develops "big picture" focus).
- Develops division strategies and defines goals.
- Responsible for policy formulation and implementation associated with human health hazard and exposure to pesticides.
- Serves as representative/spokes person of pesticide programs with regard to human health issues and policy.
- Serves as second level manager to staff level personnel.
- Consults with and informs responsible Science Assessment Review and external peer review parties and senior scientists on policy issues.
- Supervises Branch Chiefs and ADDs.
- Division planning, priority setting, resource allocation and acquisition.
- Maintains contact with other division offices and external agencies
- Stays well informed with scientific issues
- Responsive to staff.

2. ASSOCIATE DIVISION DIRECTORS

STAFF COMMENT: Define the role of ADD

DESIGN TEAM'S RESPONSE: The role of ADD is defined as follows:

- Acts on behalf of DD, supports and works with DD on strategic and external issues, resource planning and allocation.
- Coaching staff on science as needed.

Associate Division Director 1

- Responsible for registration, risk assessment process, external peer review, information management and space.
- Consults and informs with division science assessment review and external peer review groups on issues.

- Represents the division at HED SARC meetings addressing registration because of cross-divisional policy implications.
- Represents HED at RD for external peer review for registration chemicals.

Associate Division Director 2

- Responsible for reregistration and special review, exposure assessment methodology, coordination and relationships with states/other countries (including Codex), budget, FTE planning and hiring.
- Represents the division at HED SARC meetings addressing reregistration and special review because of cross-divisional policy implications.
- Represents HED at SRRD for external peer review for reregistration and special review chemicals.

3. BRANCH CHIEF

STAFF COMMENT: The BCs will situate themselves in the science process, slowing it down and thus safeguards are needed to prevent excessive involvement of BCs in scientific issues. Scientist that are BCs are supposed to be managers first.

DESIGN TEAM'S RESPONSE: The BC is responsible only for managing the branch and as discussed earlier they do not have a role either in the data review or the QC/QA process (i.e., BC's signature is not required in the data reviews). The responsibility of science management is delegated to the team and the BSS. BC, however, will receive a FYI of all actions and review the action for to keep him/herself apprised of the conclusions/ recommendations of the action.

STAFF COMMENT: Define the role of BC

DESIGN TEAM'S RESPONSE: The role of BC is defined as follows:

- Resource allocation and acquisition
- Places major emphasis (70-80%) on managing people and resources.
- Has authority on all administrative and personnel matters
- Conducts performance management
- Stays familiar with the work of the branch so individuals can be coached as necessary
- Pro active with staff relationship; lets DD know when and where to interact
- Plays a pro active coaching role in scientific area in assisting members of the branch to develop scientific expertise, thinking skill, resourcefulness, and political skills
- As individuals, participate in scientific and policy projects based on individual expertise within the constraints of the time.
- Stays in close contact with the BSS on scientific matters
- Pro actively encourages inter-branch collaboration
- Functions as team member on management team
- Participates in meetings upon team's request or if a member needs coaching

For additional roles and responsibilities of the BC refer to Chapter VI. Roles and Responsibilities in the document.

4. BRANCH SENIOR SCIENTIST

STAFF COMMENTS: Will there be two BSS (one for each discipline) in interdisciplinary branches? How will BSS in interdisciplinary branch look at DER's of other disciplines? If a branch can not be self sufficient, it will be dependent upon getting expertise from other branches and slow work down.

DESIGN TEAM'S RESPONSE: The Design Team does not recommend two BSS because, then another "layer" has to be created to ensure that there is consistency between the two BSSs (i.e., consistency for interpretation of results, science policies, regulatory decisions, etc.). To address the concern as to how a BSS in a interdisciplinary branch who is not familiar with the discipline will function, the Design Team recommends the following: after the QC/QA, the review will be submitted to the BSS for his/her review. If the BSS is not an expert in that particular field, then the BSS will consult with the member of the SAC in that discipline who is member of that Branch and/or a senior specialist in that field, either within in the Branch or outside the Branch. There must be considerable flexibility at the branch level and the interaction of scientists is "boundary-less".

STAFF COMMENT: Define the role of BSS

DESIGN TEAM'S RESPONSE: The role of BSS is defined as follows:

- Provides QC/QA function for the branch
- Signs off on data reviews and disciplinary science chapters
- Provides support to the staff at SARC and other presentations
- Interacts with the SAC member within the branch and other branches
- Maintains close contact with the Branch Chief on science and policy matters
- Maintains close contact with fellow BSS's, ADD's and DD
- May serve on SAC or SARC

STAFF COMMENT: What will be the criteria for selecting BSS? Will they be rotated? Should each branch follow the same procedure?

