

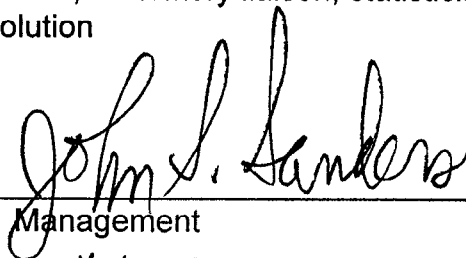
STANDARD OPERATING PROCEDURE
Personnel Organization and Responsibilities for Studies

KEY WORDS

management; project supervisor; project leader; senior scientist; field coordinator; quality assurance officer; laboratory liaison; statistician; chemist; contact person; GLP; safety; problem resolution

APPROVALS

APPROVED BY:


Management

DATE:

3/6/97

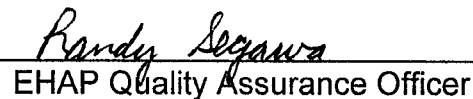
APPROVED BY:


EHAP Senior Scientist

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3-5-97

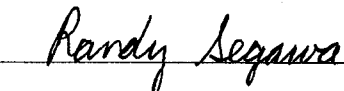
APPROVED BY:


EHAP Quality Assurance Officer

DATE:

2-26-97

PREPARED BY:



DATE:

2-26-97

No previous SOP exists; however, this SOP does supersede the following policy memos:

Goh, K.S. Responsibilities of Field Coordinator for EHAP studies. Memorandum to EHAP Personnel, dated 9/24/93.

Sanders, J. Responsibilities of Project Leaders Regarding Chemical Analysis. Memorandum to EHAP Staff, dated 6/13/88.

Sanders, J. Lab Liaison Personnel and Policy. Memorandum to EHAP Personnel, dated 7/1/87.

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1.0 INTRODUCTION

1.1 Purpose

This Standard Operating Procedure (SOP) defines and discusses the organization and responsibilities of personnel for Environmental Hazards Assessment Program (EHAP) studies. This SOP primarily applies to EHAP field studies, but can also apply to non-field projects.

1.2 Definitions

1.2.1 **Branch** refers to an organizational unit within the Department of Pesticide Regulation (DPR). There are six branches within DPR as shown in Figure 1.

1.2.2 **Protocol** refers to a written document that describes the objectives, personnel, study design, sampling procedures, analytical procedures, data analysis, and schedule for a specific study.

1.3 EHAP Organization

The EHAP is a unit within the Department of Pesticide Regulation (DPR) and provides technical support and monitoring regarding the environmental fate of pesticides. The department and organization of program personnel are shown in Figure 1.

2.0 STUDY ORGANIZATION

Figure 1 shows that the EHAP is organized into groups by function or technical specialty. Personnel are organized into a team for each study. Key study personnel include the Management, Project Supervisor, Project Leader, Senior Scientist, Field Coordinator, Laboratory Liaison, Quality Assurance Officer, Statistician, Chemist and Contact Person. The personnel listed above may not be included in all studies. With certain restrictions, the duties of two or more people may be performed by one person (e.g., the duties of the Project Supervisor and Project Leader may be performed by a single person). The most common personnel organization for a study is shown in Figure 2. The Project Supervisor is selected by the branch chief and/or program supervisor. The Project Leader and other team members are selected by the program supervisor and group supervisors. Selection of all team members should be made

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early in the developmental stages of a study to allow them time to understand what management wants to accomplish and to allow sufficient time to prepare for implementing the study.

3.0 PERSONNEL RESPONSIBILITIES

The following personnel have specific responsibilities when assigned to a study.

