

November 2007

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
CDRH Research Scientist Peer Review Program**

**STANDARD OPERATING PROCEDURES
for
CDRH Research Scientist Peer Review Program**

These Standard Operating Procedures govern the evaluation process for:

- (1) CDRH research scientists proposed for promotion to the GS-14 and above;
- (2) Applicants for vacant research scientist positions at the GS-14 and above in CDRH, and
- (3) CDRH research scientists at the GS-14 and above undergoing **mandatory five year** review (**Cyclical Review**).

COMMITTEE ADMINISTRATION RESPONSIBILITIES

A. Associate Commissioner for Science

- 1) Responsible for agency level committees.
- 2) Appoints Committee Chair and Executive Secretary for agency committees.
- 3) For Agency-level committees, reviews and appoints committee members following recommendations of Committee Chairs.
- 4) Reviews the Agency-level Committee reports.
- 5) Establishes the Agency's yearly calendar for all peer review Committee meetings with input from all Committee chairs.

B. Center Director

- 1) Responsible for center level committee.
- 2) Appoints Committee Chair and Executive Secretary for the center committee.
- 3) Reviews and appoints committee members following recommendation of Committee Chair.
- 4) Approves transmittal of package to the Committee except for self-nomination.
- 5) Reviews the Center-level Career Evaluation Reports.

C. Candidate's Supervisor

- 1) Recommends candidates for promotion review.
- 2) Reviews and assures by signature that to the best of his/her knowledge the package accurately reflects and depicts the accomplishments and responsibilities of the candidates.

- 3) Meets with candidate to discuss responsibilities and endorsement of candidate.
- 4) Discusses final committee report with employee and prepares response.
- 5) Identifies a research scientist in CDRH who is willing to serve as primary reviewer for the application. The primary reviewer a) must have a grade at least as high as the grade being sought by the applicant, b) must not have collaborated with the applicant in the last 5 years, and c) must not work in the same division as the applicant.

D. Candidate

- 1) Prepares the package and assembles all exhibits.
- 2) Discusses the package with the supervisor.
- 3) Provides the Executive Secretary (through their Program Management Office) with an electronic copy and paper copy of the package by the established due date (at least 75 calendar days in advance of the next scheduled meeting date).

E. Committee Chair

- 1) Coordinates the yearly calendar for Committee meetings with the Associate Commissioner for Science.
- 2) Provides advice to candidates and supervisors relative to preparation and submission of package for peer review.
- 3) Advises Center Director or Associate Commissioner for Science, as appropriate, to ensure committee composition sufficient in number and expertise to ensure a fair review of all potential candidates.
- 4) Assigns packages with Executive Secretary to appropriate Committee members for in-depth review at time of notification to Committee members that the package has been posted to e Room.
- 5) Identifies Committee members with potential conflicts of interest (i.e., immediate supervisor or nominating supervisor) and recuses them from participation of the review process.
- 6) Orients Committee members in the evaluation process prior to serving on the peer review Committee (in conjunction with the Classification Specialist). Stresses importance of discussions with the candidate and candidate's supervisor.
- 7) Chairs Committee meetings and participates as full voting member.
- 8) As appropriate, invites persons with special knowledge about a specific package (for example, the primary reviewer) to the peer review meeting or contacts them to aid or assist in the review process.
- 9) Ensures the confidentiality of Committee discussions and recommendations
- 10) Recommends changes in the peer review process as appropriate.
- 11) Calls special meetings for such purposes as orienting and training new Committee members and handling an unexpectedly large number of packages, etc. and ad hoc packages.
- 12) Speaks for the Committee in communication with the Associate Commissioner for Science and/or Center Director on issues associated with the review process.