DESIGN TEAM'S RESPONSE: The criteria are as follows:

- Must be technically sound and competent
- Should be good at dealing with people and capable of coaching
- Not a specific grade (i.e., independent from GS description of grades)
- Appointed from within the branch (i.e., BC may decide on how to handle this)
- Recommend that this be a rotational so the "role" does not develop into a hierarchy
- Branch input may be used in the selection
- Procedure in selection should be similar among branches, however, it can also depend on the specific requirement of a branch
- Does not handle performance management

5. TEAM LEADER

STAFF COMMENT: Define the role of TL

DESIGN TEAM'S RESPONSE: The role of TL is defined as follows:

- Distributes and tracks work assignments and monitors the activities of the team
- Coordinates and facilitates of team meetings
- Provides means for actively participation of every team member including him/herself
- Does do the work of the team (i.e., reviews data)
- Promotes positive team interaction
- Coordinates all primary reviews, QC/QA, SAC reviews, *ad hoc* SARC input, etc.
- Interacts with the BC and BSS
- Maintains close contact with fellow TL's in other branches
- May serve on SAC or SARC
- Does not handle performance management

STAFF COMMENT: What will be the criteria for selecting TLs? Will they be rotated? Should each branch follow the same procedure?

DESIGN TEAM'S RESPONSE: The criteria are as follows:

- The team recommends and the BC approves the 2 primary teams in a branch
- The team can select TLs for "mini' teams, BC need not approve
- Should be good at dealing with people and capable of coaching
- Not a specific grade (i.e, independent from GS description of grades)
- Recommend that this be a rotational based on the needs of the branch/BC
- Branch input may be used in the selection
- Procedure in selection should be similar among branches, however, it can also depend on the specific requirement of a team/branch

6. TEAM MEMBER

The role of Team Member, although not included in the document, is defined as follows:

- Accountable for quality and productivity of team's work
- Volunteers actively and instills positive attitudes
- Mentors and provides positive/constructive feed back to team members as necessary
- Promotes positive team interaction
- Interacts with TL, BSS, SAC and SARC members as well as members in other branches
- Supports professional development of other team members

STAFF COMMENTS: Several staff members also raised their concern that the redesign has "too many roles" (i.e, BC, BSS, TL, SAC and SARCS) and "too much of the responsibilities" given to these roles that actually dilutes and/or diminishes staff empowerment.

DESIGN TEAM'S RESPONSE: The Design Team has concluded that the re-design does embed empowerment. How in the re-design the staff is empowered when compared to the "existing system" is shown below for some of the "functions" of the HED.

FUNCTION	FROM (Existing)	TO (Proposed)	EMPOWERMENT
Production of a HED "product" (e.g., data review)	Staff	Staff	--
Secondary Review of "product"	Section Head (Management)	Team Review (Staff)	QC/QA by team
Tertiary Review of "product"	Branch Chief (Tox) Senior Scientist (Chemistry) (Management)	Branch Senior Scientist (Staff member)	Final QC/QA and sign-off
General decision making (e.g, work assignments in a branch)	Management	Staff	Team input
Preparation of Risk Assessment	Staff	Staff	--
"Peer" Review Process	Management	Staff	QC/QA by team
Committee Membership	Primarily Management	Primarily Staff	New selection process with staff input
Opportunity to work on Special Projects	Hand picked by Management	Policy Steering Committee (Staff)	PSC will select team members to work on projects
Performance Appraisal Input	Management	360° (staff, management & customer)	New process

The Design Team strongly believes that the BSS is a value added position that will play a major role in the immediate future (6-9 months). It is anticipated that the role of the BSS will change over time as the Division/Branches/teams becomes more proficient in the functioning of the new design. The Design Team also strongly believes that the SACs are a value added position because data produced by scientists spread among six different branches must be reviewed by a centralized group (SAC). Even if this gives the impression that this is an added layer, this layer is absolutely necessary to maintain consistency in interpretation of results, assumptions used, application of science and regulatory policies and recommendations made across the six branches.

STAFF COMMENTS: Several staff members also raised their concerns on the available resources in HED and its impact on the re-designs. Their concerns were that: 1) the discipline is "diluted" by being spread in too many branches, how will skill mix and level of skill mix be accomplished within a with emphasis on and review committee meeting, and will the scientist have time to do their own

analysis and reports as well as prepare/participate in all the meeting adequately; 2) having the staff being spread too thin (data review - team review - team leader - BSS - preparation of risk assessment - SAC - SARC) may cause possible backlogs and/or shortage of staff and 3) IMCSB does not have sufficient staff to perform all the functions assigned to this branch.

DESIGN TEAM'S RESPONSE: The Design Team concluded that:

1) the Branch Chief has to evaluate the skill mix, resources in their branch and identify the "gaps" and "needs" and initiate a process to resolve them. This can be accomplished either by getting "help" from the other branches, using the missions support contract and/or requesting additional resources. It is also the team's responsibility to ensure that adequate resources are available both in the teams and thus in the branch to perform the duties.

2) The roles and functions designed has to take place for the design to be successful. The Branch Chief, with the help from the Team Leaders as well as the team, has to monitor workload allotments as well as time spent by staff on SAC, SARCs, special projects and "other activities". The Design Team's proposals are based on the current FTEs in the Division. The prospect of obtaining additional resources (new hires) should address this concern.

3) The Design Team is aware that IMCSB does not have the adequate resources at the present time; however, new hires should resolve this concern.

VII. PHYSICAL SPACE ALLOCATION

The staff raised several concerns regarding space, their preference to sit with the discipline, make the number of moves as minimal as possible and the desire to not move at all. Part of the reasons for this preference was the desire not to move, being tired from packing up and moving too many times for the painting and carpeting, etc.