3.1 Management - Management typically consists of the Assistant Director and Branch Chief and sometimes the Program Supervisor. Management has responsibility for all policy issues, including the following:

- 3.1.1 determines the objective of a study
- 3.1.2 selects the project supervisor
- 3.1.3 gives final approval for the study protocol, including the budget
- 3.1.4 gives final approval for all SOPs
- 3.1.5 gives approval to any changes in finalized protocols
- 3.1.6 sets study deadlines
- 3.1.7 gives final approval for the study report and any interim memos

3.2 Project Supervisor - The Project Supervisor is typically the supervisor of the Project Leader (i.e., a senior environmental research scientist (supervisor) or the Program Supervisor). The Project Supervisor has overall responsibility for the administrative and technical aspects of the study, including the following:

- 3.2.1 refines the study objectives
- 3.2.2 selects the Project Leader
- 3.2.3 gives general direction to the Project Leader
- 3.2.4 acts as editor-in-chief for review of documents (e.g. protocol, memos, SOPs, report)
- 3.2.5 reviews and approves any changes in finalized protocols
- 3.2.6 supervises administrative tasks (e.g., contracts, purchases, hires)
- 3.2.7 supplies personnel and resources to the Project Leader
- 3.2.8 establishes responsibilities of each team member - consulting with Project Leader
- 3.2.9 facilitates communication with other groups and other branches
- 3.2.10 responsible for safety - determines safety procedures and disseminates hazard communication information - consulting with other DPR branches
- 3.2.11 helps resolve scientific differences of opinion

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If the study is conducted under Good Laboratory Practices (GLP), the Project Supervisor is assigned to Management and is also responsible for the following:

- 3.2.12 establishes a quality assurance unit
- 3.2.13 assures that test and control substances or mixtures have been tested for identity, strength, purity, stability and uniformity
- 3.2.14 assures that any deviations from GLP are communicated to the Study Director (Project Leader) and corrective actions are taken and documented

3.3 Project Leader - The Project Leader is typically an environmental research scientist (ERS), associate ERS, or a senior ERS. The Project Leader has primary responsibility for all technical aspects of a study, including the following duties. Some of the following responsibilities may be delegated to other team members.

- 3.3.1 gathers background information for study - conducts literature search, gathers pesticide use data
- 3.3.2 identifies personnel needs - sampling, chemical analysis, data analysis
- 3.3.3 formulates study plan after consulting with team members
- 3.3.4 writes and follows study protocol and any changes
- 3.3.5 coordinates protocol dissemination with contact person
- 3.3.6 communicates with study cooperators - growers, agencies
- 3.3.7 specifies lab goals through lab liaison - methodology, validation, reporting limits, quality control, turnaround time
- 3.3.8 interacts with interested parties through the contact person - agencies, public
- 3.3.9 develops chain of custody form - consults with team members
- 3.3.10 conducts administrative tasks - contracts, timesheets, purchases, services, budget, expenditures tracking
- 3.3.11 documents all study activities
- 3.3.12 obtains necessary permits
- 3.3.13 determines sampling methodology - consulting with team members
- 3.3.14 determines sampling schedule - consulting with field coordinator
- 3.3.15 prepares all pertinent SOPs
- 3.3.16 trains personnel in study tasks
- 3.3.17 supervises field sampling and/or data collection
- 3.3.18 arranges for special facilities - storage, experimental plots
- 3.3.19 determines sample priorities for lab analysis

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- 3.3.20 reviews and accepts data from the lab
- 3.3.21 designates samples for reanalysis
- 3.3.22 reviews laboratory SOPs
- 3.3.23 supervises data analysis
- 3.3.24 writes interim progress reports or memos
- 3.3.25 writes final report - with other team members
- 3.3.26 coordinates report dissemination with contact person
- 3.3.27 archives study data
- 3.3.28 presents results to various audiences

If the study is conducted under GLP, the Project Leader is designated as the Study Director and is also responsible for the following:

- 3.3.29 corrective actions are taken and documented when necessary
- 3.3.30 GLP requirements are followed

3.4 Senior Scientist - The Senior Scientist is typically a senior ERS (specialist). The duties of the Senior Scientist and Project Leader cannot be performed by a single person. The Senior Scientist reviews and approves a study for scientific adequacy, including the following specific duties:

- 3.4.1 gives technical advice to the Project Leader
- 3.4.2 reviews and approves protocols, memos, SOPs (including lab SOPs) and reports for scientific adequacy
- 3.4.3 helps resolve scientific differences of opinion
- 3.4.4 reviews and approves revisions to protocols and SOPs
- 3.4.5 reviews and approves final report

If the study is conducted under GLP, the Senior Scientist is assigned to the Quality Assurance Unit and assists the Quality Assurance Officer.

