

Major Duties:

documentation and provides other special program support related activities. Typically, the tasks are projects or assignments of moderate scope or parts of more complex projects; the assignments consist of interrelated tasks or problems which have been isolated or defined and which can be solved by minor adaptation of precedents and/or established practices. Successful performance requires a knowledge of program management techniques (to develop, analyze and synthesize a variety of program planning/reporting material into a cohesive approach), and communication skills to gather and discuss data, information, and facts and present that information in a variety of accepted program management formats. Gathers, analyzes, and integrates information from participating elements and ensures proper integration into the overall program effort. Prepares, using a variety of management techniques, evaluative analyses of the status of programs/projects; determines trends and forecasts capability to reach objectives. Identifies actual or potential areas of imbalance or deficiency and recommends corrective action. Information is gleaned from a variety of sources such as; records, reports computer files, data from experiments, regulatory requirements and laboratory standard operating procedures as well as interviews with the scientists. Reviews and analyzes recommended changes to personnel from major organizational elements and recommends approval or disapproval with program supervisor. Changes can result in written procedures or guidelines in order to correct existing or potential deficiencies. The SOPS encompass a wide variety of Laboratory program and administrative operations, e.g., Sampling Plans and Reports. (25%) - Data accumulation, analysis, and reports. Analyzes the workload assigned to the laboratory members and monitors the status of critical requirements. Maintains a continual accumulation of all types of data for use in preparation of a variety of reports including statistics. Compiles and prepares a wide variety of continuing or one-time special statistical and narrative reports from records maintained. Charts monthly progress and provides reports. Assists management by utilizing statistical data and developing special reports, compiling/preparing drafts. Effectively enhances the ability of the office to support overall mission requirements through developing methods for automating administrative data collection requirements and reports considering the interrelationships or reports and multiple uses of data. Determines the best software type for each requirement (such as database, spreadsheet or word processing). Determines data categories to be established, sorting and calculating functions to be performed, and procedures for entering and retrieving data. Uses graphics software to provide charts and graphs for viewgraphs or paper presentations for briefings. Provides input into the Quality Assurance Program; recommending administrative changes to the Quality Assurance Program within established guidelines to adapt to change in work environment such as new laws, regulations, and guidance documents as prescribed by FDA HQ or local management; and conducts reviews or audits or work to ensure office procedures are consistent. As a member of a management team, plans, organizes, carries out, and evaluates special projects affecting the administration of programs in the Laboratory. The employee conducts studies at management request, researches sensitive issues, analyzes and presents findings, and recommends administrative strategies or changes in internal operating procedures to incorporate new legislative requirements, changing organizational relationships within the Agency or with other groups outside the Agency, and/or new Department, Agency, or Program initiatives. Examples of this type of project include internal work processes and office procedures, special personnel efforts, organization planning (e.g. workload analysis for reorganization of support staff in the Branch or major caseload review as part of recommendation to create expended or new organizational entities (such as an scientific team or workgroup), automation projects (such as Online Reporting Analysis Decision Support System (ORADSS),) and other issues that must be coordinated through Senior level staff. (25%) - Administrative Management Represents the program in Agency meetings or as a member of working groups to advocate their policies and priorities concerning administrative or management areas. Participates in a variety of meetings (e.g., industry workshops; local, Agency-wide training seminars; and "Grass Roots" meetings with industry representatives and the general public). Assists in planning for and arranging the agenda of meetings or conferences. Assures all appropriate parties are notified and prepares specific background information about the speaker to include with the agenda. Based on knowledge of the subject of meetings that address managerial questions or program support, prepares background information and options pertaining to those specific issues, and when required, takes notes and prepares records which includes