DESIGN TEAM'S RESPONSE: The Design Team has come up with two additional options and a recommendation which will allow disciplines to sit mostly together, but also keep branches together.

Option 1: Two similar branches will be mixed together, with the individual disciplines clustered within the two combined branches (RR1 & RR2 together, RAB1 & RAB2 together, CEB1 & CEB2 together, TOX1 & TOX2 together) (Figures are in the document).

Option 2: The disciplines will sit together within one branch and the adjacent (second) branch will have the toxicologists from that branch sit adjacent to the toxicologists from the first branch. The chemists and O/R exposure scientists from the second branch will be adjacent to the chemists and O/R exposure scientists from the third branch, etc. (Figures are in the document)

The pros and cons of these two options are as follows:

Pros:

- compromise space plan between sitting solely by discipline and solely by branch
- closer interaction within a single discipline than if branch members were mixed up, to help ensure scientific integrity
- promotes interaction better than sitting strictly by discipline
- the 2 branch together model promotes similar handling of similar actions

Cons

- need to consider the possibility of the division being on 3 floors.
- there is still splitting of the scientific disciplines, making consistency more difficult

STAFF COMMENT: Poll staff for their preference: to sit by discipline or by branch. Reasons given for disciplines sitting together was for scientific integrity. PIRAT works will together, despite sitting apart.

DESIGN TEAM'S RESPONSE: The options discussed above are a compromise, keeping disciplines together within similar branches. An interdisciplinary branch with 15 staff can not be compared to the PIRAT with fewer staff members.

STAFF COMMENT:: If we sit by discipline, then branch members may be on two floors--this would not be a good idea.

DESIGN TEAM'S RESPONSE: The options discussed above keeps branches together on a single floor, while keeping disciplines within similar branches together.

STAFF COMMENT: Modern technology allows us to work together without sitting in the same office. Need to sit by discipline instead of by interdisciplinary branches. Don't spend so much time together as a small group--need time apart to think and avoid too much in-breeding.

DESIGN TEAM'S RESPONSE: The options discussed above are a compromise, keeping disciplines together within similar branches.

STAFF COMMENT: Who's watching out for our space which is being taken by RD?

DESIGN TEAM'S RESPONSE: Space is being re-negotiated, according to Dan Barolo. OPP will get an additional floor or so, which he is allocating. MSD are watching out for HED needs.

STAFF COMMENT: We should move just ONCE, keep staff located as present to minimize the number of changes, and just move as few people as possible. The move should be delayed until we really know what we need.

DESIGN TEAM'S RESPONSE: The Design Team recommends this if possible.

STAFF COMMENT: Where will staff meet? One meeting room for every 2 or 3 branches should be sufficient. Use Branch Chief Offices for meeting space.

DESIGN TEAM'S RESPONSE: The Design Team is recommending 1 meeting room to be shared by 2 branches. The recommends that the Branch Chiefs make their offices available for meeting space when they are away in meetings.

STAFF COMMENT: Interdisciplinary roommates are not efficient and not promote consistency within disciplines.

DESIGN TEAM'S RESPONSE: The options recommended above has the disciplines within types of branches sit together (e.g., Chemists in RR1 & RR2 together, Toxicologists in RR1 & RR2 together, Occupational/Residential Exposure Specialists in RR1 and RR2 together, and the same for RAB1 & RAB2, for CEB1 & CEB2, and for TOX1 & TOX2).

STAFF COMMENT: Have three person rooms be all flexiplace staff so that only two work stations are needed.

DESIGN TEAM'S RESPONSE: This "approach" should be left up to the Branches involved.

STAFF COMMENT: Map showing three branch chiefs sitting together is confusing.

DESIGN TEAM'S RESPONSE: Agreed. The map showing the three branch chiefs together was done just for the purpose of counting spaces, and was not intended to be a seating chart.

STAFF COMMENT: Discussion of lactation room is inappropriate.

DESIGN TEAM'S RESPONSE: This discussion will be removed from the document.

STAFF COMMENT: Add a training room to our space requirements. We need to have the ability to train a lot of people quickly, especially for the risk assessment tools software. It should be specific to HED.

DESIGN TEAM'S RESPONSE: HED has a conference room available. This should meet most of HED's training needs. For computer training, IRSD has a computer training room, which HED should be able to use.

STAFF COMMENT: Should specify space within each branch for a small library (e.g., bookshelves in Chemistry with discipline-specific books.

DESIGN TEAM'S RESPONSE: At the present time, the HED library does not have sufficient space to store all of the reference books from all of the libraries. There will be several branches dedicated to each discipline, plus the interdisciplinary branches, all of which have the different disciplines. The recommendation is still for an HED library. But a listing of the reference books available in each branch, plus the HED owned books and other reference materials in individual offices should be compiled for everyone to use.

VIII. HUMAN RESOURCES

Staff concerns on Human Resources were focused on three major areas: 1) performance management, 2) compressed work schedules/flexiplace and 3) training. Since most of the concerns revolved around similar themes, they are summarized with the Design Team's response. The Chapter on Human Resources has been modified to address these concerns.