3.5 Field Coordinator - The Field Coordinator is typically an associate ERS, ERS, or environmental research assistant from one of the field groups. The Field Coordinator oversees the collection of field samples and has responsibility for field safety. He/She may have more or fewer duties depending on the preference of the Project Supervisor and Project Leader. The Field Coordinator will normally act for the Project Leader in the Project Leader's absence. More than one Field Coordinator may be assigned for very complex studies. The Field Coordinator is normally responsible for the following duties:

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- 3.5.1 decides safety issues under direction of Project Supervisor - the Field Coordinator has the authority to modify or terminate any field activity which threatens the health or safety of field personnel; provides or arranges for safety training
- 3.5.2 assembles sampling materials
- 3.5.3 purchases needed materials
- 3.5.4 arranges transportation and housing
- 3.5.5 checks and calibrates equipment
- 3.5.6 assists in developing chain of custody format
- 3.5.7 assists in coordinating activities with study cooperators
- 3.5.8 assists in selecting sampling sites
- 3.5.9 gives advice on sampling methodology
- 3.5.10 assists in the preparation of SOPs
- 3.5.11 recommends personnel needs and sampling schedule
- 3.5.12 prepares sampling materials list
- 3.5.13 collects and transports samples
- 3.5.14 coordinates sampling schedule with the Lab Liaison
- 3.5.15 cleans sampling materials
- 3.5.16 supervises field sampling in the absence of the Project Leader
- 3.5.17 assists in the protocol preparation
- 3.5.18 assists in the report preparation

3.6 Quality Assurance Officer - The Quality Assurance Officer is typically an associate ERS. Duties of the Quality Assurance Officer and Laboratory Liaison are typically performed by one person. The Quality Assurance Officer cannot perform the duties of the Project Leader or Field Coordinator. The Quality Assurance Officer is responsible for documentation and the quality of the laboratory analysis, including the following specific duties:

- 3.6.1 assists the Project Leader in specifying laboratory methodology
- 3.6.2 assists the Project Leader in specifying laboratory quality control procedures
- 3.6.3 reviews and approves EHAP SOPs
- 3.6.4 maintains copies of protocols and EHAP SOPs
- 3.6.5 reviews, compiles and disseminates quality control data
- 3.6.6 notifies Project Leader of analytical problems
- 3.6.7 initiates lab corrective actions - consulting with Project Leader
- 3.6.8 arranges the preparation of quality control samples

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- 3.6.9 resolves lab discrepancies
- 3.6.10 produces method validation and quality control tables for the report
- 3.6.11 obtains and disseminates laboratory SOPs
- 3.6.12 reviews laboratory SOPs

If the study is conducted under GLP, the Quality Assurance Officer supervises the Quality Assurance Unit and is responsible for the following:

- 3.6.13 maintains master schedule of EHAP GLP studies
- 3.6.14 determines that all known deviations from the protocol or SOPs were authorized and documented
- 3.6.15 prepares and signs statement of dates of inspection and findings to be included in final report
- 3.6.16 reviews and approves protocol and final report

3.7 Laboratory Liaison - The Laboratory Liaison is typically an associate ERS. Duties of the Laboratory Liaison and Quality Assurance Officer are typically performed by one person. The Laboratory Liaison is responsible for coordinating activities between EHAP and the chemistry labs, including the following duties:

- 3.7.1 acts as liaison between the Project Leader and the labs
- 3.7.2 selects the chemistry laboratories (primary and quality control)
- 3.7.3 negotiates analytical specifications with the labs (described in SOP QAQC001)
- 3.7.4 stores and transports samples to the labs
- 3.7.5 controls timing and quantity of samples delivered to the lab
- 3.7.6 tracks movement of samples between storage facility and lab
- 3.7.7 transmits lab data to the Project Leader
- 3.7.8 administers lab contracts

3.8 Chemist - The Chemist typically works for the Department of Food and Agriculture or a commercial lab, not EHAP. The Chemist is responsible for the pesticide analysis of samples. He/she also gives advice on sampling methodology.

3.9 Statistician - The Statistician is typically an associate ERS. The Statistician is responsible for the design and statistical analysis of the study, including the following specific duties:

- 3.9.1 determines the study design - consulting with other team members
 - 3.9.2 assists in writing the protocol
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- 3.9.3 reviews and approves the study protocol and any changes
- 3.9.4 conducts statistical analysis of the study data
- 3.9.5 assists in writing the final report
- 3.9.6 reviews final report

3.10 Contact Person - The Contact Person is typically assigned from Program Representation of the Environmental Monitoring Branch. The Contact Person acts as liaison with the public, branches, and agencies that are interested but not participants in the study. His/Her specific duties include the following:

- 3.10.1 develops interested parties list - consulting with the Project Leader
- 3.10.2 acts as liaison to public/branches/agencies
- 3.10.3 disseminates appropriate documents to interested parties
- 3.10.4 coordinates review of documents with interested parties
- 3.10.5 assists the DPR communications office with media inquiries
- 3.10.6 writes executive summary
- 3.10.7 advises Project Leader on policy and regulatory issues of study

3.11 Other EHAP and DPR Personnel - Designated personnel provide support services. EHAP warehouse personnel provide storage, maintenance, equipment and transportation upon request. EHAP laboratory facilities are available for soil characterization and other analyses upon request. A number of people within and outside of EHAP provide special computer services such as programs, databases, modeling, geographic information systems, or graphics upon request. The Worker Health and Safety, and Medical Toxicology Branches can provide information on toxicity, safety precautions as well as medical monitoring upon request. These support personnel may not be available for all studies and should be requested through the Project Supervisor or the appropriate Group Supervisor.

4.0 PROBLEM RESOLUTION

Technical items that are not specified here are the responsibility of the Project Leader. Both the Project Leader and Senior Scientist should agree on all technical issues. The Project Supervisor is responsible for resolving any disagreements. Administrative, policy or other items not specified here are the responsibility of the Project Supervisor.

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5.0 SAFETY

Personnel safety is of primary importance at all times. The Project Supervisor and Field Coordinator have primary responsibility for safety. However, all team members must follow correct safety procedures. Approval for changing the protocol or a SOP should be sought whenever possible, but may not be possible if an imminent danger exists. A study should always be conducted in a safe manner, no matter what the protocol or SOP specifies. Document all changes in the protocol or SOP.

In the absence of the Field Coordinator, the ranking field group person has primary responsibility for safety while working in the field.

6.0 STUDY-SPECIFIC DECISIONS

Management, Project Supervisor and Project Leader are responsible for the following study-specific decisions:

- 6.1 Selection of study personnel
- 6.2 Responsibilities of each team member

7.0 REFERENCES

Goh, K.S. Responsibilities of Field Coordinator for EHAP studies. Memorandum to EHAP Personnel, dated 9/24/93.