F. Committee Executive Secretary

- 1) Receives packages from supervisors/PMOs. Reviews packages for format, timeliness and completeness. When not subscribing to the prescribed format or incomplete, returns package to supervisor/PMO and advises of status.
- 2) Packages submitted after the published due date for each scheduled meeting will be returned to the supervisor and advised to re-submit in accordance with next scheduled meeting.
- 3) Advises Associate Commissioner for Science of scheduled dates and package submission dates for entry on FDA web site.
- 4) Coordinates and schedules meeting dates and meeting room with the Chair and confirms the dates with Committee members in accordance with previously published schedule.
- 5) Manages Committee membership at direction of Committee Chair
- 6) Enters tracking information on each package into Science FIRST.
- 7) Notifies candidate's supervisors of scheduled cyclical review and suspense date for submission of package at least 60 calendar days in advance of the due date.
- 8) Provides appropriate documentation to the Position Classification Specialist.
- 9) Along with the Committee Chair ensures that the Career Evaluation Report for each package is prepared at each committee meeting and submitted to the Position Classification Specialist for review and approval.

G. Peer Review Committee

- 1) The committee will consist of 8 permanent members, 7 ad hoc members, and up to two optional members sufficient in expertise to ensure a fair review of all potential candidates. 6 permanent members, including the chair and 7 ad-hoc members of the committee will be scientists from CDRH at the Division Director or senior scientist level and above. Up to two temporary members of the committee may be scientists from inside or outside CDRH representative of the same specialty or expertise as the applicant. One permanent member of the committee will be a Position Classification Specialist, provided by the Office of Management Programs (PMP), and will be a full participant in the deliberations of the committee and offer guidance in the review of cases. One permanent, non-voting member will be the Executive Secretary for the committee, provided by CDRH's Office of Management Operations (OMO), who will report to the Chair and will be responsible for conducting administrative review of all cases. A **quorum** is constituted by the presence of 5 committee members, which must include the OMP representative.
- 2) Meets in accordance with prescribed schedule.
- 3) Reviews package and evaluates each case on the basis of the criteria described in the appropriate personnel management guide.
 - a. The evaluation of each package will be based on scientific merit, and the achievements and contributions of the candidate. All appropriate information prescribed in the format for submission will be included in the evaluation.
 - b. The primary reviewer interviews the candidate, recommending supervisor, and/or persons with knowledge of the candidate's achievements and contributions.

- c. A simple majority of those present will determine the final recommendation of the Committee on the disposition of a case.
- d. A Committee member who is also the recommending supervisor should be recused from the package under consideration.

H. Position Classification Specialist

- 1) Receipt of candidate's completed peer review package from Committee executive secretary.
- 2) Review and analysis of proposed promotions (re: classification criteria) prior to peer review meeting (includes using reference materials such as: Classifiers Handbook, Significant classification appeals decisions, center peer review policy and procedures, etc.
- 3) Provide classification advisory services to Chair and committee members.
- 4) Attend all Peer Review committee meetings.
- 5) Respond to appeals, grievances, congressional inquiries, etc.
- 6) Prepare final peer review position reports and evaluations.
- 7) Advise employees of appeal rights and peer review procedures.
- 8) Train new committee members in the application of classification criteria.
- 9) Train Executive Secretary (Project Officer) re: position descriptions, etc.
- 10) Respond to candidate inquiries.
- 11) Maintain administrative records for candidates.

CANDIDATE'S PEER REVIEW PACKAGE*

A. The candidate prepares the review package, and the supervisor reviews and assures that the material accurately reflects and depicts the accomplishments and responsibilities of the candidate. The candidate will ensure that the package is presented to the committee Executive Secretary at least 75 calendar days prior to the scheduled meeting date in electronic format along with an original (paper copy), signed OF-8. Electronic copies, but not paper copies, are required for supporting documentation such as publications in peer-reviewed journals.