1. Performance Management - 360 Evaluation

STAFF COMMENTS: Many people commented on the 360 evaluation system. Some of these commenters did not feel they could comment on the system itself because they did not understand how it would be designed and implemented. Several people thought it would be bad for morale, particularly if it was completely confidential and an individual would be unable to respond directly to a person providing a poor evaluation. The term "popularity contest" was used by several commenters. A few people questioned the legality of such a system.

DESIGN TEAM'S RESPONSE: A 360 evaluation system means that everyone, particularly an individual's team, will have an opportunity to provide constructive criticism and comment on positive performance factors, but that the supervisor of record is responsible for the evaluation. The evaluation of an individual by the team should be a fair and open process. The evaluation by the team should be incorporated into an individual's annual review, but the contents of the evaluation should not be a surprise, because the team should be evaluating itself at regular intervals throughout the year. Teams should be trained in how to do this effectively so that it doesn't destroy morale or turn into a popularity contest.

2. Compressed Work Schedules/Flexiplace

STAFF COMMENTS: Several staff members were of the opinion that the Design Team's recommendations on flexiplace, flexitime, and compressed work schedules were too restrictive and contradictory to the Design Drivers. A few members commented that staff abused these tools and they should no longer be offered while some thought that the recommendations did not ensure adequate coverage in the branches, especially on Fridays!

DESIGN TEAM'S RESPONSE: Greater flexibility should be given to the branches on staff selection of compressed and flexiplace days. It is the branches responsibility to ensure that the there is adequate coverage in the branches on commonly used compressed and flexiplace days, ensure that team meeting days are coordinated within the team, and allow some individual flexibility to ensure that these tools are used effectively and that any abuses are addressed in a timely manner. The document has been modified to address staff concerns.

3. Training

STAFF COMMENTS: Several staff members emphasized the need for training on all aspects of risk assessment and risk characterization. One member wanted training on effective meetings while another commented that training should be consistent across branches. Some were concerned with the why, how, and when of training: for example, how are we going to get it done effectively when we have a large backlog and will the inter-disciplinary branches have sufficient depth to train new

hires within the discipline.

Many positive comments were received on the training recommendations - having a 1/2 FTE coordinator from IMCSB and PSC involvement in training.

DESIGN TEAM'S RESPONSE: The Design Team has provided further explanation on the type of risk assessment training needed, as well as other skills which require development. The Transition Team will be faced with the challenge of ensuring that the necessary training recommendations will be implemented.

4. Miscellaneous Items

STAFF COMMENT: Have the changes in roles and activities (pp. 53-60) been reviewed by personnel and the UNION for any change in job working conditions?

DESIGN TEAM'S RESPONSE: A Union member served on the Design Team to address any specific concerns.

STAFF COMMENT: Need for dual career track so scientists can move up and stay in science to maintain scientific credibility.

Strengthen recommendation that a dual career track should become a reality. If we cannot do it at the OPP level, MSD should do what they can at the HED level.

DESIGN TEAM'S RESPONSE: The Transition Team will have to work with MSD and the branch chiefs to implement the dual career track recommendation to the extent possible.

STAFF COMMENT: One staff member was very concerned that a team based organization, the human resources recommendations, and particularly the performance management system, will not allow recognition of the best and brightest individuals. The member concluded that the end result would be development of mediocre staff in HED.

DESIGN TEAM'S RESPONSE: The Design Team agrees with the staff member that management should foster and develop individuals to the best performance possible. Staff members will work with their supervisors to develop individual development plans. Various mechanisms were recommended to ensure that all staff have training and development opportunities. While individuals will be working in teams, individual performance evaluations and awards (monetary or otherwise) will be a means to recognize the highest-performing staff. The section on the performance management system has been modified to address the commenter's concerns.

STAFF COMMENT: One commenter wanted to see empathy added in the section on criteria for good supervisors.

DESIGN TEAM'S RESPONSE: The document has been modified to reflect this.

STAFF COMMENT: After the design phase, will each branch have a new functional statement or new mission statement?

DESIGN TEAM'S RESPONSE: The Transition Team will evaluate this need for a new functional statement for each branch.

STAFF COMMENT: HED should develop a contingency plan for addressing lack of buy-in from staff, and particularly other divisions where we request their participation in our process.

DESIGN TEAM'S RESPONSE: The Design Team determined that the Transition Team will develop a "Performance Measurement Plan" and evaluate 1) if we are getting the input from the staff, customers and other divisions and 2) if the input is making a difference in HED's process. Results of this evaluation will inform us if the process is beneficial or needs modifications.

IX. COMMUNICATION AND DECISION MAKING

STAFF COMMENT: Attendance at purely social functions should not be required. The ability to party is not a job requirement and cannot be held against those who choose not to party.

DESIGN TEAM'S RESPONSE: The design team's intent was to encourage social gatherings as a means to promote greater communications between individuals and stronger relationships within HED. Attendance as such events would be voluntary.

STAFF COMMENT: How does design ensure communication between HED, registration, and reregistration staff and registrant

DESIGN TEAM'S RESPONSE: The Design Team agrees that such communication is critical for OPP to operate efficiency and effectively. The division design team proposed having the OPP chemical team (i.e., including risk management and risk assessment team members) meet frequently during the process. The Transition Team will propose the system for such meetings to occur. The registrant will also be included in the risk assessment process by submission of their risk assessment (with labels) and subsequent meetings as necessary with the registrant, during the data review process.

