



**FDA PEER REVIEW GUIDE
FOR THE EVALUATION
OF**

FDA REGULATORY REVIEW

SCIENTISTS (EXPERTS)

GS-14 AND 15

**FDA PEER REVIEW GUIDE
FOR THE EVALUATION OF
FDA, REGULATORY REVIEW SCIENTISTS (EXPERTS)
GS-14 AND 15**

PURPOSE:

The purpose of this Guide is to establish written grade level criteria at the GS-14 and 15 levels for the evaluation of FDA, regulatory review scientists, and to establish the responsibilities and procedures to be followed in an Agency-wide peer review classification system.

COVERAGE:

The policy, responsibilities, procedures, and criteria found in this Guide will be applied to all requests received from FDA management to establish new regulatory review scientist positions at, and to promote regulatory review scientists to the GS-14 and 15 grade levels.

CLASSIFICATION ISSUE:

The regulatory mission of the FDA has grown both in size and sophistication with passage of new legislation and the progress of the sciences supporting the products regulated by the Agency. Consequently, the number of scientists and regulatory review organization have grown to meet the increased volume, variety, and complexity of those products regulated by the Agency.

The various FDA centers are organized into a number of pre and post-market regulatory review officers which are staffed, depending on the enabling legislation of each center, by a wide variety of scientific and engineering disciplines, as well as, medical officers, and veterinary medical officers. The scientific disciplines include, but are not limited to biologists, microbiologists, pharmacologists, physiologists, social scientists, toxicologists, pharmacists, animal scientists, nutritionists, chemists, mathematical statisticians, and mechanical, electronics, materials, and biomedical engineers. Depending on the products regulated, the relationship of seemingly unrelated products to each other, and the demands of the various scientific disciplines in relation to those products, many of these disciplines require knowledge of and expertise in related disciplines in order to fully understand the complexity of the applications received from the regulated industries to develop and market the wide variety of products regulated by the FDA.

Regulatory review medical officers, veterinary medical officers, scientists, and engineers are responsible for evaluating applications to develop and market human drugs, foods, animal drugs, medical devices, and biologicals in order to insure that applications to

develop and market these products meet and scientific and regulatory requirements of the enabling legislation, regulations, and requirements that apply to each of the products regulated by the Agency; for providing recommendations and guidance to the regulated industries and Agency organizations; and for representing the Agency at national and international meetings on matters concerning the products regulated by the Agency.

Regulatory review work covers such as analyzing and determining the adequacy of data, tests, and other scientific information received from the regulated industries requiring the requirements of the legislation and regulations that apply to the products being reviewed, determining if additional data, tests, or information may be necessary within the context of applicable laws, policies, regulations, and guidelines, providing verbal and written consultation to the industries, other Federal agencies, universities, and foreign governments, developing and recommending new and revised research treatises and guidelines for the regulated products and proposing areas of study for in-house and contract research projects, recognizing the need for initiating new and amended regulations, policies, and procedures, maintaining comprehensive surveillance of the impact and significance of complex periodic experience reports and tests submitted by the sponsors of products including information on unexpected side effects, injuries, toxicity, or sensitivity reactions, and advising on difficult issues associated with product development technological changes, environmental impact, industrial changes, and toxicity assessment in advance of or during the early stages of product development.

RESOLUTION:

To address the concern of FDA management for the appropriate and consistent evaluation of regulatory review scientists performing work at GS-14 and 15, the FDA has decided to establish the FDA, Regulatory Review Scientist Review Committee composed of senior scientists and science managers to assist in the classification of senior level regulatory review scientist positions at GS-14 and 15. The Review Committee offers two advantages. Highly scientific and technical positions are evaluated by scientists familiar with the nature of the work being performing and evaluated, and the scientific community can be expected to have greater confidence in the decisions made by peer scientists, and so more readily accept those decisions.

GS-13 is the accepted full-performance level in the FDA center regulatory review offices and divisions. Therefore, promotions of review scientists to and the establishment and filling of review scientist positions at the GS-13 grade level will continue to be made through accepted personnel merit promotion procedures, and will both be a part of this peer review process.

Regulatory review scientists at GS-14 and 15 may also be found as team leaders or supervisors. The grade of a team leader is based on the personal competence of his regulatory review scientist in the performance of the work for which the scientist is

personally responsible. The grade of a supervisor may be based on supervisory responsibilities or on the work performed as an individual depending on whichever situation yields the highest grade. This Guide may only be used to evaluate the work performed by a supervisor as an individual.

The Guide is augmented by a number of supplements which are designed to assist and meet the needs of the principle users. The following matches the three principle users with the supplements.

- § The Review Committee- Supplements 1, 5, and 6.
- § Recommending supervisors - Supplements 2, 3, and 4.
- § Candidates - Supplements 2, 3, and 4.

Supplement One, Plan for the Evaluation of FDA, Regulatory Review Scientist Positions at GS-14 and 15 establishes the responsibilities and procedures which will govern the conduct of the Committee.

Supplement Two, Documentation Requirements, Memorandum of Recommendation, Supplement Three, Position Description Format, and Supplement Four, Sample Position Description address and set the requirements which must be met for cases submitted to the Committee.

Supplement Five, Guidelines for Conducting In-depth Reviews offers guidance to Committee members.

Supplement Six, FDA Regulatory Review Scientist Grade level Criteria establishes the criteria based on written grade level criteria found in appropriate U.S. Officer of Personnel Management position classification standards that the Committee will use in evaluating positions proposed by FDA management for classification at GS-14 and 15.

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SUPPLEMENT ONE

EVALUATION PLAN FOR FDA REGULATORY REVIEW SCIENTISTS

1. PURPOSE

This Evaluation Plan establishes the responsibilities, procedures, and standards that will be followed in evaluating regulatory review scientists proposed for hiring at and promotion to the GS-14 and 15 grade levels.

2. THE REVIEW COMMITTEE

A. Members. The Review Committee will consist of seven members.

1. A senior scientist or science manager will be appointed by the Commissioner of the FDA to serve as the Chair of the Committee. A position classification specialist made available by OHRMS will serve as a permanent member of the Committee.

2. One scientist and one alternate will be appointed by each of the five FDA center directors from their respective five center regulatory review offices at the senior scientist level and science management or higher level to serve on the Committee. Committee members will serve three year terms with one third of the membership rotating off the Committee each calendar year.

3. The position classification specialist will serve as a full member of the Committee and offer guidance in the review and evaluation of cases that com before each committee.

4. An Executive Secretary who will not be a voting member of the Committee will be provided by the Director, OHRMS. The Executive Secretary will report to the Committee Chair.

5. Five members present at a meeting including the Chair and the OHRMS position classification specialist will constitute a quorum.

