Science Prioritization Process

Office of Science Engineering Laboratories

Center for Devices and Radiological Health

Food and Drug Administration

The Office of Science and Engineering Laboratories (OSEL) has implemented a process to prioritize its research activities in order to focus research to meet the needs of the Center as well as enhance the scientific merit. This Science Prioritization Process is the cornerstone of all science activities carried out in the office in support of Center's regulatory processes. The office uses the results of prioritization not only to set programmatic directions but also to improve collaboration with stakeholders within and outside the Center.

Major Goals of the Science Prioritization Process

1. Seek input from stakeholders in the Center, Agency, and experts outside of the Agency so that the Office can begin charting new directions in undertaking appropriate, relevant, and value-added research.
2. Use results for building a cutting-edge scientific laboratory performing regulatory science research.
3. Develop new collaborations using participation of experts.

The Office uses recommendations resulting from this process to:

- Meet Center/Agency, and public health needs
- Identify scientific areas to target and expand
- Identify scientific areas of lower priority
- Improve collaborations within CDRH and between agencies
- Help attract future high-quality staff

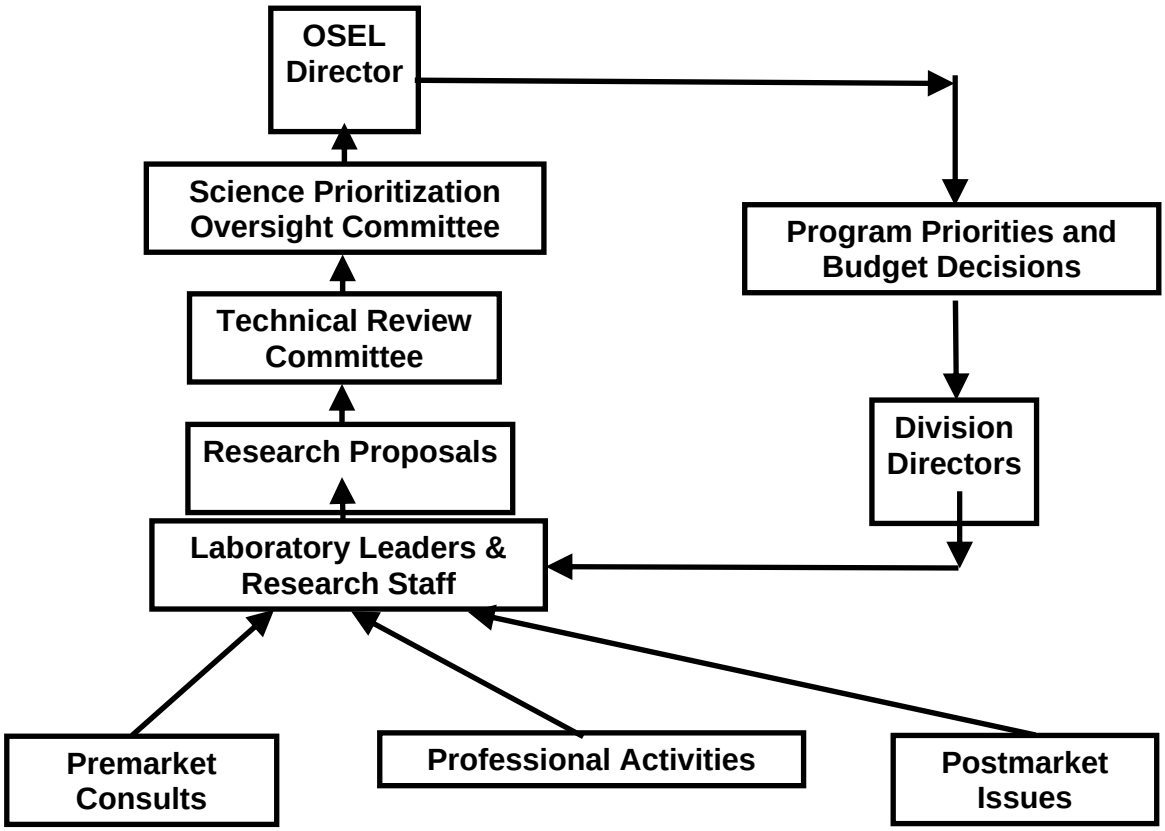
Science Prioritization Process

Since 2003, a formal Science Prioritization Process has been implemented in OSEL which involves the review of research projects by a panel of experts consisting of members from within the Center as well as outside the Center. The schematic of the process shown on page 3 consists of the following steps:

- Preparation of research proposals - - Research staff, Laboratory Leaders, and Division Directors develop research proposal based on their collaborative work with the Center's pre- and post-market staff, and professional interactions, including standards organizations.
- These proposals are prioritized at the division level and forwarded to the Deputy Director of the Office, who manages the entire process, including chairing the Science Prioritization Oversight Committee (SPOC). The Office compiles and sends research proposals as well as laboratory descriptions to the relevant Technical Review Committee (TRC).
- Each Laboratory (contains multiple research projects) research is reviewed by a TRC. The TRC consists of experts in the Center as well as from other government agencies and academia.
- Each TRC meets in OSEL with a specific agenda to review all research projects under the laboratory. The agenda consists of presentations by OSEL research staff on proposed research, laboratory visits, and TRC discussion of proposed research. The TRC reviews and scores each project using a standardized format (shown on pages 4-6). The focus of the TRC is to assess scientific merit as well as relevance to the Center's regulatory mission.
- The TRC evaluations (scores and recommendations) are in turn reviewed at the Laboratory level by the SPOC which consists of seven deputy directors or their designees from the Center's seven offices. The SPOC evaluation focuses on the public health and regulatory impact of the proposed research in each laboratory. The SPOC develops its recommendations based on written information, TRC evaluation, and relevant division director's presentation on regulatory impact of the research. The final output of the SPOC in the form of recommendation is sent to the OSEL Director for decision making and implementation.
- The OSEL Director makes decisions taking into consideration of TRC evaluation, scores, and SPOC recommendations in conjunction with OSEL division directors, and laboratory leaders.

- The TRC and SPOC members are kept informed periodically of the progress by the OSEL staff, laboratory leaders, and division directors.

The implementation phase consists not only of termination of some projects, but also the major impact is on making the recommended changes to research projects to make the project outputs more relevant and useful to Center stakeholders. Often the TRC-level interactions result in collaboration with internal and external stakeholders.



The major changes implemented for the 2006-2008 cycle are:

- Review of 1/3 of OSEL laboratories each year on a rolling 3-year cycle
- Inclusion of one faculty member in each Technical Review Committee (TRC)
- Different roles for TRC and Science Prioritization Oversight Committee (SPOC)
- Completion of the prioritization process in November of the preceding implementation year

Since the science prioritization process is very time-intensive and involves a large number of staff and management, it was decided to alter the process in which each year only approximately one-third of the projects will be reviewed. Hence, beginning 2006, a 3-year cycle of review is implemented where the entire review process will be completed during October-November for the following year. For example, TRC and SPOC review for 2006 projects would be completed in October 2005. The rotational review as well as advanced completion of review helps the staff to maintain continuity of projects as well as for the management to synchronize performance evaluation and allocation of budget to prioritized projects. In addition, we have modified the project evaluation criteria and weight factors so that TRCs focus on

evaluation of technical/science merits at the project level; whereas, SPOC would focus on relevance to the Center of the proposed research at the laboratory level.

Schedule of TRC meetings in 2005

During October 2005, 6 laboratories were reviewed in 4 separate locations, involving 70 TRC members from the Center, Agency, as well as other agencies. The meetings included presentations of research projects as well as laboratory visits.

Standardized Format for Review

Major aspects of the Science Prioritization Process, including research proposal format, laboratory description format, and TRC scoring and review format have been standardized. For example, Laboratory Description and Research Proposal Contents describe the necessary features required for review by stakeholders in the Center.