STAFF COMMENT: Standard times for branch and team meetings are needed to aid in the scheduling process

DESIGN TEAM'S RESPONSE: The Design Team agrees. Due to limited meeting room space available, standard meeting times/places will be necessary.

STAFF COMMENT: It appears that too much time will be spent in meetings. A greater balance is needed between meeting time and work.

DESIGN TEAM'S RESPONSE: The Design Team acknowledges that the proposed division re-design does indicate a greater frequency of meetings. As HED moves toward a team approach, more meetings may be needed, specifically at the team level. In addition, more meetings will be necessary due to the development of new committees (eg. SAC and PSC). However, other committees such as the SARC subcommittees will be meeting with similar frequency as occurs now. Even though overall meeting times and frequency may be increasing, this will be compensate by increased consistency and effectiveness in decision making and work processes.

STAFF COMMENT: Time is needed to prepare for teams and meetings

DESIGN TEAM'S RESPONSE: The Design Team considered time needed to coordinate and prepare for team/committee meetings under the administrative support activity in the roles section of the re-design proposal. This responsibility will be included for each role defined in the re-designed organization.

STAFF COMMENT: Weekly reports are needed for team and individual outputs.

DESIGN TEAM'S RESPONSE: Reports of significant branch outputs will be provided in the respective branch weekly reports.

STAFF COMMENT: Communication should be standardized. How communication is improved should be specifically discussed.

DESIGN TEAM'S RESPONSE: The Design Team's proposal highlighted approaches to improve communication both internally and externally. In addition, the design team proposed the development of SOP's for distribution of work products.

STAFF COMMENT: Reviewers should be to allowed to informally cross branch boundaries to receive input on science/policy prior to BSS review.

DESIGN TEAM'S RESPONSE: The design team agrees and encourages such activity as addressed in the culture section of the re-design proposal.

STAFF COMMENT: A central mechanism is needed for communicating priorities from the division level to all members of HED on a regular basis.

DESIGN TEAM'S RESPONSE: The Design Team agrees. This suggestion is addressed by the establishment of the Master Scheduling System to prioritize and schedule work assignments. Updates of these reports will be provided by the Branch Chiefs, working as a team, at weekly HED management meetings.

X. PLANNING, GOAL SETTING, BUDGET, WORK ASSIGNMENTS

1. MASTER SCHEDULING

The Design Team proposed a central Master Scheduling System for the Division which would: 1) aid in determining which chemical goes where based on the chemical distribution plan; 2) serve as the master division schedule for all actions and projects for registration, reregistration, special review and other projects and 3) include progress in the review process (i.e., when the chemical is scheduled for a SARC or SAP) and reasons for deviations from previous schedules. Data for this schedule would be supplied by the individual Branch Chiefs.

STAFF COMMENTS: Several staff members commented that not enough details were provided on this system.

DESIGN TEAM'S RESPONSE: The Design Team evaluated these comments and determined that the Transition Team will "define" the process (i.e., the need for it and how it will be used). Also, the Design Team changed the name of this system to "Master Schedule System" because, 1) it is basically a system than maintains the schedules (rather than tracking) and 2) to avoid confusion with the "tracking" done by PRATS.

2. WORK ASSIGNMENTS

The Design Team proposed two Work Assignment Managers (WAMs) for each contract; an Administrative WAM (AWAM) to handle administrative matters and a scientific WAM (SWAM) to deal with the technical aspects of the work assignments. A number of responsibilities were listed for these WAMs.

STAFF COMMENT: One staff member suggested that the SWAM should assist IMCSB in preparing work assignments and Requests For Proposals (RFPs) as well as reviewing proposals and responding to questions raised by the Contracting Office (CO) regarding expenses incurred by the Contractor such as the use of certain equipment, literature search costs, etc.

DESIGN TEAM'S RESPONSE: The Design Team has determined that the WAMs in the existing structure do assist in the preparation and review of RFPs (as stated in the document, page 97) as well as assist the Project Officer in all aspects of the contract.

STAFF COMMENT: One staff member commented that on the location of the SWAM and what effect that would have on prioritization of work (i.e, how will the SWAM located in one branch prioritize work from different branches ? - will the SWAM give priority to work coming out of his/her Own branches rather than the other branches?).

DESIGN TEAM'S RESPONSE: Location of the SWAM should not have any impact on the priorities. Priorities will be established by the Branch Chiefs at their week management prioritization meeting to balance workload and requirements for contract support.

STAFF COMMENTS: One staff member suggested that there is a need to develop a plan for contract management across branches.

DESIGN TEAM'S RESPONSE: The Design Team has concluded that the Project Office in IMCSb will work with the AWAMs and SWAMs to develop a plan as soon as the Design Team is implemented.

STAFF COMMENT: One staff member needed clarification on the number of SWAMs.

DESIGN TEAM'S RESPONSE: As stated in the document, there will be ONE SWAM/CONTRACT; residue chemistry, occupational/residential exposure and toxicology.