B. Advisory Participants. The Committee has the authority, when seen fit, to call on candidates, recommending officials, other scientists, and any other appropriate individuals who may be of assistance in the review of a case.

3. RESPONSIBILITIES

A. The Commissioner of the FDA. Selects the Committee Chair.

B. The center directors.

1. Appoint members and alternates to serve on the Committee.
2. Sign transmittal memoranda for cases to be submitted to the Committee from the center directors

D. The Committee Chair.

1. Schedules, calls, and chairs stated meetings of the Committee, and notifies the centers of those dates. Special meetings may be called at the discretion of the Chair for such purposes as handling unexpectedly large numbers of cases.
2. Orients new members, establish guidelines for the review and evaluation of cases, and provide guidance in instances that are not specifically covered by the Plan.
3. Receives all case material. With the OHRMS members, decides whether cases have been submitted in the proper format, are adequate and complete, and that all appropriate supervisory signatures are present.
4. Assigns cases to Committee members for in-depth review prior to scheduled Committee meetings.
5. Insures the confidentiality of Committee meetings and proceedings.
6. Prepares Committee recommendations on the disposition of cases.
7. Speaks for the Committee in communications with the center directors, regulatory review division and officer directors, sponsors, candidates, and any others having business with the Committee.

E. The Committee.

1. Meets regularly on a schedule established by the Chair, and when called by the Chair due to special circumstances.
2. Review and evaluation of case material.
 - a. Each case will be carefully reviewed, and evaluated on scientific merit.
All appropriate information such as memoranda of recommendation, reports and evaluations by supervisors, and work examples will be used.

b. The Committee may schedule interviews with the recommending supervisors or person with knowledge of a candidate's achievements and contributions. Representatives of disciplines not represented on the Committee may be invited to provide information on the role and impact of the discipline on the review word.

c. Any Committee member who is also the recommending supervisor may discuss, but not participate in deciding on the disposition of a case.

d. A consensus of those present at a Committee meeting will determine the recommended disposition of a case.

e. The Chair, or a member designated by the Chair, will summarize the findings and make the final Committee recommendation in writing. On acceptance of the recommendation, the Chair will notify the recommending supervisor through the appropriate recommending officials.

f. The activities of the Committee including both written and verbal communications and actual Committee deliberations, discussions, and decisions are considered to be confidential.

F. The Position Classification Specialist.

1. Works with the Chair and the Committee in all aspects of the evaluation process.
2. Serves as a full member of the Committee.
3. Applies the appropriate OPM position classification standard, or standards, to cases being considered by the Committee, and prepares evaluation statements.
4. Informs the Committee of any modifications or changes in appropriate position classification standards and any other criteria used in the review and evaluation of Agency regulatory review scientists.

G. The Executive Secretary.

1. Keeps track of the terms of Committee members and alerts the Chair when terms are the expire so that replacements can be nominated and selected.
2. Coordinates and schedules meeting dates with the Chair, and confirms

dates with the Committee members.

3. Receives cases from the center directors, and distributes case material to Committee members.

4. PROCEDURAL STEPS

A. The Chair establishes the dates of states Committee meetings, and any necessary special meetings, and notifies center managers through the Committee Executive Secretary.

B. Candidates and their supervisors are responsible for preparing requires case material. The immediate supervisor is responsible for certifying the completeness and accuracy of the case material. The supervisor is responsible for submitting the original and eleven copies of a case through appropriate management channels to the Committee Chair.

C. Cases must be received by the Committee Chair eight weeks before the date on which a Committee meeting is scheduled.

D. The Chair and the position classification specialist will review all cases and make an initial evaluation of the documentation and recommendations. Cases that are accepted will be given to the Executive Secretary for distribution to the Committee members. If a case is found to be insufficient, the case will be returned to the recommending supervisor for the collection and resubmission of pertinent information. Failure to respond with relevant material, or in a timely fashion, may result in the deferral of a case until the next scheduled meeting of the Committee.

E. The chair in consultation with the position classification specialist assigns each case to a Committee member as an in-depth reviewer. The in-depth review will obtain any additional information that will help the Committee better understand a case. The in-depth review will consist of a personal interview with both the recommending supervisor and the candidate. When the work of the candidate is directly related to or impacts the program of another distinct organizational entity, an effort should be made to interview the manager or scientist responsible for, or associated, with the program. See Supplement Five, Guidelines for Conducting In-depth Interviews.

F. Prior to a scheduled Committee meeting each Committee member will review each case and reach a tentative conclusion based on the criteria found in Supplement Six, FDA, Regulatory Review Scientist Grade Level Criteria.

G. Committee meetings will be conducted in accord with accepted

guidelines. Committee Discussions are considered to be absolutely confidential, and Committee recommendations and decisions will be distributed through official channels only.

H. After completing the review of a case, the Chair, or a member appointed by the Chair, will prepare a written recommendation in behalf of the Committee that will be sent to the recommending supervisor through the appropriate center management channels.

I. The position classification specialist will prepare an evaluation statement for each case which has been found acceptable by the Committee, and insure that the necessary personnel action is taken.

J. Cases which do not meet the necessary criteria for the grade level proposed will be returned to the recommending supervisor through appropriate center management channels with a written explanation signed by the Chair detailing the reasons for the decision. Any subsequent resubmission must clearly address the points raised in the Committee decision.

K. All scientist covered by this Plan may appeal the final classification of their positions through established Agency and OPM classification appeal procedures.

5. DOCUMENTATION REQUIREMENTS

A. The supervisor in conjunction with the candidate prepares an original package and ten copies for submission to the Committee Chair through the appropriate center management channels.

B. The original package will contain the following in sequential order:

1. **Transmittal Memorandum** from the immediate supervisor through appropriate center director to the Committee Chair for the establishment of and promotion to regulatory review scientist positions at GS-14 and 15.

2. **Memorandum of Recommendation.** The memorandum should come from the immediate supervisor, or from the immediate past supervisor, if that official is more familiar with the work of the candidate. The memorandum must be signed or countersigned by the candidate's current supervisor as appropriate.

The memorandum of recommendation must address the following points:

a. The name, title, series, and current grade of the

candidate, and the nature of the action requested.

b. A brief summary of the career. This summary may address the candidate's educational background, the area in which the candidate is considered to be especially qualified, the reputation which the candidate has build, related and pertinent FDA experience in other program areas, and recognition which the candidate has earned and received such as honors, awards, invitations, or any other appropriate information.

c. List of accomplishments to the Agency, regulated industry, scientific community, and the regulatory process. See Supplement Two, Documentation Requirements, Memorandum of Recommendation. **Each accomplishment should be described as completely as possible with primary emphasis on what was accomplished and why the accomplishment was significant to the mission of the Center and Agency.** The substance and impact of the contributions are of the greatest interest to the Committee. Volume and numbers are not critical.

d. Special expertise. Briefly describe the kind and level of expertise that enables the candidate to function at the senior level being proposed. Recommendations should focus particularly on the Knowledge Required by the Position, Supervisory Controls, Guidelines, Complexity, and Scope and Effect. See Supplement Six, FDA, Regulatory Review Scientist Grade Level Criteria.