B. The package must contain, in the order shown, the following:

1. Transmittal memo from the immediate supervisor to committee chair which includes a proper endorsement from the Center Director. The transmittal letter shall list the name, title, series, and current grade of the candidate and the nature of the action requested.
2. A brief summary of the candidate's career (one paragraph) and a list of accomplishments and contributions to the agency, regulated industry, scientific community, and the regulatory process, and any special expertise pertinent to the execution of the candidates duties. The summary should have 4 sections corresponding to the 4 factors in the **Research Grade Evaluation Guide** at <http://www.opm.gov/fedclass/html/gsfunctn.asp>: 1. Research Assignment, 2. Supervisor Controls, 3. Guidelines and Originality, and 4. Contributions, Impact and Stature. Each section should make specific association wherever possible to bulleted items provided for the factors in the **Research Grade Evaluation** (in *italics* followed by parenthetical references to Factor and Level). Here are some examples:

Susan has become very proficient at acoustic microscopy, which is a *sophisticated research technique* (Factor 1, Level C) because it requires a deep understanding of subtle phenomena that affect high frequency acoustic measurements including diffraction, attenuation, absorption, and scattering.

Guidelines for Joe's work *are largely absent because of the novel nature of the work* (Factor 3, Level C). This is evidenced by ...

Jane has had several *invitations to address national professional organizations* (Factor 4, Level E) including invited talks at the 2002 Acoustical Society of American Conference, the 2004 American Institute of Ultrasound in Medicine Conference, and the 2006 Western Pacific Acoustics Conference.

3. A Curriculum Vitae (CV) (see **Appendix 2**).
4. A Bibliography (see **Appendix 3**).

5. OF-8 and Position Description. For information on the respective guides for each series and the preparation of the respective position descriptions see Appendix 1. **The proposed position description should follow the format required by the Factor Evaluation system.**
6. Current position description of record.
7. Electronic copies of no more than 3 recent publications that the employee considers most significant. The primary reviewer and other panel members may request copies of additional publications cited.

***Note:**

1. The candidate's package is to be submitted to the committee executive secretary electronically along with an original (paper copy), original/signed OF-8.
2. Letters of reference may be requested as part of a package for consideration of a candidate for promotion.

CYCLICAL REVIEW:

The purpose of cyclical review is to assure that those individuals who occupy positions covered by one of the Agency Peer Review plans continue to perform the duties that originally supported the assigned grade. Therefore, FDA peer review committees will perform cyclical review of candidates as follows: CBER every four years, all other committees 5 years. If the candidate is promoted between reviews, a new review cycle begins. This process also applies to those supervisors at GS-14 or 15 whose grades are based on the individual duties which they perform rather than upon their supervisory responsibilities. It also applies to those GS-14 and GS-15 non supervisors who may have received their grade via non-peer review classification.

Findings and Recommendations:

The committee, based upon the member's findings, may recommend the following;

- Certification -- that the incumbent was found to be performing work which satisfies the requirements to sustain the GS-14 or GS-15 grade level;
- Further review of the position within a prescribed timeframe (usually 6 months), due to incomplete or inaccurate information that prevents the committee from making a final determination as to the appropriate grade level;
- Inform the supervisor that the incumbent is not performing the duties as outlined in their position description of record, and direct the supervisor(s) to assign the duties that was the basis of the promotion;
- Inform the supervisor that the incumbent is not performing the duties as outlined in their position description of record, and recommend an appropriate course action (reassignment, downgrade, etc).

CANDIDATE'S CYCLICAL REVIEW PACKAGE

A. The candidate prepares the cyclical review package, and the supervisor reviews and assures that the material accurately reflects and depicts the accomplishments and responsibilities of the candidate in the past **five years**, in support of the current grade level. The candidate will be notified by the Committee Executive Secretary 60 calendar days in advance of the required submission date to prepare the package.

B. The package should contain the following:

1. Transmittal memo from immediate supervisor to Committee Chair (**see Appendix 6**).
2. Cyclical Review Recertification package addresses the following:
 - a. Name, title, series, and current grade level of the candidate.
 - b. List of accomplishments and contributions to the Agency, regulated industry, scientific community, and the regulatory process, including scientific achievements (research and regulatory), originality, and quality and reputation in the local, national and/or international scientific/regulatory community over the last 5 years (since last review). This should have the same format as described above in **CANDIDATE'S PEER REVIEW PACKAGE**, Section B. 2.
3. Description of special expertise, if any.
4. Career evaluation committee report from last peer review.
5. Curriculum Vitae (CV).
6. Current position description of record.

