

Questions to be brought up at Human Subjects Meeting
at the request of Susan Rose

1. If a project is funded by an agency or organization other than NIH, what type of document should be used in lieu of HHS-596?
2. How will DOE-funded research be tracked as opposed to WFO research? Ops office to track
3. When the new OHER policies and procedures are implemented, will the field be required to obtain a formal response from OHER before the research project can be approved? This could cause delays in executing interagency agreements and contracts, which could be a serious problem at the end of the fiscal year.

0021245

REPOSITORY DOE-OAK
 COLLECTION Environment & Safety Support Division
 BOX No. Central Files
 FOLDER 1300.3.d Human Subjects - General (ESS)
 #11 1994

MISCELLANEOUS INFORMATION (MISC)

Proposal Number: S E

1. Funding Organization: S

Sponsor: S

a. Proposed Period: S

E

b. Funded Period: S

E

E To S

E

E

c. Funded Amt in Original Contract: S

E

d. SNL Acct No: S E

e. Proposed Funding by Fiscal Year

FY 1986 Amt: S

E

FY 1989 Amt: S

E

FY 1987 Amt: S

E

FY 1990 Amt: S

E

FY 1988 Amt: S

E

TOTAL : S

E

f. Contract/Agreement No : S

E

2. Full Description of Work: S

W

3. Contract Status: E

*BHO WFO Database
Screen Covering
Human Subjects*

E

4. HUMAN SUBJECTS

- a. Are human subjects involved? (Y/N) E
- b. Has Form HHS-596, Protection of Human Subjects, been provided? (Y/N) E
- c. Has blank "Informed Consent Form" been provided? (Y/N) E
- d. If not, explain why: S

5. ANIMAL SUBJECTS

- a. Are animal subjects involved? (Y/N) E

6. REQUEST FOR WAIVER OF FULL COST RECOVERY

- a. Amount of Waiver: S E
- b. Was waiver approved or disapproved? (A/D) E
- c. Date of approval or disapproval: S E

END OF MISC

MISC 2 of 2

0021247

memorandum

DATE: March 9, 1987

REPLY TO
ATTN OF: ER-42

SUBJECT: Preparation for Preliminary Data and On-Site Review

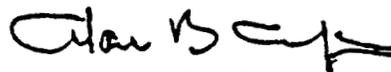
TO: Jerry Bellows, EHD ✓
Edward Cimesty, CH
David Goldman, AAO
Joseph Lenhard, OR
Connor Mathews, OR
Dennis Neely, LBSO
Richard Nolan, SAN
Joe Sutey, RL

Correspondence on the Institutional Plan process. See pages marked with paper clips for information regarding human subjects reporting.

The approval letters for the Energy Research multiprogram laboratory FY 1987-FY 1992 Institutional Plans and the institutional planning instructions are en route. Comments received from the program reviews of the Institutional Plans are attached for your information. These should also be forwarded to the laboratory for their use in preparing the Preliminary Data, which is due May 1, 1987. Pending receipt of the final institutional planning instructions, the laboratories should follow the draft instructions which have been sent to all planning officers.

Work for Others remains an important concern of Departmental Management. The Work for Others midyear program review report is due at Headquarters by May 1, 1987. The report should follow the attached general format developed in conjunction with the Operations Offices responsible for the ER multiprogram laboratories. The report content has also been coordinated with Management and Administration so that it can satisfy their needs for the annual summary report of WFO required by DOE Order 4300.2A.

The on-site reviews for all Energy Research multiprogram laboratories will be held prior to the internal review of the budget. We will establish the schedule in the near future. We will want to discuss the laboratories' responses to appraisal recommendations and the exploratory R&D program at the on-site reviews. Please provide us with your suggested agenda items for the Operations Office caucus and the on-site review.