Laboratory Description Contents

- Main technical/scientific focus of the laboratory
- Goals of the laboratory
- Description of experimental/theoretical work planned to address each goal
- Medical device challenges/problems being addressed
- Approach to address these problems
- Relationship to Center's Strategic plan
- Benefits to Center in terms of regulatory as well as scientific areas
- Abstracts of research projects

Research Proposal Contents

- Abstract of proposed research
- List of principal investigators and collaborators
- Three-year budget projection
- Technical/scientific needs of the Center
- Research objectives and methodology
- Major milestones
- Benefits to the Center and relationship with Centers' strategic plan

TRC Project Evaluation Form

Laboratory Number: **Project Number:**

1. Please evaluate and rate each criteria of the project on a sale of 1 to 10, with 10 beginning the highest rating.
2. Using the same scale, please rate familiarity with the subject. If you feel that you are not familiar with the subject, it is OK to mark this form as "NOT FAMILIAR with the subject."
3. We plan to use 50, 30 and 20 weight factors to criteria 1, 2, and 3, respectively, to calculate the final numerical score based on your individual scores on the three criteria

Your familiarity with the subject: 1----------10

Criteria for Evaluation

1. Technical /Scientific Excellence of research

a. Are these aspects of the work that would be considered "cutting-edge" research?

b. Are the collaborators appropriate? Are there other major players we need to consider?
c. What is the probability of success of achieving stated goals?
d. Are the project costs reasonable for the proposed work?
e. Is the work output clearly stated?
Score for Criteria 1:
Evaluation:

2. Public Health Impact of the work

f. To what extent this laboratory science improves the knowledge of pubic health problem?
g. What is the immediate public health CDRH/FDA need that this work will satisfy?
h. Are there advocates in CDRH/FDA for the work?
Score for Criteria 2:
Evaluation:

3. Regulatory Impact of the work

i. Does this work contribute significantly to solving an outstanding regulatory need through publications, independent data, standards, guidance documents, etc?
Score for Criteria 3:
Evaluation:

Overall weighted score:

Additional comments on the project:

1. Potential positive and negative aspects of the proposal
2. Suggestions to improve the project and its usefulness to regulatory issues.

SPOC Evaluation of Laboratory Programs

This newly adopted approach provides a clear distinction of roles and responsibilities of the Science Prioritization Oversight Committee (SPOC) and Technical Review Committees (TRCs). Specifically,

1. SPOC will focus on the evaluation of the impact of research at the laboratory-level, rather than the project-level
2. TRCs will focus on the scientific and regulatory aspects of projects within each laboratory.

Since technical disciplines as well as membership vary from one TRC to the next one, we found in the past exercise that the scores among TRCs varied widely. The SPOC involvement at the laboratory level has the potential for creating a degree of uniformity among the scores of different laboratories. In addition, SPOC's focus at the laboratory level provides a degree of oversight at a higher level from the point of view of Center's regulatory needs.

Process for Evaluation of Laboratory by SPOC

SPOC will develop its recommendations based on information received from three sources:

1. Presentation of laboratory program by Division Directors to SPOC
2. Written laboratory descriptions
3. Summary of TRC scores and evaluation of projects within each laboratory.

Criteria for Evaluation by SPOC

The primary criteria for SPOC evaluation is regulatory impact of the work as evidenced by:

a. Clarity of work output.
b. Significance of the public health problem addressed by the results of this work.
c. Who wants the work done? Are there advocates in the Center/Agency for the work?
d. Will this work contribute significantly to solve an outstanding regulatory need through:
    1. consults,
    2. publications,
    3. data,
    4. standards,
    5. guidance documents, and
    6. reports?

Score: Each laboratory will be rated on a scale of Low, Medium, High and Critical.
Evaluation: Provide written comments to support the score.

Questions and Answers

The staff and management of OSEL receive guidance in the beginning of the planning year, and in addition, during the year when questions arise. This guidance is provided in the form of questions and answers, and posted on the internal server. Some examples of the questions are shown here:

Q1. What is the process for submitting new proposals and how are they reviewed?

Q2. What is the process for termination of existing projects?

Q3. What is the process for recommending and selecting TRC members?

Q4. What are some criteria for selection of TRC members?

Q5. Which research projects should be included for review?

Q6. What is the budget process that OSEL Director would use to fund prioritized projects in FY 2006? Similarly, what is the funding mechanism for projects approved in 2005 and 2004, and not being reviewed in October 2005?