***Note:**

1. The candidate's package is to be submitted to the committee executive secretary electronically along with an original (paper copy), the original/signed OF-8.
3. Letters of reference may be required as part of a package for consideration of a candidate for promotion.

SELF-NOMINATION

Self-nomination is a request to reconsider the classification of a position covered by the peer review process. The self-nomination process begins only after an employee has contacted his or her immediate supervisor and has requested a management nomination for peer review. If the supervisor declines to make the nomination, the employee who meets the minimum qualifications for promotion has the option of either: 1) initiating a self-nomination, or 2) filing a formal position classification appeal. As part of the self-

nomination process, the employee must document the meeting with the supervisor, to include the supervisor's name and the date of the meeting.

To proceed with a self-nomination, the employee applies for peer review through established procedures to the appropriate committee chair. The employee must submit all items that are required by the applicable peer review plan, including scientific and/or technical information, and in accordance with the published schedule. The accuracy and adequacy of information provided to a peer review committee will be verified as part of the normal peer review process. Failure to provide the necessary documentation will result in the return of the nomination package.

AD HOC PEER REVIEW

This Evaluation Plan will be used for ad-hoc review of candidates for recruitment and selection purposes when management is filling a vacant permanent position. To expedite this process, the servicing Position Classification Specialist may serve as OHRM representative. The ad-hoc Panel will be composed of the Chair and at least two other GS-15 level or above members of the Committee. In such cases, the Plan will govern and the OMP representative will obtain any necessary classification concurrences required by existing OMP delegations of authority.

APPEALS

Any candidate dissatisfied with the final classification of his/her position, may resubmit a package. However, a resubmitted package must specifically address the deficiencies identified in committee reports as well as any changes in the employee's position. All resubmissions will be treated as new package and scheduled for peer review accordingly.

FDA employees have the right to formally appeal the classification of their positions (5 CFR, Part 511, Subpart F). They may appeal within the Agency to the Director, Classification Services Staff (CSS), OMP, or directly to the U.S. Office of Personnel Management (OPM). Appeals must include the documentation described in Article 32, Classification, Section 2-B and C of the CBA. CSS classification appeal decisions may be further appealed to OPM, but OPM classification appeal decisions are final within the Federal government and are binding on the Agency.

Classification appeals directed to OPM should be addressed as follows:

**U.S. Office of Personnel Management
Classification Appeals Office
Washington, DC 20415**

COMMITTEE OPERATION PROCEDURES

A. Prior to the Committee Peer Review Meeting

1. The candidate will prepare his/her package according to the format described in the Plan and with concurrence of the immediate supervisor.
2. All packages must be received by the Committee Executive Secretary at least 75 calendar days before the Committee meeting. All candidates scheduled for mandatory review will be notified in writing by the Chair and will be allowed at least 60 calendar days to prepare their package.
3. The immediate supervisor will thoroughly review the package for adequacy, accuracy, and format.
4. If the immediate supervisor concurs, the package is forwarded to the Committee Executive Secretary.
5. If the immediate supervisor does not concur, the supervisor and candidate will discuss and attempt to resolve differences in the package prior to forwarding it to the Committee Executive Secretary.
6. If differences cannot be resolved, the package will be forwarded to the next supervisory level for resolution of the package.
7. The Committee Executive Secretary will thoroughly review each case for format and completeness and then forward the package to the Center Director for review and concurrence.
8. Committee Executive Secretary forwards all complete packages to the Committee Chair.
9. The Committee Executive Secretary will provide the package to Committee members for each scheduled meeting a minimum of 60 calendar days prior to each meeting.
10. Prior to the Committee meeting, each member will review each case and reach a tentative opinion and rating based on the criteria in the appropriate evaluation guide.
11. Each candidate and the recommending supervisor will be interviewed by at least one in-depth interviewer assigned by the Committee Chair. Additional interviews may be scheduled with other officials, employees, or other persons with knowledge of a candidate's achievements and contributions. 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 Medical Officer, scientist, or manager responsible for or associated with the program. The in-depth reviewer will also obtain any additional information that will help the full Committee to better

understand and evaluate a case.