3. OF-8 and Position Description. The proposed position description must follow the nine factor format required by the Factor Evaluation System. See Supplement Three, Position Description Format, and Supplement Four, Sample Position Description.

SUPPLEMENT TWO

DOCUMENTATION REQUIREMENTS

MEMORANDUM OF RECOMMENDATION

The memorandum of Recommendation should be restricted to actual accomplishments within the recent past such as two to three years, not future plans or problems or accomplishments that are long past. The memorandum should begin with a brief paragraph summarizing the scientist's career by giving the total time that has been devoted to regulatory review work and the various organizations and locations in which that work has been performed, and a general statement about the scientist's reputation and recognition which has been earned and received.

Following the introductory paragraph, the scientist's area or areas of expertise and the most significant accomplishments over the scientist's career should be addressed in chronological order. There is not particular limit to the number of accomplishments which may be addressed.

Each accomplishment should be described as concisely as possible with primary emphasis placed on what was accomplished and why the accomplishment was significant. In the case of a team effort, it will be necessary to explain exactly what the scientist contributed to the total effort. Since the significance of an actual accomplishment sometimes changes with time, these statements should be carefully written.

The memorandum may document accomplishments by the inclusion or attachment of memoranda, final technical reports, manuscripts, publications, or any other pertinent document. Good judgement should be used concerning the quality and numbers of such documents. Any documentation should be chosen with the following in mind:

- § while past accomplishments may be important, recent accomplishments show maintenance of scientific competence,
- § for most situations, one or two carefully selected references will be sufficient to support a well-stated accomplishment, and
- § the significance of a particular accomplishment may have increased with time.

If publications are offered, they should be referenced to a particular accomplishment which they accompany. When more than one publication is used to document an accomplishment, all the publications must support the single accomplishment.

A scientist's position may include duties and responsibilities that are not specifically oriented to regulatory review. If this kind of work is performed on a regular and recurring basis, it should be documented in the position description.

SUPPLEMENT THREE

POSITION DESCRIPTION FORMAT

DUTIES:

The object of the “Duties” section of the position description is to present the major duties of the position in the order of importance. Major duties are those that usually occupy more than ten percent of a scientist’s time, and are performed on a regular and recurring basis. Regular and recurring duties are those which are performed on a day-to-day basis or seasonally, such as one a year, but every year. Major duties are not one time duties such as special projects, or of a temporary nature such as acting for a supervisor or filling in for another scientist. Major duties are the primary reason for the existence of a position. All other duties are minor or peripheral, and do not enhance the grade of a position.

The duties of a position are best described in simple, straight forward language. Sentences should be in the active voice, using action verbs, and made up words with as few syllables as possible. Enough information should be presented so that the in-depth reviewer and other members of the Committee can understand what is going on. Do not use words and phrases such as assists, executes, coordinates, participates, facilitates, or serves as a focal point. The Committee wants to know what the scientist actually does.

In addressing each one of the following nine factors, it would be well not only to consider the questions, but also to carefully consider the grade level criteria presented under each factor description in Supplement Six, FDA Regulatory Review Scientist Grade Level Criteria.

FACTOR 1 - KNOWLEDGE REQUIRED BY THE POSITION.

What knowledge is required to perform the work of the position such as the scientific discipline or disciplines, the categories of products and samples, functional specialties, other Agency programs, the regulated industry or industries, programs of State, local, and foreign governments, programs of national and international organizations?

What knowledge is required of Agency enabling legislation, policies, rules, regulations, court decisions and precedents, past decisions and practices, the way in which industry and others approach the Agency, the wishes and desires of the Congress?

What kinds and levels of skills are necessary to perform the work such as identifying problems, gathering and analyzing information, drawing conclusions, recommending solutions, writing reports and paper, organizing and delivering briefings, negotiating acceptance and implementation of recommendations, and leading the work of others?

FACTOR 2 - SUPERVISORY CONTROLS.

How does the supervisor assign work? With detailed or general instructions, with instructions for new, difficult, or unusual aspects of the work only, with only general suggestions on approaches to work

What responsibility does the scientist have for carrying out the work? Within general guidelines establishes the approach to assignments, handles all work independently according to accepted policies and practices, resolves conflicts, determines approaches to be taken?

How is the work reviewed? For appropriateness, accuracy, adequacy, and compliance with instructions; is it expected to be technically accurate, accepted as authoritative?

FACTOR 3 - GUIDELINES.

What guides are used in performing the work, such as laws, rules, regulations, manuals, precedents?

How are the guidelines used, how applicable are they, are they lacking, are precedents available, is judgement needed to follow established guidelines, in deviating from or interpreting guidelines, in adapting or developing new guidelines?

If new or modified guidelines are developed as a result of the scientist's work, who must use them, does the scientist continue to be the source of information on the intent of the guidelines?

FACTOR 4 - COMPLEXITY

What is the nature of the work and assignments? Are they related, sequential steps; different processes; independent assignments with varying duties?

What kind of variations exist in the work? Is the scientist concerned with factual situations, with identifying interrelationships or deviations, with originating new approaches or techniques, with establishing new standards?

FACTOR 5 - SCOPE AND EFFECT.

Does the scientist's work impact others and the way in which they work?

Does the work affect the accuracy, reliability, or acceptability of other work processes?

What impact does the work have on regulated industry, other Federal agencies, State, local, or foreign governments, national and international organizations?

FACTOR 6 - PERSONAL CONTACTS.

What kind of people and organizations does the scientist come into contact? Coworkers, various supervisors and managers in the Agency, representatives of industry, other Federal agencies, State, local, and foreign governments, trade organizations, national and international organizations?

What positions do those contacted hold and what levels do they occupy in their organizations?

FACTOR 7 - PURPOSE OF CONTACTS.

What is the purpose of the scientist's contacts? To give and receive information, to resolve problems, to motivate and influence others, to justify, defend, negotiate, or settle matters?

Does the scientist deal with people who are skeptical, uncooperative, unreceptive, hostile?

Does the scientist settle controversial issues or arrive at compromise solutions with persons who have different viewpoints, goals, or objectives?

What kind or level of commitment authority does the scientist have in representing the Agency?

FACTOR 8 - PHYSICAL DEMANDS.

What is the nature of the scientist's physical activity? Sedentary, walking, standing?

FACTOR 9 - WORK ENVIRONMENT.

What is the nature of the environment in which the scientist works?