STAFF COMMENT: One staff member needed further clarification on roles of AWAMs and SWAMs and they should prepare work assignments.

DESIGN TEAM'S RESPONSE: SWAMs will be responsible for preparation of work assignments as done in the existing system.

XI. TOOLS AND TECHNOLOGY

STAFF COMMENT: WordPerfect 5.1 is adequate for HED's needs. Upgrades to Windows and WP 6.1 are not necessary and place a burden on the reviewers.

A strong attempt to upgrade our computers within HED should be made. [Note: In support of this statement, the commenter provided results of the OPP PC survey, which showed that a number of HED employees considered their 486 PCs inadequate to do their work, at a time when the predominant type of PC within HED and OPP was a 386.]

DESIGN TEAM'S RESPONSE: Although many people are happy with the word processing capabilities of WordPerfect 5.1, including many members of the Design Team, the Agency Standard for word processing is WordPerfect 6.1, and any documents transmitted to the Assistant Administrator must be in WordPerfect 6.1. There will be a short learning curve to learn the new software, however, once HED staff see the capabilities of WordPerfect 6.1, they may be less reluctant to switch. These capabilities include:

- easier copying from one document to another and from other types of files, such as spreadsheets and databases; and the ability to have 9 documents open at the same time
- easier to share documents in different formats, such as Microsoft Word documents used by most of Corporate America.
- easier to switch from one program to another, as might be needed to check information needed for use in your document.
- additional features of the updated program

STAFF COMMENTS: Files must be kept organized across discipline and branch. Electronic filing and record keeping will be critical. Keeping old files to help complete records is a good idea. Limit or monitor access to paper files to protect their integrity.

Files in the central file room should be arranged by chemical and then by discipline. There should be consistency in the way the files are named - either by chemical name or by code.

Electronic copies stored on the LAN should include the date the document was signed as part of the document.

There is nothing that addresses current Branch files and databases that are utilized by one or more branches.

How do we decide on essential files such as those shared by Branches such as cultural practices file and the Ag Census volumes?

Who will decide and how will it be determined what databases are added for our use?

DESIGN TEAM'S RESPONSE: The Design Team concurs that electronic filing is critical. The organization of the electronic and paper files kept by chemical received a lot of consideration by the team. The driving factor for the Design Team's recommendation was the difference in the degree of archiving which has already been done on the existing paper files in the different disciplines. The TOX files are currently being microfiched. Some of the chemistry files are microfiched, but the microfiched copies are not complete. None of the OREB files have been microfiched. None of the RCAB (Risk Assessment) files have been microfiched. Considering the different amounts of archiving which have been done on the various files, it was felt that keeping the disciplines separate was best for the time being.

The special files, including the chemistry petition files, the cultural practices files currently maintained by chemistry, the AgCensus volumes currently kept in OREB, the literature references kept by OREB, and other similar files will need to be available to everyone. So these files will need to be kept in a central location.

The Design Team agrees that the date of the memo (or sign off) should be included in the electronic file. There are several ways to accomplish this. One would be to include the date electronically at the top of the memo, as was recommended by the Science Review Documentation Workgroup. Another way would be to include the sign off date at the bottom of the memo as is currently done by TOX. Another way would be to include a concurrence line at the bottom of the memo as is currently done by Chemistry.

The Design Team agrees that databases should be available to all division staff who need them. If additional databases are identified to which HED staff need access, the Division Computer Specialist and the Branch Chief should be informed, so that the need for the database can be evaluated.

STAFF COMMENT: Rephrase the statement on page 110 about the HED staff lacks certain qualifications.

DESIGN TEAM'S RESPONSE: The statement will be rephrased to indicate that we need additional staff with these types of expertise.

STAFF COMMENT: Need a greater emphasis on electronic submission of data. Considerable emphasis is placed on requiring registrants to submit data via electronic format. Is it really feasible at this time or will it be phased in?

DESIGN TEAM'S RESPONSE: Agreed. Electronic data submission is feasible, but the process for accepting electronic submissions is not completely worked out. Equipment for producing CD-ROMs if commercially available at reasonable cost (< $1000). OPP computers are expected to have CD-ROM drives in the near future, enabling the reviewers to read data submitted on CD-ROM. The electronic submission of data will not be mandatory, but rather encouraged. Some of the registrants will not have the capability to provide submissions on CD-ROM. The registrants have a number of concerns regarding the electronic submission of data, including their desire that the files they submit will not be changed, and the fact that most of the registrants use Microsoft Word and other Microsof software, rather than WordPerfect. Submission by CD-ROM will provide unchangeable files. The exact formats for the submission will still need to be worked out. IRSD (PMSD) has been moving forward with a plan to implement the CADDY system for electronic submission, which is being

developed for the European Community primarily to reduce paper. The CADDY format includes graphics files in the TIFF format for all of the pages of the submission. CADDY does allow additional files to be included on the CD-ROM, but this portion of the system does not seem to be emphasized by IRSD. The emphasis seems to be on how to assign the MRID numbers to the submission so that the files are named by MRID number as has being done by PMSD since June 1996 when they stopped microfiching the submissions and began putting them on CD-ROM.

STAFF COMMENTS: Access to open literature should be decentralized and made available to designated contact persons (who are trained) within each branch.