B. During the Meeting

1. Committee discussions will be thorough and confidential. All members will have signed a confidentiality statement, recognizing the importance of confidentiality of Committee actions and discussions.
2. Committee members present at a meeting will determine the final recommendation on the disposition of a package.
3. Each Committee will establish the required number for a quorum.
4. A Committee member who is also the recommending supervisor may not participate at the meeting.

C. After the Meeting

1. The in-depth reviewer will provide thorough written evaluations to the Committee Chair in electronic format, as well as a signed hard copy within two days of the meeting (segments added to the original review based on Committee discussions should be noted).
2. The Committee Chair will ensure the preparation of Career Evaluation Report of the findings for final approval by the Center Director.
3. The Career Evaluation Report will include Committee-decisions and recommendations and a brief summary clearly stating the reasons for the Committee decision and other pertinent information agreed to at the meeting.
4. Upon approval by the Center Director the Committee Chair will distribute the Career Evaluation Report to the supervisor for each candidate.
5. The incumbent's supervisor will discuss the Career Evaluation Report with the employee. When requested, will respond to the Chair of the Committee, in writing within 30 days.
6. The Committee Executive Secretary will ensure follow-up of any required personnel action through submission of SF-52s and accompanying documents.

APPOINTMENT OF COMMITTEE CHAIR AND MEMBERS

Agency-level

1. It is the responsibility of the Associate Commissioner for Science and the Center Directors to appoint Committee Chairs and members.
2. For the Agency level committees, the Associate Commissioner for Science will work closely with the Center Directors in the appointment of new Committee chairs and center representatives on the committees.
3. For the Agency level committees, representatives from each Center/ORAs will be included, unless participation is declined by the Center/ORAs.
4. For all committees, the year for review/rotation from each committee will be established for the chair and all committee members at the time the committee is established or when a chair or committee member is appointed to the committee. It is the decision of the Associate Commissioner for Science and the Center Directors to extend a chair or committee member for another term.
5. The Associate Commissioner for Science and Center Directors will establish the term of service for all chairs and committee members.
6. The duration of the appointment of the Committee Chair, Executive Secretary, and Committee Members will be established by the Associate Commissioner for Science.

Center-level

1. It is the responsibility of Center Directors to appoint Committee Chairs and members for Center-level Committees.
2. The duration of the appointment of the Committee Chair, Executive Secretary, and Committee Members will be established by Center Director.
3. Each Committee will establish the required number for a quorum.

APPENDIX 1

FDA Research Scientist Peer Review Committees

Uses the USOPM Position Classification *Functional* Guide;

Research Grade Evaluation Guide

Format - 4 Factors

LINK: <http://www.opm.gov/fedclass/html/gsfunctn.asp>

APPENDIX 2

Format for **CURRICULUM VITAE**

Each of the following headings must be listed and addressed. Even if there is nothing to report under a heading, include the title of the heading and state "none" or "nothing to report." The reviewers will then know that the heading was not overlooked or inadvertently omitted.

1. Educational Background - List the name of each institution and the dates attended, majors and minors, and degrees awarded.
2. Additional Training - List part-time or short-term training not included in Educational Background. Any government-sponsored training should be listed under this heading. Give dates and duration of courses, credit hours, course hours, etc.
3. Professional Experience - List professional positions held in chronological order giving titles, grade, and dates in each grade or position. Include present position.
4. Honors and Awards - List dates and a brief but sufficient description to enable the reader to determine significance and prestige.
5. Special Invitations - These are usually specific invitations to present a paper before scientific or industry groups, prepare a paper or a chapter for a book, conduct a seminar, etc. Be selective, since the stature of the group which made the invitation is as important as the receipt of the invitation. For each invitation, list the title of the presentation, date, location, and organization or purpose of gathering. Provide sufficient information for the reader to determine scientific significance. If a paper was subsequently published (as an abstract, manuscript, etc.), cross reference it to the publication list.
6. Licenses and Certificates - List professional licenses and certifications showing kind, licensing authority, year granted, current or expired, and brief description of special significance, if appropriate.
7. Membership in Professional or Honorary Societies - List each and show dates of membership, whether invited or elected.