SUPPLEMENT FOUR

SAMPLE POSITION DESCRIPTION

This sample position description is intended to be used as a general frame of reference, and should not be applied mechanically. Good judgement should be used in deciding whether any part of this sample meets the specific situation work situation being described. **It is expected however, that each regulatory review scientist position description will be unique** because of those functions that are peculiar to the organization to which the scientist is assigned, the areas of responsibility in which the scientist has become recognized as an authority, and the way in which the scientist has uniquely impacted the positions.

Regulatory Review Scientist GS- XXX-14

I. BACKGROUND:

II. DUTIES and RESPONSIBILITIES:

Serves as a regulatory review scientist in the center regulatory review organization with responsibility for the review of a variety of proposed scientifically complex application; providing recommendations and guidance to Center review organizations and review scientists, and the regulated industry; and representing the Center at local, State, and national meeting on matters concerning regulated products. Assignments cover such work as:

Analyzing and determining the adequacy of data and tests submitted by a manufacturer regarding the safety and efficacy of a regulated product or products.

Determining if additional data or other information is necessary within the context of applicable laws, policies, regulations, and guidelines.

Providing verbal and written conclusions to other Federal agencies, industry, universities, and State, local, cal foreign governments.

Developing and recommending new and revised research treatises and guidelines for regulated products, and proposing areas of study for in-house and contract research projects.

Recognizing the need for the initiating new and amending regulations, policies, and procedures.

Maintaining comprehensive surveillance of the impact and significance of complex periodic reports of clinical experiences, studies, and tests submitted by sponsors of important products including scientific information on unexpected side effects, injuries, toxicity, or sensitivity reactions associated with the product and similar products.

Based on a mastery of the functional area, advises on difficult issues associated with product development, technological changes, environmental impact, industrial changes, and toxicity assessment in advance of or during the early stages of product development.

III. FACTOR LEVEL DESCRIPTIONS:

FACTOR 1 - KNOWLEDGE REQUIRED BY THE POSITION

Mastery of a scientific discipline and associated disciplines sufficient enough to allow the regulatory review scientist to review a variety of complex applications from manufacturers of products intended for use nationally.

This mastery includes a through knowledge of recent developments in the scientific discipline and associated scientific disciplines; applicable FDA laws, regulations, policies, and guidelines; the regulated industry; scientific information on unexpected side effects, or scientific reactions associated with the products and any related products.

Skill identifying problems, gathering information, drawing conclusions, recommending solutions, preparing reports, and negotiating acceptance and implementation of recommendations.

Ability and skill in accomplishing work through others when necessary at all necessary levels within the Center and with all other organizations with the Center impacts.

Ability to present finding and recommendation scientific terms both verbally and in writing.

FACTOR 2 - SUPERVISORY CONTROLS

The supervisory provides administrative direction only making assignments in terms of broad program objectives. The regulatory review scientist independently plans, designs, and carries out work, functions, projects, and studies that may also come from sources other than the supervisor.

The results of the work are considered to be scientifically and technically authoritative, and are normally accepted without significant change. Recommendations for new work and projects, and the alternation of objectives are usually evaluated only for such

considerations as availability of funds and other resources, broad program goals and national priorities.

FACTOR 3 - GUIDELINES

Guidelines are mostly broad and general policy statements, scientific and trade literature, Agency and Center regulations, and pertinent legislation that are either inadequate or unavailable for most of the questions and issues encountered. Considerable judgement and ingenuity must therefore be used in interpreting and modifying the available guidelines. As an authority, the regulatory review scientist is responsible for initiating and developing policies, instructions, and guidelines which must be used by other Center scientists and the regulated industry.

FACTOR 4 - COMPLEXITY

The work involves a combination of scientific and regulatory responsibilities which are difficult because of the advanced scientific and technical complexity surrounding and wide variety of products reviewed, and that call for a number of unique scientific and regulatory approaches. The work requires the regulatory review scientist to deal with such matters as new products, industrial changes, technological changes in the products of regulated products, and new scientific knowledge. The regulatory review scientist's approaches are influenced by precedents drawn from ongoing improvement in the regulatory review process, advances in the applicable sciences and the regulated industry, new product problems, and disagreements in the application of science and regulatory review procedures.

FACTOR 5 - SCOPE AND EFFECT

The work involves resolving critical problems and developing new approaches to problems which are difficult because of the advanced scientific and technical complexity surrounding the products reviewed, and which affect the work of other Center scientists and the regulated industry. The regulatory review scientist provides authoritative advice to officials and scientists in the Agency and Center, other Federal agencies, and the regulated industry. Findings and conclusions affect the Agency and Center, other Federal agencies, and the regulated industry. Findings and conclusions affect the Agency and Center regulatory mission and the safety and health of those affected by the regulated products.

FACTOR 6 - PERSONAL CONTACTS

The regulatory review scientist makes contacts with a variety of key and top officials, managers, scientific professionals, and executives both within and outside the Agency such as directors and scientists in public and private laboratories, corporate officials and representatives or regulated firms, official representatives of other Federal agencies and foreign governments, and representatives of professional and grade associations.

FACTOR 7 - PURPOSE OF CONTACTS

The purpose of the regulatory review scientist's contacts is to discuss, justify, defend, resolve, negotiate, and achieve common understand and satisfactory solutions of controversial scientific and technical issues and regulatory requirements and policies. Because contacts are made iwth individuals of widely differing viewpoints, goals, and objectives, the regulatory review scientst must use tact, expert scientific an product knowledge, and authoritative knowledge of Agency and Center policy and regulations to persuade others to accept the Agency point of view or in the development of suitable alternatives.

FACTOR 8 - PHYSICAL DEMANDS

The work is primarily sedentary with occasional walking, standing, bending, and carrying of light items.

FACTOR 9 - WORK ENVIRONMENT

The work is usually performed in an office setting.

SUPPLEMENT FIVE

GUIDELINES FOR CONDUCTING IN-DEPTH INTERVIEWS

Prior to a scheduled meeting, the Committee Chair will assign cases to appropriate committee members for the conduct of in-depth reviews. Objectivity in the reviewer is critical to this process. The reviewer will be expected to read both the case and any material which has been submitted to enhance the case such as recommendations letters to appreciation. The review should be conducted in enough detail to allow the reviewer to critically evaluate and intelligently discuss the assigned case with the whole committee.

The review will be expected to go beyond the written case material in an attempt to clarify and check the significance of the scientist's accomplishments, sort contributions from those of other scientists, and bring any additional information to the Committee meeting for discussion which may not have been made available in the case material.

The in-depth review will involve a interview with the review scientist under consideration. An interview with the immediate supervisor is also expected. The supervisor usually is the best source on points that need to be clarified and nay additional information which may be pertinent to the case. The reviewer may also find it necessary to interview others as well, depending on the reviewer's familiarity with the scientist and the position, the impact of the scientist outside the organization, the mission of the organization, and any other aspects which may be relevant to the case.

