Exhibit 10: The Panel Peer Review Process: Step by Step Guidelines

(See Flowchart on the last page.)

Preliminary Planning

4 months

1. OSQR gives the National Program Team (NPT) an orientation to discuss:

- projects found to be coded greater than 50% to the National Program,
- policies on adding, exempting, or postponing projects. Also discusses methods of grouping projects,
- schedule of key deadlines: starting the process, when prospectuses and project plans are due to OSQR, anticipated implementation date. Holidays and standard non-working days are integrated,
- requirement for National Program direction memos and approvals,
- National Program Action Plan and National Program overview,
- discuss requirement for the NPT to make a presentation at the panel's orientation,
- suggestions for peer reviewers, (OSQR also clarifies the absence of direct involvement of ARS employees, other than those in OSQR, in the selection and activities of panel chairs and peer reviewers.)
- overview of the Peer Review Process,
- grouping projects into panels and approach to establishing panels for small National Programs, (less than 10 projects in the program.)
- providing a good example of a project plan to research teams writing project plans.

2. National Program Team prepares a list of projects to be peer reviewed and another list of projects not being peer reviewed and the rationale for exempting or postponing them. The two lists are reviewed for concurrence by each appropriate Area Director and Associate Deputy Administrator.

3. Using the list of key dates provided by OSQR, the National Program Team begins coordinating deadlines with the Area offices for:

- reviewing working drafts of prospectuses,
- final prospectuses,
- project plans and revised project plans.

4. For each project being peer reviewed, the National Program Team prepares a direction memo containing information about:

- directions to begin the peer review process by writing a prospectus,
- requests for working drafts of the prospectuses,
- possibly the project's objectives and relationship to the National Program Action Plan,
- a form for suggesting peer reviewers,

- schedule and format instructions for writing prospectuses and project plans,
- list of projects in the review session.

Copies of the approved lists given to OSQR and the appropriate Area Offices prior to sending direction memos.

5. OSQR verifies that the format of the lists, schedule, prospectus directions, and project plan directions are consistent and up-to-date.

6. The National Program Team distributes their memos. Any changes to the initial list of projects, whether adding or removing projects, require direction to the Peer Review Program Coordinator from the appropriate Area Director's Office, through the appropriate National Program Staff or vice versa, depending on which office is guiding the decision. The direction must state the rationale for the change.

7. OSQR begins retaining panel chairs.

8. Area Offices work with their research units to prepare staff for completing the requirements of the peer review, including but not limited to:

- referencing this Manual, other related instructions, training¹, and websites. (i.e., such as the OSQR website--osqr.ars.usda.gov.)
- discussing roles and responsibilities of the research unit and other ARS offices in writing and approving peer review-related documents
- tracking and formatting of peer review-related documents
- clarifying the project implementation process and overall requirements for intramural peer review and other reviews required by ARS
- scientists and research team take advantage of training opportunities, particularly to build project plan-writing skills.

Prospectus Development

8 weeks

1. Research leaders and lead scientists draft their 5-page prospectuses and conflicts of interests. If requested, lead scientists send working drafts to the National Program Team <u>before</u> beginning the approval process. Once complete, lead scientists gain comments and approval from their Center, Institute or Lab Director. The prospectuses are then sent to the appropriate Area Director.

¹Includes, but not limited to, scientist and research leader courses and meetings, the OSQR video (scheduled for release August 2001), and meetings sponsored by the National Program Team for a specific review session. In each case, the SQR Officer may be invited to speak on the Process.

2. Area Directors perform their review and approval and also direct the labs to set up a peer review approval record in Research Management Information System, for each project, using the project's new title and background information stated in their prospectuses. Area Directors send the prospectuses on to the National Program Team.

3. National Program Team performs their review and approval and then forward the fully approved prospectuses to OSQR. The National Program Team also distributes directions to begin preparing the project plans, and specifies deadlines.

4. OSQR gives Panel Chairs an orientation.

Project Plan Development

4 months

1. Research Leaders and lead scientists write their project plans and gain comments and approval from their Center, Institute or Lab Director. The project plan is then forwarded to the Area Director within the first 2 months of the project plan development stage. The Area Director reviews and approves each project plan, as well as gains input and approval from the National Program Team. The Area Office ensures that project plans are in the format requested by OSQR.

2. The Area forwards the fully approved project plan to OSQR in electronic and hardcopy format.

3. OSQR and panel chairs prepare peer reviewers for the peer review.

4. The National Program Team prepares an Overview of all projects coded and related to the National Program. Gives OSQR the Overview and National Program Action Plan.

Peer Review

6 weeks

OSQR distributes project plans, National Program Overview, and National Program Action Plan to peer reviewers.