the development of an action item listing with appropriate follow-up until completion. May be required to design and recommend for implementation major or new ADP tracking systems and spreadsheet applications in all phases of Laboratory operations in which major problems and discrepancies are identified by management as barriers to more effective program evaluation and planning. Provides expertise for office automation efforts directed towards creating a paperless environment (i.e automating documents, records, forms and communication). Analyzes current work methods used throughout Laboratory operations as subjects for automation. Serves as the liaison to various FDA information resources management staff on those projects. Provides immediate and continuing support by briefing the supervisor on a variety of confidential matters pertaining to administrative operations, recommending courses of actions, and keeping her/him informed of activities occurring when s/he is absent for the office for extended periods. Keeps informed of the supervisor's views and policies and helps in carrying them out by handling special assignments as they develop. Provides immediate and continuing support by briefing the supervisor on a variety of confidential matters pertaining to administrative operations, recommending courses of actions, and keeping her/him informed of activities occurring when s/he is absent for the office for extended periods. Keeps informed of the supervisor's views and policies and helps in carrying them out by handling special assignments as they develop. (25%) - Provides Information, Communication and Liaison Services Monitors and reviews incoming requests for programmatic action or information, takes judicious interim action on deadline items, and arranges appropriate extensions for less urgent items. This responsibility requires that the incumbent discern important issues and apprise appropriate members of the staff of any circumstances that might alter or complicate issues. These duties may involve direct and tactful contact with high level officials throughout the Laboratory, Office, Center and Agency, in regulated industry and trade organizations throughout the United States, in consumer groups, and in other government agencies. Obtains and coordinates responses for general programmatic information requested by members and committees of Congress, officials of other government agencies, industry and consumer representatives. Represents the program in Agency meetings or as a member of working groups to advocate their policies and priorities concerning administrative or management areas. Participates in a variety of meetings (e.g., industry workshops; local, Agency-wide training seminars; and "Grass Roots" meetings with industry representatives and the general public). Assists in planning for and arranging the agenda of meetings or conferences. Assures all appropriate parties are notified and prepares specific background information about the speaker to include with the agenda. Based on knowledge of the subject of meetings that address managerial questions or program support, prepares background information and options pertaining to those specific issues, and when required, takes notes and prepares records which includes the development of an action item listing with appropriate follow-up until completion.

Other Duties: Performs other duties as assigned.

Position Requirements: This position requires no travel.

Factor Evaluation System (FES)

Grade: 09 Total Points: 1885 Points Range: 1855 - 2100

1. Knowledge Level: 6 Points: 950

Knowledge and skill to utilize standardized analytical tools when applying fundamental administrative principles and practices to evaluate complex, non-controversial, and factual issues for which there are one or more readily apparent solutions. Ability to perform management advisory services for specific requests related to immediate administrative problems of limited scope, and to analyze and recommend solutions to issues concerning broader specializations including their impact on the occupational area. Conducts fact-finding interviews with supervisors and employees to obtain information about organizational functions and work procedures.

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AST Knowledge

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Position Unique Knowledge 1

Ability to communicate orally to obtain and coordinate findings and responses for information, to conduct fact-finding or general investigations, and to present findings and recommendations. Conducts fact-finding interviews with supervisors and employees to obtain information about organizational functions and work procedures. Knowledge of pertinent laws, regulations, policies, and precedents which affect the program or work processes studies, and knowledge of the major issues, program goals and objectives substantive work processes and program operations of the organization. Knowledge to plan, schedule, and conduct projects and studies to evaluate, identify, and resolve issues and problems. Knowledge of information management to assist in the automation of various organizational functions, acquire and manipulates data/information, and schedule and check the status of programs or projects. Ability to conduct research in order to gather factual information related to program issue and to provide time saving literature services to the professional staff. Knowledge is applied in developing reporting processes and advising management officials. Knowledge of the organizational functions to identify readily-observable conditions, consider and resolve issues or problems which are of a procedural or factual nature. Knowledge to compile and prepare of a variety of statistical and narrative reports or briefings, including charts, graphs and narrative.