Preparation before interviews are conducted is essential in order to save the time of both reviewer and those being interviewed. In addition to reading and being familiar wioth the case material, the reviewer should also read and be familiar with the grade level criteria and those assignments which are characteristic of the grade level being requested as found in Supplement Six, FDA, Regulatory Review Scientist Grade Level Criteria, the memoranda of recommendation and list of accomplishments, and the position description submitted with the case. It should be remembered that the position description is an official document which the requested supervisor certifies as containing both an adequate and accurate description of the work assigned to the regulatory review scientist. Both the grade level criteria and the position description are presented in the Factor Evaluation System format. Supplement Three, Position Description Format offers suggested questions for each of the major factors which can help the reviewer prepare for the interview to gather the available information if there is any additional information which may come to mind.

SUPPLEMENT SIX

FDA, REGULATORY REVIEW SCIENTIST GRADE LEVEL CRITERIA

INTRODUCTION

The accepted full-performance level for review scientists in FDA review organizations is GS-13. This level has been established through long experience with and application of those position classification standards which are used to evaluate FDA review scientists. The full performance level may be defined as the highest grade level of work in an occupation that involves the independent performance of the full range of duties found in an organization. An established career ladder allows all who enter the ladder to rise to the top grade, or full performance level, without being subject to merit promotion procedures when the employee satisfactorily demonstrates the knowledge, skills, and abilities to perform at the next higher grade level. This Supplement speaks to those unique scientists who because of the combination of the work which they perform and the personal qualifications which they bring to that work are performing at levels above the full-performance level of GS-13.

OCCUPATIONAL INFORMATION:

Regulatory review scientists apply their skills in the context of the regulatory framework of the consumer protection responsibilities of the FDA. They review a variety of applications submitted by the regulated industry to ensure the safety and efficacy of human drugs, foods, animal drugs, medical devices, and biologicals. Regulatory review scientists must have considerable knowledge of current scientific methods and procedures, the abilities to interpret data, and the ability to explain decisions by means of written and verbal presentations. They must be able to demonstrate the arability to conduct and bring to proper conclusion, appropriate scientifically based review activities solving novel situations that involve complex, scientific data and methodology, and related issues.

Regulatory review scientists may be classified to any one of several occupational series such as microbiologist, pharmacologist, toxicologist, chemist, mathematical statistician, or other appropriate series. The occupational classification appropriate to any specific position will depend on the qualification requirements established by management for the position. Although the academic qualifications for a regulatory review scientist position may vary greatly, there is a high degree of consistency among the various position classification standards used to evaluate the various scientific disciplines in FDA. Accordingly, positions in different scientific disciplines, but involving assignments and responsibilities of comparable levels of difficulty will be classified at the same grade. The criteria in this Guide are developed for use across occupational series in determining the grade levels of regulatory review scientists in FDA.

It must be stressed that GS-14 and 15 grade levels represent exceptional levels of responsibility combined with exceptional degrees of scientific and technical complexity. To justify classification at these grade levels, a regulatory review scientist is required to possess expertise in an area of **on-going** functional importance to the FDA. This responsibility should not be fragmented beyond that which is necessary for effective management control. Ideally the work which controls the grade of a position should occupy a majority, at least 50 percent or more, of a regulatory review scientist's time. It is understood that regulatory review scientists who are classified at GS-14 and 15 hold their positions on an incumbency basis only, and that those positions will be abolished when vacated.

FACTOR EVALUATION SYSTEM:

The classification criteria in this Supplement have been derived from the published, written grade level criteria in those position classification standards which address the various biological, life , and physical science occupational series found in FDA. The classification factors, factor levels and point values, and the conversion table are identical to those requires by the Factor Evaluation System. Positions must be evaluated on a factor-by-factor basis, comparing the duties of a positions, the work situation, and any special competence of the scientist with the various factor level descriptions. A position must be fully equivalent to the overall intent of the factor level selected for each factor.

Examples of work described in this Supplement are for illustrative purposes only. These examples are to be used as a general frame of reference or bench mark, and should not be applied mechanically. Good judgement must be used in deciding whether a position fully meets the essential requirements of a particular factor level. In order to be assigned to a particular factor level, it is necessary for the position to satisfy the overall intent of the factor level description rather than just matching the specific examples provided.

The FES requires that the following **nine factors** be used in the evaluation of regulatory review scientist positions.

1. Knowledge Required by the Position. The nature and extent of information and facts which must be understood to perform acceptable work, and the kinds of skills necessary to apply this knowledge.

2. Supervisory Controls. The nature and extent of direct and indirect controls exercised by the supervisor, the scientist's responsibility, and the review of completed work.

3. Guidelines. The nature of the guidelines and the judgement needed to apply guidelines.

4. Complexity. The nature, number, variety, and intricacy of the tasks, steps, processes, or methods in performing the work, and the difficulty and originality involved.

5. Scope and Effect. The purpose, breadth, and depth of the work assignments, and the effect of the recommendations or services both within and outside the organization

6. Personal Contacts. With whom and the level at which contacts are made.

7. Purpose of Contacts. Purpose and difficulty in communicating with those contacted.

8. Physical Demands. The requirements and physical demands place on the scientist by the work assignments.

9. Work Environment. The risks and discomforts in the scientist's physical surroundings.

These factors form a pattern which establishes the grade level of a position. Within the Factor Evaluation System, certain factors are considered to be more important than other factors and so are more heavily weighted in the scoring system. The first five of the nine FES factors control the grade of a regulatory review scientist position. These factors are Knowledge Required by the Positions, Supervisory Controls, Guidelines, Complexity, and Scope and Effect. The remaining four factors, Personal Contacts, Purpose of Contacts, Physical Demands, and Work Environment will never separately or as a ground control the grade of a position. While these factors are not as important as the others in terms of the points necessary to establish the grade level of a position, they must be complimentary to and consistent with the purpose and intent of the first five factors.

The critical **difference between GS-13 and GS-14** will always be found in Factor 2, Supervisory Controls, and Factor 3, Guidelines. Factor levels 2-5 and 3-5 for these two factors must be met before a position can be classified at GS-14 grade level. The factor levels for the other seven factors should also follow the pattern which is distinctive of and complimentary to GS-14. This pattern of factor levels is 1-8, 4-5 or 5-5, 6-3, 7-3, 8-1, and 9-1. If a position fails to meet this pattern of factor levels which is complimentary to the critical levels of 2-5 and 3-5 and is typical of GS-14, it is usually a strong indication that the factor levels chosen for the critical factors of Supervisory Controls and Guidelines have not been met. In such cases, the levels assigned to those two factors should again be carefully reviewed to make sure that they have been properly evaluated.