8. Offices, Committee Assignments, or Special Assignments Held in Professional and Honorary Societies - List each and give dates.
9. Participation in National Scientific Meetings, Technical Conferences, Workshops, Seminars, etc. - List each giving date, location, type of meeting, title of talk or paper if one was presented, or brief description of role or reason for attendance if no paper was presented . Do not include items already listed under Special Invitations. If a paper was presented, cross reference it to the publication list. If the same meeting or conference has been attended a number of times, summarize the information rather than listing individually.
10. Outside Professional Advisory and Consulting Activities - List each giving dates, name and type of organization or situation, and type or significance of contribution. Generally, these should be activities outside of FDA which are not a part of the regular work assignment. If there are numerous activities, summarize the information or list activities since the last review.
11. FDA Special Assignments and Advisory Committees - These should be of a technical and professional nature within FDA but outside of the immediate work assignment or organization. Include items such as participation in hearings or testimony preparation, science advisor, or other task force assignments, etc. List each giving dates and a brief description of the role and significance.
12. Other Significant Information - List or present any information not covered in Items 1-11 above that is considered important in the evaluation of the individual as a research scientist. For example, include any scientific publication or article that has been completed but for which no acceptance has been given by the publishing agent. Educational and public relations efforts may also be listed under this item as they may be a part of the candidate's responsibilities (e.g., EEO counselor, safety committee representative). A brief description of the intended role of the individual in meeting the goals and objectives of the organization, how well this role is fulfilled and how effective the individual is in cooperating with others when this is necessary or desirable in the total program can be indicated . Any exceptional or extenuating circumstances that may have affected the quality or quantity of research output (either favorably or unfavorably) should be discussed if not covered by other items in the case material.

APPENDIX 3

Format for **BIBLIOGRAPHY**

Publications should be listed in chronological order (earliest first) and numbered sequentially. Make separate numbered listings for: A) manuscripts, B) abstracts, and C) technical reports (you can use "Manuscript #1, Manuscript #2, Abstract #1,...", "Mans.#1, Mans. #2, Abstr.#1, ..." or "M#1, M#2, A#1, etc" or some other means as long as it is clear and consistent). Give full reference including journal, volume, complete pagination, date, and type of publication (if other than peer-review journal article; see below). If the information was previously published as an

abstract, indicate by referring to the appropriate abstract (or vice versa). To be listed, a scientific article must have been accepted by the publishing agent (*i.e.* “in press”). Those publications submitted, but still in review, may be listed under section 12 of the *Curriculum Vitae*, Other Significant Information. Publications since the last review should be identified with an asterisk.

Publications other than refereed articles in scientific journals should be identified as one of the following:

1. Thesis or Dissertation
2. Review Article
3. Book
4. Book Chapter
5. Conference or Society Proceeding
6. Patent
7. Popular Publication
8. Other (give specific identification)

APPENDIX 4

Format for POSITION DESCRIPTION

The following format must be followed:

I . INTRODUCTION

Begin the position description with an introductory paragraph describing the organizational relationships and general characteristics of the position.

II . DUTIES AND RESPONSIBILITIES

A. Research Assignment

Identify the field of research and outline specifically or generally the problems, research objectives, and lines of investigation that constitute the scientist's research activities or program. If the assignment is part of a team approach, be specific in showing the candidate's part. If the assignment includes research leadership, the broad objectives of the research group should be included. The research assignment reflects the scientist as well as the job. Here is where the scientist defines the "person-in-the-job" concept

because researchers have their own unique capabilities and ideas. In research, these capabilities and ideas expand the scope and effect of a position. For example, capabilities may permit changing or modifying a research approach. The research assignment should state generally the research plan(s) and expected results that the scientist and supervisor have mutually agreed should be conducted by the scientist during the next few years.