Q7. How do we handle research projects that are requested by the post-market side of the Center? (an example of this is a project requested by the Office of Compliance to study suspected counterfeit meshes)

Q8. How will the industry and academia members participate in the Science Prioritization Process?

Q9. Memo containing the information related to Laboratory Budget Issues and Proposed Options as developed on July 11, 2005, and later revised 7/20/05 based on comments from Larry and Angie was released to Division Directors, Deputy Division Directors, and Laboratory Leaders on July 22, 2005.

Q10. What is the process for allocating $1.5M from the MDUMFA funding for infrastructural purposes?

Office of Science and Engineering Laboratories

The Office of Science and Engineering Laboratories (OSEL) is the laboratory of the Center for Devices and Radiological Health (CDRH). OSEL accomplishes its mission by performing laboratory evaluations and analyses in support of CDRH premarket and postmarket activities; developing data needed for current and future regulatory challenges; performing research; managing, developing, and supporting standards used for regulatory assessments; and anticipating the impact of technology on the safety effectiveness, and use of regulated products.

Specifically, OSEL develops and conducts research and testing programs in physical, life and engineering sciences related to medical devices and radiological health products. OSEL provides expertise and analysis for health risk assessments. The Office also develops new or improved measurement methods, techniques, instruments, and analytical procedures for evaluating product performance and reliability. OSEL provides innovative solutions to public health problems through the development of generic techniques to enhance product safety and effectiveness.

One of the major functions of OSEL is to provide an independent source of data generated in its core laboratories. The basic strength of the office is derived from its staff's ability to generate laboratory data on device performance or a test procedure to enable the Center and device manufacturers to gain an improved understanding of issues related to the safety and efficacy. OSEL contributes to Center-wide teams on issues identification as well as science-based analysis of postmarket approval level. In reality, the research has major impact on the postmarket end of the Center's business because most often the research is anticipatory in terms of potential issues of medical devices.

The laboratory activities focus on the following areas:

- understand and elucidate the physical, chemical, biological mechanisms which underlie the operation of medical devices;
- develop test methods to objectively assess the safety and effectiveness of medical devices; and
- advance the state of engineering practice within the medical device industry with regard to assuring the quality of medical devices.

OSEL research is strategically managed with the aim of anticipating future regulatory challenges and providing a scientifically sound basis for responding to current challenges. Toward that end, OSEL research is guided by technical review committees for each major laboratory program as well as an oversight committee with representation from postmarket as well as premarket interests from across the Center.

OSEL Organization

OSEL was reorganized in 2004 to increase transparency and reduce management layer. The current structure of management consists of two layers of management which is unique to the Center and Agency. There are no branches in the office. The divisions are managed by division directors with the assistance of laboratory leaders who have no administrative responsibilities, except to provide programmatic responsibility for their laboratory. Two exhibits on pages 9 and 10 show the organization at the office level and laboratory title and laboratory leaders, respectively.

Summary

We have developed an efficient and useful process to prioritize scientific research conducted in OSEL for CDRH. The primary goal of the Science Prioritization Process is to enhance the usefulness of OSEL research and research products for CDRH as well as FDA needs. We accomplish this goal in a variety of ways, one of which is to seek the input of Centers as well as outside experts to increase the applicability of research as well as the quality of science. The staff in OSEL and other offices in CDRH invest considerable amount of time and energy to perform this task. The process produces recommendations at two levels: score and recommendation of TRCs at the research project level, and SPOC recommendations at the broader laboratory level. The SPOC has a higher level of responsibility to examine the impact of research at the laboratory level.

These recommendations form the basis for programmatic as well as budget decisions for the following year. There are several significant actions that take place resulting from TRC as well as SPOC recommendations. The first and the most important one is the incorporation of changes to research projects as recommended by experts in TRC. These recommendations are most often either a change in scientific direction or a change in the schedule of the development of regulatory products (standards, test procedures, guidance, etc.).