The critical differences between GS-14 and GS-15 will always be found in Factor 1, Knowledge Required by the Position, Factor 4, Complexity, and Factor 5, Scope and Effect. Factor levels 1-9, 4-6, and 5-6 for these three factors must be met before a position can be classified at GS-15 grade level. The factor levels for the other six factors should also follow the pattern which is distinctive of and complimentary to GS-

15. This pattern of factor levels is 2-5, 3-5, 6-3 or 6-4, 7-3 or 7-4, 8-1, and 9-1. IF a position fails to meet this pattern of factor levels which is complimentary to the critical levels of 1-9, 4-6, and 5-6 and is typical of GS-15, it is usually a strong indication that the factor levels chosen for the critical factors of Knowledge Required by the Position, Complexity, and Scope and Effect have not been met. In such cases, the levels assigned to those three factors should again be carefully reviewed to make sure that they have been properly evaluated.

The pattern of factors which would be typical for FDA regulatory review scientists at the GS-14 and 15 grade levels addressed above can be seen more clearly in the following table:

<u>GS-13</u>	<u>GS-14</u>	<u>GS-15</u>
1-8	1-8	1-9
2-4	2-5	2-5
3-4	3-5	3-5
4-5	4-5	4-6
5-4 or 5-5	5-5	5-6
6-3	6-3	6-4
7-3	7-4	7-4
8-1 or 8-2	8-1 or 8-2	8-1 or 8-2
9-1 or 9-1	9-1 or 9-2	9-1 or 9-2

It should be noted that the presence or absence of, or the number of publications attributed to a regulatory review scientist may not be used to establish a grade level. None of the many, established position classification standards that have been established to evaluate the work of scientists in the Federal government, including those that serve as the basis of the grade level criteria found in this Plan, use publications as part of the classification grade level criteria. For regulatory review scientist, as is the case with all other non research scientists, publications serve as evidence along with other appropriate information that a regulator review scientist has in fact performed a certain kind of work, has contributed to a project, is actually recognized for expertise in a certain area, etc.

Also, authorship, co-authorship, primary, secondary, or otherwise, as in the issue of presences and number of publications cannot be considered in establishing the grade of a regulatory review scientist position. As with publication in general, authorship serves as evidence of work performed. However, this evidence may vary from scientist to scientists because of the habits of research scientist or research managers with whom a review or regulatory review scientist may have been working. Some research scientists generously recognize the work of others by including their names as co-authors of papers, other research scientist do not. While authorship may be an indicator, it may also be an inconsistent indicator. Other sources of information are important and have

been demonstrated through long use to be more reliable in the Federal government. These sources include in-depth interviews with workers and their supervisors, positions descriptions, staffing charts, and other traditional sources used to classify positions.

GRADE LEVEL CONVERSION CHART

Total points on all evaluation factors are converted to General Schedule grades as follows:

POINT RANGE

3155 - 3600 = GS-13

3605 - 4050 = GS-14

4055 - up = GS-15

GRADE LEVEL CRITERIA

FACTOR LEVEL DESCRIPTIONS

FACTOR 1 - KNOWLEDGE REQUIRED BY THE POSITION.

This factor measures the nature, variety and intensity of knowledge, skills, and abilities required to perform the work of the position successfully. In order to be credited, the knowledges, skills, and abilities must be both required by the position, and actually be applied on a regular and continuing basis by the master reviewer scientist. Possession of a professional knowledge of the fundamental theories, principles and methods in a scientific discipline equivalent to that obtained through the successful completion of a bachelor degree program, or equivalent experience or training, is the minimum requirement for positions covered by this criteria.

Factor Level 1-8 = 1550 points. (GS-13, GS-14)

Regulatory review scientists must possess a mastery of the theories, principles, and methods in a scientific discipline and associated scientific disciplines sufficient enough to allow the review or regulatory review scientist to review a variety of complex industry applications, to apply new scientific and technological developments to novel and critical problems which cannot be solved by the use of conventional methods; and to extend and modify approaches, precedents, and methods in order to resolve and prevent obscure, and unprecedented problems. This mastery includes a thorough knowledge of recent developments in the scientific discipline and associated scientific disciplines; applicable FDA laws, regulations, policies, procedures, and guidelines; scientific information on unexpected side effects, injury, toxicity, or scientific reactions associated with the regulated products and related products.

Regulatory review scientists must possess the ability to recognize the need for and develop new procedures to solve critical or novel problems or to perform more refined analyses; the ability to advise others in the application of Agency rules, regulations, and procedures; the skill to identify problems, gathering information, drawing conclusions, recommending solutions, preparing papers and reports for publication, providing advise to other scientists, and negotiating acceptance and implementation of recommendations; the ability and skill in accomplishing work through others when necessary; and communication skills sufficient to draft papers or guidance documents, and provide advice to other scientists.

Factor Level 1-9 = 1850 points. (GS-15)

The regulatory review scientist must possess extraordinary program, scientific, and technical knowledges, skills, and abilities which are used to develop and materially redefine or redesign broad and complex categories of products; and master of all related Agency regulatory programs and the science which supports those programs in

order to function in behalf of the Agency as the recognized authority responsible for dealing with the critical scientific issues, problems, and policies in the area or areas of interest. The regulatory review scientist must possess a thorough knowledge of the policies and practices, differences, and peculiarities, and past and present intentions of those regulated industries with whom the scientist deals; and a thorough knowledge of, as well as the intent of, FDA enabling legislation, policies, implementing regulations, and procedures, court decisions and precedents, organizational structures, and interrelationships of the area of concentration with other scientific organizations both within and outside the Federal government including the regulated industries.

The regulatory review scientist must possess the ability to analyze complex and sensitive scientific situations involving numerous variables, to identify and prove root causes and anticipate ancillary problems, and to decide on appropriate courses of action, and to implement decisions; the ability to select, plan, and organize work in order to accomplish a variety of concurrent activities performed in a variety of companies within the regulated industry; and the ability to gauge the effort at hand, to select what needs to be done, by whom, and how to proceed, and to recognize impact in terms of trade-offs, scheduling of the time of various participants, and the costs both to the Agency and the regulated industry; and the ability and skill to accomplish work through others at all necessary levels within the Agency and with other organizations which the Agency impacts.

These knowledges, skills, and abilities are well known not only to Agency officials, but may also be known to officials in other Federal agencies, State, local, and foreign governments, the regulated industry, and professional and trade organizations who are directly or indirectly affected by the work of the regulatory review scientist.