B. Supervisory Controls

Describe the type of leadership exercised by the candidate in selecting problems, defining objectives, organizing, planning, evaluating and reporting, either as an active member of a cooperative research team or by directly supervising research scientists. Indicate the number, titles, range of grades, and location of the scientists and other employees supervised, and outline supervisory responsibilities of an administrative nature.

C. Guidelines and Originality

Guidelines and originality deal with information similar to that required by the research assignment. Guidelines speak to the extent and nature of available written guides, the intrinsic difficulty in applying them, and the degree of judgment required in their selection and adoption. Originality is the requirement for, and demonstration of, original interpretation or translation of findings to solutions of problems.

D. Contributions, Impact, and Stature

Contributions, impact, and stature focuses on the researcher's total contributions, impact, and stature as they bear on the current research assignment. It is not restricted to present and immediate past accomplishments and achievements. However, recency of accomplishment is important.

Contributions - The researcher's contributions reflect the knowledge, skills, and experience the incumbent brings to the position. Professional journal articles are an important product of research results for communicating scientific findings to the broader research community. Journal articles should be balanced with other forms of communications to ensure broad impact from the results of the work. Indicators of the researcher's contributions may include:

- research publications (journal articles, monographs, books, reviews); and
- innovations and technology transfer

Impact - Consider whether the researcher::

- has an impact on scientific and/or societal issues;
- sets new research directions;
- develops new methods, techniques, or tools to be used by other researchers; and
- drives management and policy outcomes.

Stature – Stature is established when the researcher is recognized by the scientific field and/or society, as indicated by:

- requests for expert advice/consultation by other professions and managers;
- requests to exercise leadership on research teams or projects;
- invitations to serve on advisory boards;
- requests to organize or chair committees, workshops, or symposia;
- invitations to address scientific or professional organizations;
- invitations to write synthesis papers;
- recognition by professional societies and external groups; or
- honors and awards.

E. Other Duties and Responsibilities

Many research positions include duties and responsibilities which are not research in nature; however, because they reflect the mission of the Agency as officially delegated to scientists in research positions, they are properly documented in the position descriptions when performed on a regular and recurring basis. This includes work such as preparation of handbooks, special assignments, application reviews, consultation on compliance cases, etc. Non-research responsibilities which are extensions of research may help to support the significance and impact of the research.

III. Supervision Received

Identify the supervisor by title or working responsibility. Describe the nature and purpose of the supervision. If technical supervision is received from someone other than the immediate supervisor, identify by title and show the kind of responsibility for the work.

The description should clearly define:

1. the degree of responsibility which the scientist has for selecting problems, defining specific objectives, organizing, planning, executing, interpreting, and reporting research,
2. the kinds of actions that require approval of the supervisor or technical leader, and
3. the nature and extent of commitment authority when dealing with professional, nonprofessional, or other cooperating or interested groups.

FDA Research Peer Review Committees

Uses the USOPM Position Classification *Functional* Guide;

Research Grade Evaluation Guide

Format - 4 Factors

LINK: <http://www.opm.gov/fedclass/html/gsfunctn.asp>

APPENDIX 5

GUIDELINES for CONDUCTING IN-DEPTH INTERVIEWS

Prior to a scheduled Panel meeting, the Committee Chair will assign a package to the appropriate Committee member to conduct the in-depth review. The in-depth reviewer will be expected to read all submitted materials prior to any interviews.

The in-depth reviewer assigned to a package should have separate personal interviews with the candidate under consideration, his/her immediate supervisor and Division Director to discuss: 1) the significance of the candidate's research and regulatory accomplishments, 2) the direct contributions of the candidate vs. collaborators on research accomplishments, 3) the resources and mentoring support allocated to the candidate since joining CDRH, 4) candidate's supervisory role and performance, if applicable 5) quality of team work, 6) demonstrated leadership, and 7) anything else the interviewee would like to discuss. Summaries of the interviews and any additional information should be presented to the committee members during the Panel meeting.