How will literature searches be handled under Information Management Branch? Before we had an HED INFO QAT.

DESIGN TEAM'S RESPONSE: The Design Team considered access to open literature and recommended that a single person within IMCSB be available for conducting literature searches. It is more efficient to have a professional searcher who is more proficient at structuring and refining searches and choosing the appropriate databases to search. The literature searching skill is one which needs to be maintained or it is lost. This recommendation does not preclude the possibility that some branches will have a large need for literature searching and have their own person available to conduct the searches. But to have 11 people trained to conduct literature searches, and then to have them do enough searches so that training isn't forgotten might be difficult.

STAFF COMMENT: Toll-free telephone numbers should be established for voice mail and ONLAN to accommodate employees that occasionally or routinely work from home or need access while on travel.

DESIGN TEAM'S RESPONSE: Agreed. This will be added to the document. An alternative would be telephone credit cards issued to employees much like the American Express cards issued for travel.

STAFF COMMENT: How will DRES and PHED runs be initiated and who will do them? Who will maintain the databases for DRES and PHED?

DESIGN TEAM'S RESPONSE: The DRES database will be maintained by Chemistry and Exposure Branch I. The PHED database will be maintained by Chemistry and Exposure Branch II. Individual assessments by DRES and PHED will be conducted in the six branches performing exposure assessments. It will be their responsibility to forward the results and the resulting chemical specific data files to CEB I or II, as appropriate. The Design Team recommends that the Branches conducting exposure assessments assign two people in their branch to perform the DRES analyses and two people to perform PHED analyses. This recommendation is based on the experiences of the PIRAT, who found that a certain amount of proficiency was required to perform the analyses accurately and efficiently. Both DRES and PHED have a number of intricacies which require practice to maintain. An SOP is needed for conducting DRES and PHED analyses, and for capturing and archiving the resulting data files.

STAFF COMMENT: Who will do DRES runs in interdisciplinary branches? Who will QC/QA DRES runs? Who will enter status (pending, published, etc.) of tolerance in database?

DESIGN TEAM'S RESPONSE: DRES analyses result in the need to update the central database. Maintenance of the integrity of the central database is critical to the accuracy of future assessments, each of which builds upon the last. As such, it will be incumbent upon staff conducting analyses to forward the results and interim data files to the gatekeeper in CEB-I. CEB-I will be responsible to maintain the files and system, perform complex analyses as needed, upgrade the system overtime, including introduction of new data, and train new staff.

STAFF COMMENT: Provide more details on PHED issues

DESIGN TEAM'S RESPONSE: The operation and maintenance of PHED in the new division will be managed by CEB II. The Agency relies heavily on this database to conduct risk assessments for REDs, Section 18s, 24Cs, and Section 3 actions. With the current database manager pursuing other interests in CEB I, and with handler exposure assessments to be conducted by six new branches, interim guidance for new PHED users is highly recommended. Improper use of the database can result in wildly varying exposures estimates. Furthermore, the database is being upgraded with a new version 2.0 to be released sometime in the future. Based on discussions with the current manager, the following items are recommended for the design and transition teams to consider:
An Exposure Scenario Table: The current manager is developing a table to present well documented PHED runs representing the range of scenarios in the database. It is suggested that these be used for exposure assessors conducting risk assessments for Reregistration Eligibility Decisions, Section 18's, and 24C's. The use of the table will result in more timely, consistent and defensible assessments. The scenarios to be presented in the table are more general than a highly refined individual run. However, for the more important scenarios (mixer/loaders, ground-boom and airblast applicators) there are more replicates in the general runs. The table will be accompanied by a print-out of the PHED runs supporting each scenario presented in the table. Users of the table are strongly urged to review the accompanying PHED runs to determine which type of personal protection equipment to recommend if risk mitigation is required. Review of the run will provide insight regarding the patterns of exposure for the individual PHED run. For Section 3's, a more refined/custom run is recommended. This is because many Section 3's use much lower rates and are liquids. The database is more robust for liquids than any other formulation type. The custom runs require a savvy user of the database.

It is recommended that CEBII develop two PHED managers, one for internal needs and one for external needs. Internal needs include the ability to perform custom runs and review registrant submissions, which vary according to the skill of the submitter. OREB experience has indicated many submissions are incorrect. External needs include interfacing with the PHED Task Force consisting of representatives of Cal-EPA, Health Canada, industry, and increasingly OECD. Tasks will include the QC/QA of the new version (PHED 2.0), generation of reference manuals, addressing the issue of data compensation, and addressing NAFTA issues. However, many of the NAFTA issues have been addressed. Lastly, the CEBII personnel should work with representative from the other division users as a work group. That is, each branch conducting exposure assessments should have a PHED representative who will periodically meet with the mangers in CEB II to develop the skill of a greater pool of individuals using the database.

STAFF COMMENTS: Shouldn't we also recommend working closely with BEAD to improve LUIS reports that really satisfy the needs of each HED discipline? I think renewed effort on HED's part if warranted, considering the cost of the system so far and the fact that it has become more sophisticated over the last several years.