FACTOR 2 - SUPERVISORY CONTROLS

This factor measures the degree of guidance and control exercised over the regulatory review scientist=s position. The three aspects to this factor are: how assignments are received, especially the specificity of instructions or directions provided at the beginning of an assignment; the amount of responsibility given to plan and carry out the assigned work, and the extent to which advice and assistance is provided while the work is in progress; and the manner in which the work is reviewed. The nature of the relationship between the regulatory review scientist and the supervisor should be examined closely before any judgment is made. Contact with the supervisor, or with other officials in the supervisory chain, is often consultative in nature, that is, to exchange information or to arrive at mutually agreeable decisions, rather than for the purpose of requesting assistance or receiving guidance.

Factor Level 2-4 = 450 points. (GS-13)

Controls. The supervisor defines overall scope of work, sets objectives, workload and resources available, and assists in initial planning and setting of priorities. The supervisor and the review scientist cooperatively decide on deadlines and approaches.

Responsibility. The regulatory review scientist independently plans, organizes, and carries out assignments; resolves technical conflicts; coordinates with others; and applies established policy and guidelines to achieve objectives. The supervisor is consulted only on very unusual or controversial matters.

Review of work. The work is reviewed from an overall standpoint for quality, completeness, and effectiveness in meeting assigned objectives and expected results. The work is considered to be scientifically and technically accurate without any need for major change. Written work is reviewed for editorial purposes rather than content.

Factor Level 2-5 = 650 points. (GS-14, GS-15)

Controls. The supervisor provides administrative direction only, and makes assignments only in terms of broadly defined national programs, missions, and functions.

Responsibility. The regulatory review scientist is responsible for independently planning, designing, and carrying out projects, assignments, studies, or other work.

Review of work. Results of the work, conclusions, and decisions are considered to be scientifically and technically authoritative, and are accepted without significant change. Any review typically concerns broader issues which are not the regulatory review scientist's responsibility such as impact on overall Center programs and goals, resource constraints, or national priorities and authorities.

FACTOR 3 - GUIDELINES

This factor measures the availability, specificity, and applicability of guidelines, including law and regulations, policies and procedures, instructions, established practices, precedents, textbooks, manuals, professional journals, handbooks, and other reference materials. This factor also evaluates the degree of judgement exercised by the regulatory review scientist in selecting, applying, adapting, interpreting, modifying, extending, and creating guidelines.

Factor Level 3-4 = 450 points. (GS-13)

Availability. General guidelines are available in the form of Agency and Center policies, written manuals and procedures, regulations, scientific and technical literature, and general scientific consensus.

Utility. The nature of the work and the assignments are such that available guidelines are not directly applicable.

Judgment demands. The regulatory review scientist is therefore required to use judgment based on personal scientific background and understanding of broad legislation, policy, and program definitions in order to deviate from traditional approaches and methodology, to extend and adapt guidelines in order to meet novel and difficult situations, and to develop new or revise existing procedures and criteria to solve problems and meet unique requirements. Initiative is exercised to implement new and revised procedures and to incorporate them into the work.

Factor Level 3-5 = 650 points. (GS-14, GS-15)

Availability. Few guidelines apply to the work being performed, and those that do are very general and therefore inadequate such as broad legislation and general Agency policy.

Utility. These guidelines require extensive interpretation of the intent of basic Agency policy, as well as major and untested deviations from or adaptations to currently accepted procedures and practices.

Judgment demands. Considerable independent judgement and ingenuity are required to interpret and adapt the few existing guidelines. As a recognized authority, the regulatory review scientist must assess the impact of new policies, regulations, and pending legislation on the area of functional responsibility, recognize the need for new procedures in the area of functional responsibility to close gaps in knowledge or increase understanding about critical processes, identify areas where new or improved policies and procedures are needed, and develop new policies and procedures which must be applied and followed by other review and regulatory review scientists and by the regulated industry.

FACTOR 4 - COMPLEXITY

This factor measures the nature, variety, and relative difficulty of the functions performed, and the systems, methods, procedures, and techniques used. Also considered under this factor, is the difficulty encountered in determining what needs to be done; the nature of the problems and obstacles encountered; the degree of analysis, evaluation, and insight required; and the opportunity for creativity and ingenuity. Other complicating factors, including administrative and management issues, should also be considered under this factor. Noteworthy professional achievements or recognition should also be considered under this Factor.

Factor Level 4-5 = 325 points. (GS-13)

Assignment. The regulatory review scientist=s assignments principally consist of interpreting scientific information in terms of existing standards. The work requires the comprehensive critique of data, recommendations for additional studies, gathering of pertinent scientific information, and written evaluations and professional conclusions. The work assignments anticipate that the regulatory review scientist has the full capability to apply the necessary personal knowledges and skills to the full range of problems encountered. The problems encountered are usually limited to those delegated to the organization to which the review scientist is officially assigned.

Discretionary judgement. Judgement is generally limited to the interpretation of scientific data within the area of personal expertise. Limited precedents may be set which affect internal Center and regulated industry activities and the marketing of regulated products. Approaches to the work ordinarily involve fairly well established methods and procedures. The regulatory review scientist may have authored papers, presented papers or posters at conferences, or served on technical panels or committees.

Factor Level 4-5 = 325 points. (GS-14)

Assignment. The regulatory review scientist is recognized as a Center authority in the area or areas of interest, and as such develops guidelines, science policy, and Agency and Center requirements for application to the regulated industry. It is expected that the regulatory review scientist integrates personal knowledge and experience in the resolution of problems, the modification of procedures, and in the development and interpretation of policy to meet difficult, controversial, and new and novel situations and conditions. Actions taken and solutions devised cut across other functional areas within the Office and Center. The regulatory review scientist frequently represents the Office and Center, or acts as liaison, with outside professional groups. When appropriate, the regulatory review scientist, assumes responsibility for work groups or teams. Some assignments may address continuing international health problems. Because of the visibility of such problems, the regulatory review scientist must employ a knowledge of worldwide problems and technological advance. The regulatory review scientist participates in the development of technical solutions to these kinds of problems, and is recognized as the authority in the area of functional responsibility. The regulatory review scientist has attained significant professional recognition such as achievement awards and professional certification. Creativity and originality are evident in such areas as the introduction of new and novel approaches to the problems and issues encountered.

Discretionary judgment. In the resolution of difficult problems and precedent-setting issues, considerable ingenuity and professional judgement are required, notably in the selection and evaluation of approaches and methods and in the modification of previously formulated requirements. Negotiating skills and skill in the resolution of scientific and regulatory problems play an important role in the work assignments.

Factor Level 4-6 = 450 points. (GS-14,15)

Assignment. Because of the regulatory review scientist's broad and widely accepted reputation as the Agency authority in an area or areas of interest, assignments involve broad and extensive scientific programs and problems, specific scientific problems of extraordinary emergency, public interest, or economic significance. Problems and issues dealt with have been previously attacked without success, previous work in the area addressed has failed to yield satisfactory results, and issues are currently unknown or undefined and require the development of new scientific and regulatory methodologies. Such issues and problems often involve other Federal agencies and foreign governments.