Revision and Implementation

6-10 weeks, depending on the results of the review.

1. OSQR electronically sends Area Directors the results of the panel reviews for individual projects and copies the National Program Staff. The peer review results include:

- instructions to respond to each recommendation,
- the SQR Officer's comments on the review and possibly suggestions for handling projects that receive "major revision" and "not feasible" action classes,
- the primary reviewer's recommendations,
- the SQR Officer's Action Class Judgment Worksheet.

2. Steps to revision and implementation:

A. Lead scientists of projects that receive a "no revision," "minor revision," or "moderate revision," revise their project plans and document their response to the review as instructed by OSQR. Revisions should be highlighted in bold text.

B. Lead scientists then gain comments and approval from their Center, Institute or Lab Director.

C. Project plans and their accompanying "ARS Response" files are then forwarded to the appropriate Area Director. Area Directors review and approve project plans and ARS Responses, as well as gain input and approval from the National Program Team. The Area Office ensures that project plans and "ARS Responses" are in the format requested by OSQR.

D. The Area Office forwards fully approved project plans and their accompanying ARS Responses to OSQR in electronic and hardcopy format. The project plan hardcopy formats have a "Post-Peer Review Signature Page" attached, whereby the Area Director's signature is in original format.

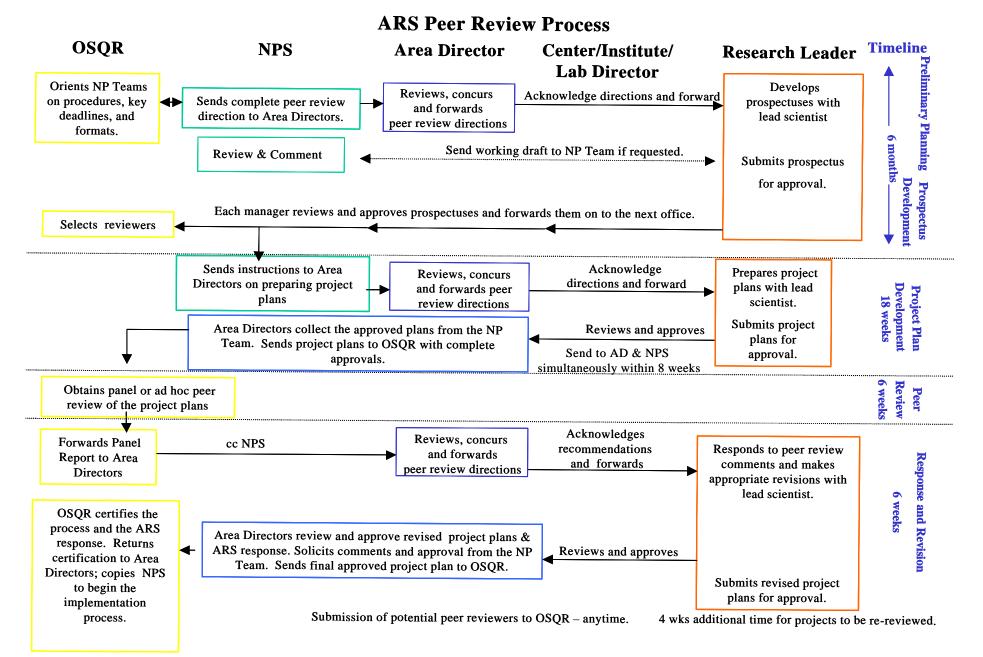
E. The SQR Officer reviews the ARS Responses. If necessary, he/she sends the appropriate Area Directors suggestions to improve the ARS Response, and completes all certifications to close the Process. OSQR sends the certification to Area Directors and copies the National Program Staff.

F. Panel reviewers receive ARS's response to their recommendations.

3. Project plans that receive a "major revision" or "not feasible" action class require the appropriate Area Director's decision for how to proceed. (See the "Action Classes" section in the Manual.)

4. Lead scientists with project plans that need a re-review by the original panel complete steps in #2 above, however the "Post-Peer Review Signature Page" is not signed until the project plan receives a more favorable peer review.

5. OSQR assigns projects plans that require a complete re-write to the next ad hoc review scheduled for that National Program.



1. While it is appropriate for companies to conduct such evaluations for company products, research under ARS National Program 306 (Quality and Utilization of Agricultural Products) will address precommercial evaluation of new food safety interventions on product quality. An objective under Problem Area 1c., 'Factors and Processes that Affect Quality', of the NP 306 Action Plan, is to 'Evaluate effects of safety and environmental protocols on quality of foods.' This activity was sanctioned by NP 306 stakeholders in workshops and fits the mission and objectives for NP 306.