Preparation before interviews is essential in order to save time of both the in-depth reviewer and those being interviewed. In addition to reading and being familiar with the case material, the in-depth reviewer should also read and be familiar with the grade level criteria and those assignments which are characteristic of the grade level being requested. It should be remembered that the position description (PD) is an official document, in which the requesting supervisor certifies as containing both an adequate and accurate description of the work assigned to the research-regulatory scientist.

Interviews should be scheduled at a time that is mutually convenient to the reviewer and those being interviewed. To conduct a successful interview, the in-depth reviewer should make sure that the questions are clear, let the interviewees take the lead whenever possible, ask open-ended questions and be sure to clearly understand the answers, restate the important points during the interview, take notes, look at work samples, summarize the main points at the end of the interview, and let the interviewee know that the in-depth reviewer is available if there is any additional information which may come to mind.

Interviews should be held in person whenever possible, but if necessary, it is acceptable to hold interviews by telephone. As with in-person interviews, telephone interviews should be held by advance appointment so that both participants can devote complete attention to the interview.

(**Sample questions** to ask the supervisor, past or present co-workers, co-authors, industry and/or university cooperators, user groups, etc.)

Factor I – Research Assignment

What are the limits or boundaries of the incumbent's research assignment?

Does the scientist work independently of others?

Is the scientist involved in team/collaborative efforts? Is it a “formal” team (within the laboratory)? Is the incumbent functioning in a lead role versus junior role? In what types of studies or aspects of the work does the incumbent function as the “leader”?

Does the incumbent have “service” responsibilities, i.e., teaching, insect identifications, vaccine production? What percentage of time does the incumbent spend (approximate over a 6-month period) in non-research activities that are part of the incumbent’s assignment?

Which objectives stated in the case write-up are currently being pursued? What problems or obstacles are being encountered? To what extent were you involved in selecting the objectives and methods?

Are methods available or must they be adapted or developed for progress to be made? Tell me about the methods being used. Do you consider them difficult? sophisticated? novel? Why?

What publishable results do you expect within the year? How significant will they be on science/industry?

Factor II – Supervisory Controls

How much supervision does the incumbent require?

Where could/does the incumbent go for help if the problem is not in your area of expertise?

What types of decisions require your concurrence or approval:
choice or changes in specific objectives?
choice or changes in approach?
choice or changes in methodology?

What types of review do you give to the incumbent’s work and when? i.e., review experimental plan prior to the conduct of experiment? review draft manuscripts? Are major revisions to the manuscript or additional verification of results required? How often?

Factor III – Guidelines and Originality

For what aspects of the work is theory or methods lacking?

To what extent are precedents available? i.e., none, in related field.

What other approaches could be used that the scientist decided against? Why?

In your opinion, which accomplishment (s) reflect the incumbent’s best evidence of original thinking, reasoning, choosing between methodology, interpretations in a form usable by others or upon the scientific field or his/her research effort?

In your opinion, is there anything in particular that sets this scientist apart from others working in the same field?

Factor IV – Contributions, Impact, and Stature

Which of the incumbent’s accomplishment (s) do you consider the most significant? Why? (If a team effort, what was the incumbent’s role and who was the “idea” person)?

Is the incumbent recognized for his/her work by the scientific community -- Is the recognition based on specific accomplishment (s)? Which one (s)?

By whom is the incumbent recognized? Are they working in the same field or related field? Are the people seeking out the incumbent considered an expert in the same field?

APPENDIX 6

Suggested text for **Cyclical Review Transmittal Memorandum**

DATE: 30 Month 2006
FROM: Name
Director, Division of _____
SUBJECT: Cyclical Review Evaluation of (*candidate name*)
TO: Name,
Chair, CDRH Research Scientist Peer Review Committee

The attached case material is submitted in accordance with the guidelines for the CDRH Research Scientist Peer Review Program Standard Operating Procedures for the purpose of evaluating (candidate name).

(candidate name) is being reviewed for the purpose of fulfilling requirements of a mandatory cyclical review.

I have reviewed this case material and to the best of my knowledge find that it accurately reflects and depicts the accomplishments and responsibilities of (candidate name).

signature
(name)
Director, Division of _____