Discretionary judgment. In carrying out assigned projects or programs, the regulatory review scientist develops alternative courses of action which become national or international standards for the regulated industry and for future regulatory activity. The highest degree of judgment is required to select, evaluate, and resolve problems which will typically change, modify, and create new scientific and regulatory policies, procedures, and methods. The regulatory review scientist must be exceptionally sensitive and resourceful in order to build scientific consensus for the most practical solutions to problems.

FACTOR 5 - SCOPE AND EFFECT

This factor measures the purpose of the work and the impact, influence, and importance of the efforts of the regulatory review scientist in accomplishing the mission of the organization, and in the advancement of scientific and regulatory principles, methods, and procedures. This factor is also designed to recognize those situations where the unusual initiative and exceptional abilities of the regulatory review scientist have resulted in the expansion of the job beyond expected dimensions.

Factor Level 5-4 = 225 points. (GS-13)

Criticalness of work. The purpose of the work is to provide essential, standard, and defined expertise in the area or areas of interest. The regulatory review scientist may modify established procedures and develop new methods and approaches to meet unique requirements or upgrade current capabilities, and advise others in their application.

Scope of work. The review scientist is regarded as a full professional in an assigned area who is working at the full performance level. The scope of the work includes evaluating new applications and communicating results of the work to other review scientists and to the regulated industry.

Impact of work. These efforts enhance the ability of the Center to increase the efficiency of services delivered. Documentation of new and improved methods and

procedures impact other review scientists. On occasion the regulatory review scientist becomes involved with issues outside of the immediate work environment and area or areas of interest.

Factor Level 5-5 = 325 points. (GS-14)

Criticalness of work. The regulatory review scientist receives the more difficult and significant work, and provides authoritative expertise in the resolution of unusually difficult or long standing problems, and critical, sensitive, and controversial issues related to the area or areas of interest. The regulatory review scientist is expected to be the crucial resource in the effective solution of these problems and issues by the application and integration of personal knowledges, skills, abilities, and experience.

Scope of work. The recognition which the regulatory review scientist has achieved extends to other Agency organizations and outside the Agency into the regulated industry and professional and trade organizations as evidenced by requests for consultation. The regulatory review scientist may represent the Office and Center on intercenter, national, or international committees and forums; frequently works with other regulatory review scientists and other professionals; and is relied on to assume responsibility for team and group efforts.

Impact of work. The work of the regulatory review scientist affects Office, Center, or Agency policies and programs and the regulated industry. The professional skills and stature of the regulatory review scientist play a significant role in getting recommendations approved and accepted. Assignments are regarded as particularly important and critical by Office and Center management. The regulatory review scientist's counsel is also solicited in formulating long range plans. The results of the regulatory review scientist's efforts have potential for advancing the state-of-the-art in the area of functional responsibility.

Factor Level 5-6 = 450 points. (GS-15)

Criticalness of the work. The purpose of the work is to provide authoritative expertise in the resolution of especially critical, sensitive, and controversial issues related to the area or areas of interest. The issues and problems are especially critical because of their regulatory and public health significance and scope.

Scope of work. Based on established and widely recognized expertise, knowledges, skills, abilities, and experience, the regulatory review scientist isolates and defines unknown conditions and develops new approaches and methodology for use by other review and regulatory review scientists, and provides expert guidance to others on professional issues within the area or areas of interest. The regulatory review scientist represents the Agency in decision-making conferences, and is expected to recommend which Agency resources should be devoted to chosen courses of action.

Impact of work. The regulatory review scientist=s work affects the Office, Center, Agency, and the regulated industry as well as similar programs. Guidance and direction are given to others on scientific and regulatory issues in the area or areas of interest; findings and conclusions are of considerable significance in altering and modifying Agency science and regulatory concepts on a long-term and continuing basis, and influence the science and programs of other Federal agencies, State, local, and foreign governments, and the regulated industry; and decisions are frequently questioned and challenged at the highest levels, but the established and recognized professional stature of the regulatory review scientist is such that results of the work are proven and accepted.

FACTOR 6 - PERSONAL CONTACTS

This factor measures the kind, level, role, and authority of those contacted by the regulatory review scientist and the conditions and circumstances surrounding the contacts. Careful consideration should be given to the regular and recurring nature of the contacts in order to avoid crediting contacts made only on an occasional basis.

Factor Level 6-3 = 60 points. (GS-13)

Personal contacts are made with other Agency scientists and regulatory professionals, and with industry representatives and scientists and others from outside the Agency concerned with the science and technical matters addressed by the regulatory review scientist.

Factor Level 6-4 = 120 points. (GS-14,15)

Personal contacts are made with top management in the Agency such as Agency program managers and administrators; and high ranking officials in other Federal agencies, State, local, and foreign governments, and the regulated industry. Contacts often extend beyond the boundaries of the regulatory review scientist=s area or areas of interest.

FACTOR 7 - PURPOSE OF CONTACTS

This factor measures the reasons for the contacts made by the regulatory review scientist addressed in Factor 6 - Personal Contacts above, and the difficulty involved in justifying, defending, or persuading others to accept the opinions, positions, and information presented.

Factor Level 7-3 = 120 points. (GS-13)

The purpose of the personal contacts is to persuade, influence, or motivate others who are skeptical, uncooperative, or have different and conflicting opinions such as

persuading other scientists within and outside the Agency to accept changes in procedures and methods about which there is technical disagreement.

Factor Level 7-4 = 220 points. (GS-14, GS-15)

The purpose of the personal contacts is to justify, defend, or settle matters involving significant, delicate, or controversial issues. Those contacted typically have widely differing viewpoints, objectives, or goals which require the regulatory review scientist to convince those contacted to accept the Agency position or to develop suitable compromises or alternatives. Negotiations are conducted in behalf of the Agency for the purpose of resolving divergent viewpoints by achieving common understanding and satisfactory solutions, enlisting support on key matters, and insuring concerted action by all involved. The regulatory review scientist represents the Agency at meetings, hearing, conferences in the area or areas of interest which deal with such issues as controversial scientific and

regulatory policies or the development of Center and Agency wide standards and guidelines.

FACTOR 8 - PHYSICAL DEMANDS

This factor measures the intensity and regularity of physical demands imposed on the regulatory review scientist, and any requirement for possessing and exercising unusual physical characteristics or special abilities.

Factor Level 8-1 = 5 points.

The work is primarily sedentary and involves only occasional walking, standing, bending, and carrying of light objects.

FACTOR 9 - WORK ENVIRONMENT

This factor measures the physical surroundings in which the regulatory review scientist works including the need to take precautionary measures to avoid exposure to hazardous materials or other physical risks.

Factor Level 9-1 = 5 points.

The work is performed in an office setting with adequate lighting, heating, and ventilation.