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APPENDICES

Figure 1. Department of Pesticide Regulation Personnel Organization

Figure 2. EHAP Study Personnel Organization

Figure 1

Department of Pesticide Regulation Personnel Organization

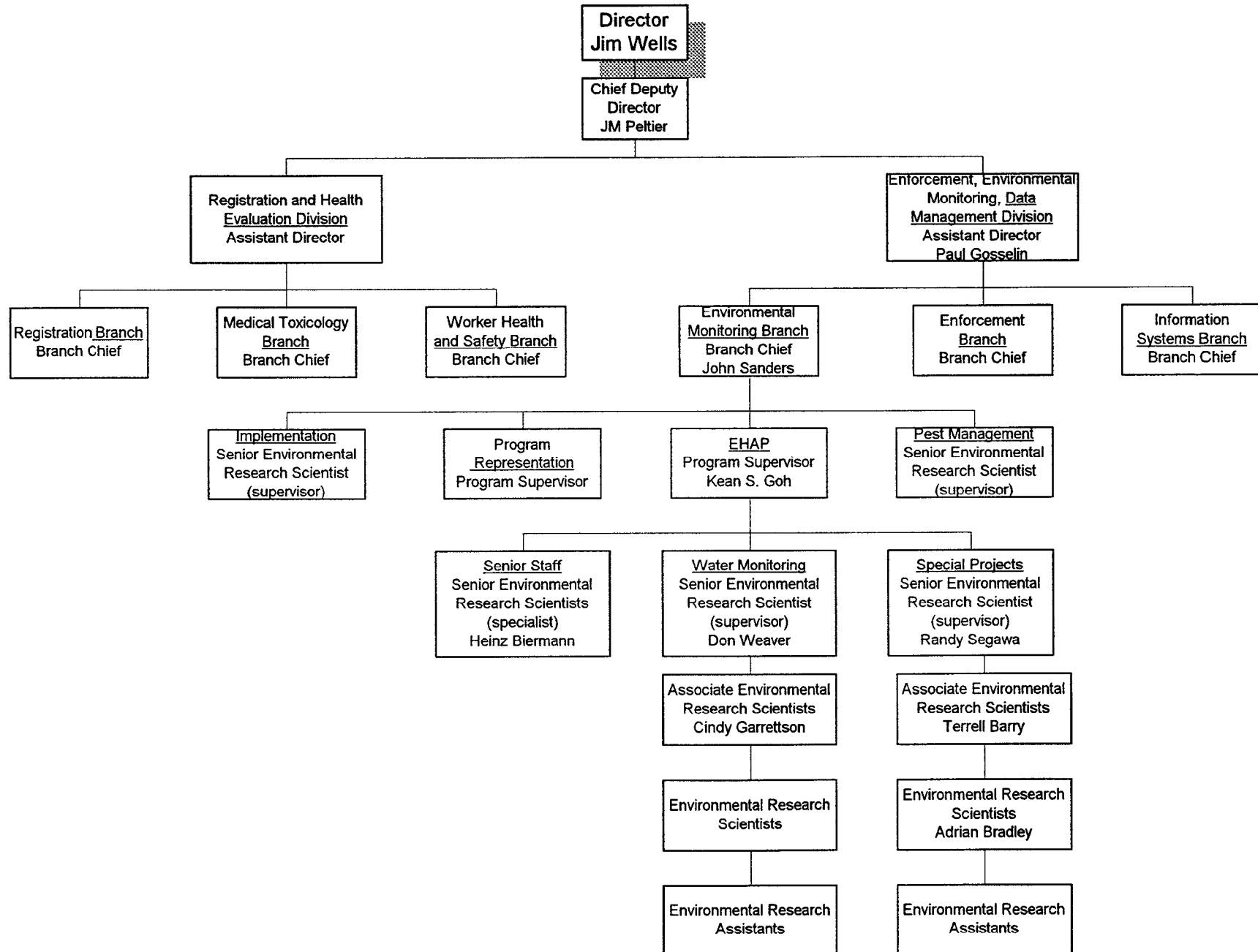
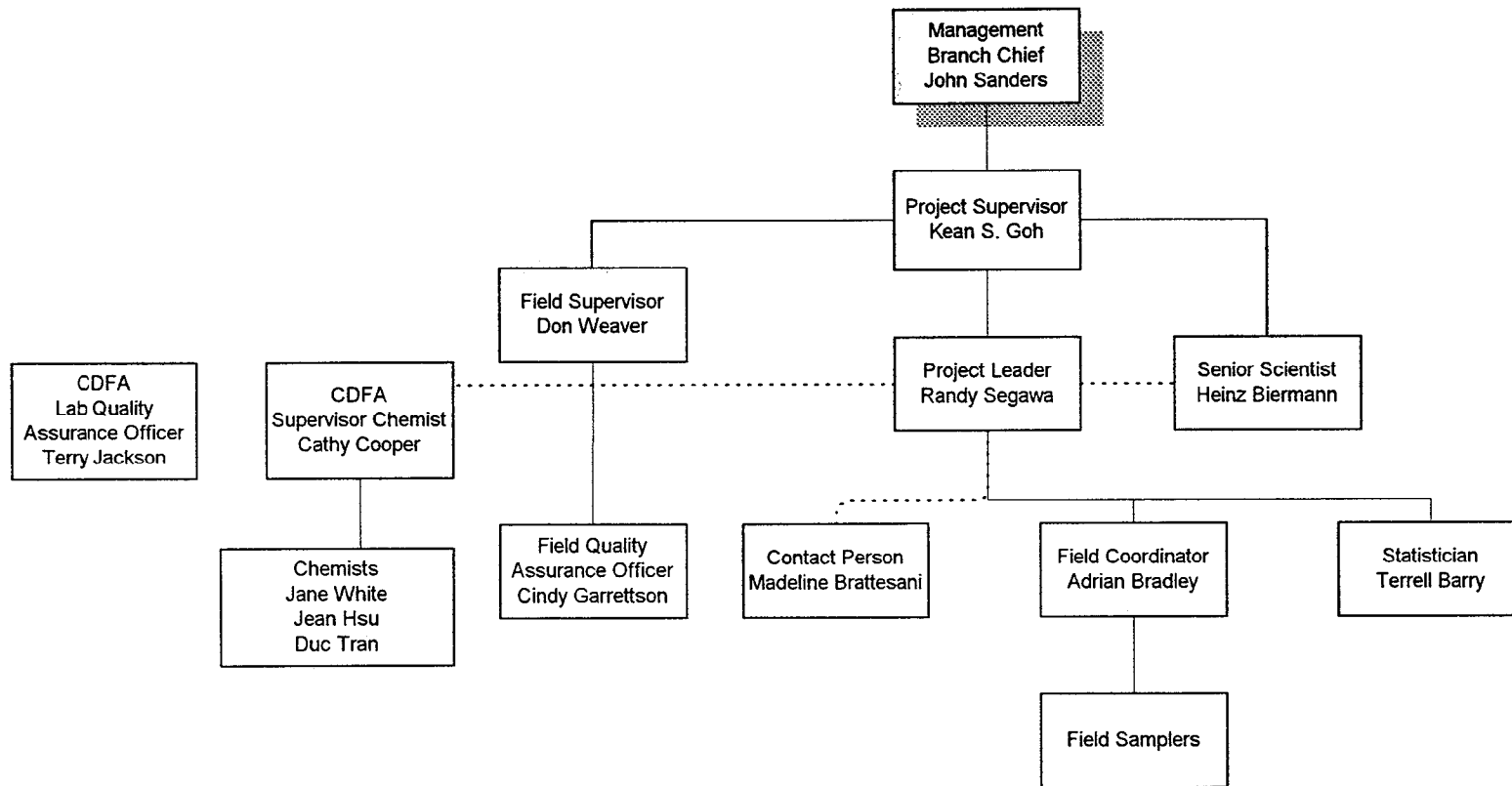


Figure 2

EHAP Study Personnel Organization*



*For GLP studies, the Senior Scientist and Quality Assurance Officer make up the Quality Assurance Unit and report to Management