Position Unique Knowledge 2

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Position Unique Knowledge 3

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Position Unique Knowledge 4

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2. Supervisory Controls

Level: 3

Points: 275

The supervisor makes assignments by defining objectives, priorities, and deadlines and assists the employee with unusual situations that do not have clear precedents. The employee plans and carries out the successive steps and handles problems and deviations in the work assignments in accordance with instructions, policies, previous training, or accepted practices in the occupation. Completed work is usually evaluated for technical soundness, appropriateness, and conformity to policy and requirements. The methods used in arriving at the end results are not usually reviewed

in detail.

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3. Guidelines

Level: 3

Points: 275

Guidelines are available but are not completely applicable to the work or have gaps in specificity. Guidelines consist of Departmental, Agency, and ORA policy statements, enabling legislation regulations, procedures, court decisions, precedents, and mission statements, and organizational structures. The employee uses judgment in interpreting and adapting guidelines, such as agency policies, regulations, precedents, and work directions for application to specific cases or problems. The employee analyzes results and recommends changes.

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4. Complexity

Level: 3

Points: 150

The work includes various duties involving different and unrelated processes and methods. The decision regarding what needs to be done involves various choices that require the employee to recognize the existence of and differences among a few easily recognizable situations. The employee makes decisions based on incomplete or conflicting information to assess circumstances to adapt and modify standard analytical methods and techniques to meet the requirements of individual assignments. In addition, work entails working with analytical methods and techniques to identify and analyze and resolve issues and problems affecting the effectiveness and efficiency of the office scientific, administrative and program activities. Studies involve fact finding problem identification and definition, determining the cause and effect relationships, conclusions, and recommendations for decision and action. Actions to be taken or responses to be made differ in such things as the source of information, the kind of transactions or entries, or other differences of a factual nature.

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5. Scope / Effort

Level: 3

Points: 150

The work involves treating a variety of conventional problems, questions, or situations in conformance with established criteria. Incumbent is responsible for providing analyses, evaluations, recommendations and advisory services to office management and staff. The incumbent conducts studies of the work processes, activities, and procedures found in the organizations and the effect of work processes and procedures on commodity area, ORA headquarters, other FDA centers, Federal and State agencies, and regulated industries. Recommendations are meant to address new and solve long standing, critical problems which have been resistant to solution. Results obtained and recommendations made have a direct impact and substantial bearing on operations and influence the course and direction of the office and occasionally program or national management decisions and operations. The incumbent is also

responsible for providing management with early indications of potential or emerging problems that may require attention and also to ensure that priority items are addressed promptly and responsively. The work product or service affects the design or operation of systems, programs, or equipment; the adequacy of such activities as field investigations, testing operations, or research conclusions; or the social, physical, and economic well being of people.

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6. Personal Contacts

Level: 2

Points: 25

The personal contacts are with employees in the same agency but outside the immediate organization. People contacted generally are engaged in different functions, missions, and kinds of work, e.g., representatives from various levels within the agency, such as headquarters, regional, district, or field offices, or other operating offices at the immediate installation; AND/OR The contacts are with members of the general public, as individuals or groups, in a moderately structured setting. For example, the contacts generally are established on a routine basis, usually at the employee's work place; the exact purpose of the contact may be unclear at first to one or more of the parties; and one or more of the parties may be uninformed concerning the role and authority of other participants.

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7. Purpose of Contacts

Level: 2

Points: 50

The purpose is to plan, coordinate, or advise on work efforts, or to resolve operating problems by influencing or motivating individuals or groups who are working toward mutual goals and who have basically cooperative attitudes. Controversial and critical recommendations for substantial change in established work processes or new processes, activities, and other functions, and to facilitate change in managers, workers, and others who are or may be reluctant to accept change and do not share the same conclusions, point of view or need for actions to be taken.

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8. Physical Demands

Level: 1

Points: 5

The work is sedentary. Typically, the employee sits comfortably to do the work. However, there may be some walking; standing; bending; carrying of light items, such as papers, books, or small parts; or driving an automobile. No special physical demands are required to perform the work.

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9. Work Environment

Level: 1

Points: 5

The work environment involves everyday risks or discomforts that require normal safety precautions typical of such places as offices, meeting and training rooms. The work area is adequately lighted, heated, and ventilated.

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