DESIGN TEAM'S RESPONSE: Representatives from HED have been actively participating n a LUIS enhancement project. The Design Team believes this current participation will continue to ensure the needs of each HED discipline are met in the new organization.

XII. CULTURE

STAFF COMMENTS: work may be the building block of HED, but there must be a way to recognize the brightest and the best. Every one is capable of doing good work. But, some staff are simply more capable or have more areas of competency. It could be that they work harder than others, try harder and put in extra hours. Doesn't this deserve to be rewarded? How are you going to mentor the future senior scientists and branch chiefs if there is no reward for doing more, or doing it better? If there is no reward for being the best, if you are held to the level of the team, then the best will leave for other divisions and offices where they can be rewarded and promoted. Do you want staff in HED to be just average? Do you want to always go out of the division for vacancy announcement selections because the highly qualified are not in HED? There has to be a system that (1) rewards the cooperative work and thanks those who do their job and nothing more, but also (2) advances and grooms those who are willing and have a bit more to offer.

DESIGN TEAM'S RESPONSE: Concern about continued ability to demonstrate outstanding individual performance in a setting and the impact of activities on individual performance are understandable. However, experience on the PIRAT and the chemistry teams suggest that individual performance is often enhanced by participation in a team, because more people are scrutinizing work performed and there is a greater tendency to try to do it right the first time. In addition, opportunities to demonstrate individual excellence will also not disappear. Individuals who develop unique and creative approaches and solutions to problems will continue to be recognized. Participation in work groups and committees will provide opportunities for recognition in areas other than review. Finally, performance as team leaders and members of committees will give staff the opportunity to develop leadership skills, learn how to implement ideas and deal with projects.

MISCELLANEOUS ITEMS

The Design Team appreciates the following comments. Responses would be beyond the scope of our charter but we thought it was important to include them here:

- I did not appreciate the "election" process. I prefer that members of a group that are tasked with a job as important as this one be serving due to merit and ability, not as the result of a popularity contest in which they campaigned to have write-in votes. I would have liked a balanced group - a mixture of introverts and extroverts, people who have worked in HED for 2 years and people who have worked in HED for 15 years, people who have worked in HED only and people who have worked in other offices and agencies and the private sector. I would also suggest that participating as a member of the HED design team should have meant that the individual would be remaining in HED and living with what they helped to create, not going to another division.

- The basic concept of doing away with section heads is flawed. The basic instructions to the were in error. Who is going to stand up and accept blame when some new product gets on the market that has major hazards not identified because the first and most important peer review level has been eliminated and people, thousands, are injured? Where will the buck stop? At the AA level? At the Division level? At the Branch Level? At the level? At the empowered individual level? Will I assume blame if an exposure issue is not assessed properly?

- The structure is flawed. HED should be divided into three divisions. There is too much emphasis on behavior modification. Popularity will become important in the environment, there will be social peer pressure: the quality of the science should remain the primary factor in performance reviews. Eliminate SAB RCAB IMCSB. Everyone in division should help review data.

- Section heads appear to have been replaced by committees. This seems less efficient.

- Process needs rethinking. The constraints under which the functioned are inappropriate, especially elimination of the section heads.

- IMCSB/SAB are not really necessary.

- The division should be all disciplinary or all interdisciplinary, but the plan gives staff options to work in both systems.

- Are we really addressing public health in the document? The American people are our ultimate customer - should they be able to review the design? Also in getting input from customers in performance management we meet with registrants but not with public. They are the ultimate customers. (This biases the process towards speedy reviews and away from careful reviews.)

- Need to address external EPA relationships particularly congress and the public.

- "Pirat" - ization run amok. Higher management should recognize that the success of PIRAT and other pilot programs should be shared because all of HED helps to support PIRAT.

- I do not believe that there should be confidentiality of input from other members, etc. If the results are to be rolled into a document that becomes part of your permanent record, then you have a right to know who was displeased with your performance and why. You have the right to give your side of the story (something in the Constitution about facing your accusers). You cannot if it is all an anonymous print-out that has sketchy details and you have no idea how, when, where and under what circumstances. What about honesty and trust? You could believe that you are pulling your share and then feel that the team has stabbed you in the back. That instead of trying to work it out in the team, instead of using all those communication skills that we are going to be trained in, that the would just type some anonymous comments. If a person who is displeased, is not willing to stand up and give specific incidents of how someone else on the is a poor performer, then it is not real information that can be used against you to deny you awards, bonuses, or promotions. I'm not sure that this is all legal and suggest that this be checked against Title 5.

- Performance appraisals by other than technical experts in the reviewer's own discipline can not be valid. The 360 degree review process will be nothing but a popularity contest.

- We should consider roles for existing 14's commensurate with their grade (as appropriate). Grade equality between scientists and non scientists. There should be affirmative action for scientists and grade parity at the GS-14 level.

- The forced inter-personal interactions will cause high stress (especially when combined with a lot of work and few resources). Some minorities migrated out of the department in the staff preference process. Will the current design increase this migration? Needs of the individual will be suppressed in the group environment, leading to less flexibility. Same grade as other lower stress OPP positions (grade stratification) will make HED an undesirable location. Team player may be interpreted to force people into acting in a group think mode. No evidence has been presented that teams are more efficient than individual efforts.