Finally, it is the OSEL director's responsibility to transform recommendations of the two groups (TRC score and evaluation, and SPOC priorities) into a coherent research program. The OSEL director implements these recommendations by working with division directors and other managers in OSEL. These recommendations are the basis on which budget as well as programmatic decisions are made. During the year, while implementation process is in progress, the TRC and SPOC are kept informed through variety of mechanisms.

Overall, the Science Prioritization Process has served the Center very well by continuing to make progress in focusing on high priority areas and redirecting away from low priority areas. The added benefit is the value of Center staff's ownership in the process because they help us direct the research toward Center's high priority areas.

OFFICE OF SCIENCE AND ENGINEERING LABORATORIES

Center for Devices and Radiological Health

OFFICE OF THE DIRECTOR

DIRECTOR: Larry Kessler, Sc.D.
Deputy Director, Program Policy & Evaluation: Subhas Malghan, Ph.D.
Deputy Director, Science & Strategic Initiatives: William Herman*

Associate Director for Compliance Activities: Thomas Lee
Associate Director for Laboratories: Charles Warr
Outreach Coordinator: Ann Mastradone

STANDARDS MANGEMENT STAFF (SMS)

DIRECTOR: Carol Herman
Deputy Director: Gail Strieter *

MANAGEMENT SUPPORT SERVICES (PMO)

PMO DIRECTOR: Angie Clingerman

KM DIRECTOR: Ginnie Mashburn

DIVISION OF BIOLOGY (DB)

DIRECTOR: Marilyn Lightfoote, M.D., Ph.D.

DEPUTY DIRECTOR: Melvin Stratmeyer, Ph.D.

DEPUTY DIRECTOR: John Langone, Ph.D.

DIVISION OF CHEMISTRY AND MATERIALS SCIENCE (DCMS)

DIRECTOR: Steven Pollack, Ph.D.

DEPUTY DIRECTOR: Joyce Whang, Ph.D. *

DIVISION OF PHYSICS (DP)

DIRECTOR: Joel Myklebust, P.E., Ph.D.

DEPUTY DIRECTOR: Brian Beard, Ph.D.

DIVISION OF SOLID AND FLUID MECHANICS (DSFM)

DIRECTOR: Laurence Grossman, Ph.D.

DEPUTY DIRECTOR: Jon Casamento

DIVISION OF IMAGING AND APPLIED MATHEMATICS (DIAM)

DIRECTOR: David Brown, Ph.D.

DEPUTY DIRECTOR: Thomas Shope Jr., Ph.D.

DIVISION OF ELECTRICAL AND SOFTWARE ENGINEERING (DESE)

DIRECTOR: Alford Taylor Jr.

DEPUTY DIRECTOR: Brian Fitzgerald

* Acting

Current Laboratories and Laboratory Leaders in OSEL

DIVISION OF BIOLOGY

- Toxicology (biocompatibility): Peter Goering
- Cardiovascular and Interventional Therapeutics: John Karanian
- Biological risk assessment (infection control): Ronald Brown
- Radiation biology (incl. photosciences): Howard Cyr
- Biomolecular mechanisms (molecular biology, immunology, allergy, cell biology, genomics/genetics): Marilyn Lightfoote
- Biotechnology: John Langone

DIVISION OF CHEMISTRY AND MATERIAL SCIENCE

- Materials chemistry: Dinesh Patwardhan
- Experimental pathology: Steve Hilbert

DIVISION OF ELECTRICAL AND SOFTWARE ENGINEERING

- Software: Brain Fitzgerald
- Electrical Engineering: Al Taylor
- Systems Engineering: Al Taylor

DIVISION OF IMAGING AND APPLIED MATHEMATICS

- Medical imaging and diagnostics: Kyle Myers
- Ionizing radiation metrology: Frank Cerra

DIVISION OF PHYSICS

- Electro-physiology and electrical stimulation: Victor Krauthamer
- Electromagnetic and wireless technology: Howard Bassen
- Optical diagnostics and therapeutics: Joshua Pfefer
- Optical radiation safety and devices: Sharon Miller

DIVISION OF SOLID AND FLUID MECHANICS

- Fluid dynamics: Mike Berman
- Mechanics: Stan Brown
- Ultrasonics: Gerald Harris

Sgm/10/24/05