Alan B. Claflin
Director, Laboratory
Management Division
Office of Field Operations
Management, ER

2 Attachments

0021248

memorandum

DATE: JAN 30 1987
REPLY TO
ATTN OF: NE-1
SUBJECT: FY 1987-92 Institutional Plans

TO: A. W. Triveipiece, ER-1

The subject plans for Brookhaven National Laboratory, Lawrence Berkley Laboratory, Oak Ridge National Laboratory, Argonne National Laboratory, and Pacific Northwest Laboratory have been reviewed by this office and found to be acceptable for their intended purpose. We have no comments to offer on the BNL and LBL plans. The ANL, ORNL, and PNL plans adequately represent planned efforts sponsored by Nuclear Energy and are generally consistent with program trends. However, all plans are subject to management and budgetary decisions with specific direction and funding levels being provided by program offices. Some specific comments are attached for your use in communicating final plan approval to the laboratory directors. Nuclear Energy program coverage is acceptable for approval of the plans.



A. David Rossin
Assistant Secretary
for Nuclear Energy

Attachment

0021249

ANL

1. The Activity Trend (p. 3.4) covering LWR fuel life extension and safety is the province of the private sector and not DOE.
2. The IFR discussion (p. 4.4 & 4.5) of a fuel cycle facility should reflect \$4.0M construction in FY 88 and \$0 in the outyears. Equipment should be \$1.5M, \$3.0M, and \$1.5M in FY 88, 89, and 90. HFEF-S modification discussion should be modified accordingly. More definitive guidance on the Civilian Reactor Development program will be provided in February 1987, which should be reflected in ANL operations in this area.
3. Resource Table E-1 (p. 8.8) should reflect a phase out and \$0 funding for the "Nuclear Waste Technology" line in FY 87 and beyond. The AH account title should read "Remedial Action and Waste Technology."

PNL

1. Funding levels and specific program initiatives will be provided in the FY 1989 Program Guidance memorandum in February, subject to final budget decisions. The outyear estimates in Space/Defense activities are unlikely to be realized. The funding references on page 38 are no longer accurate.
2. The discussion on Nuclear Waste Treatment (pp. 39-41) area is inconsistent with budget decisions and program guidance. It is incorrect and needs major revision to reflect management decisions to complete work on the Liquid Fed Ceramic Melter in FY 87 and complete other tasks.
3. The discussion on the Critical Mass Laboratory (p. 41) is at least one year out of date. It speaks to "...completing work in FY 1986," which has been completed. This needs major overhaul. Also, (p. 42) change the second sentence to read "These experiments are scheduled to be completed by the end of FY 87."
4. The discussion on Nuclear By-Products (p. 42) does not reflect program decisions and guidance. It reads like a justification for work rather than planned activities.
5. ID has the overall lead role for MMW.

ORNL

1. The Advanced Control Test Operation initiative (p. 19) is fundamentally acceptable but the pace and scope need to be modified to current program guidance.
2. Funding and resource allocations should reflect current program and budget decisions.

0021250

memorandum

DATE: JAN 23 1987

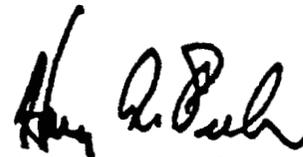
REPLY TO
ATTN OF: MA-2.2

SUBJECT: Approval of Institutional Plans of Energy Research Multiprogram
Laboratories

TO: Director, Office of Energy Research

In response to your memorandum dated December 31, 1986, subject as
above, the Office of Management and Administration has no comments.

We appreciate the opportunity to comment.



Harry L. Peebles
Acting Assistant Secretary
Management and Administration

0021251

memorandum

DATE: January 20, 1987
LY TO
ATTN OF: ER-50.2
SUBJECT: Institutional Plans for the Multiprogram Laboratories

TO: Alvin W. Trivelpiece, Director, Office of Energy Research

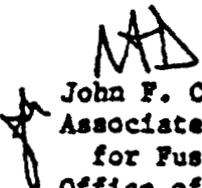
The Institutional Plans for the Multiprogram Laboratories have been reviewed and the Office of Fusion Energy (OFE) agrees with the general baseline for OFE programs discussed in these documents. There are some qualifications, which we note, that should be communicated to the appropriate Laboratory Director. They are:

o Oak Ridge National Laboratory -

- While design of a follow-on to ATF (ATF-II), is interesting and worthwhile, actual construction of such a device is likely to proceed only in the context of an International collaboration. The siting of such a device at ORNL is not ruled out, but is not likely if the fusion program continues at the present level of effort.
- At the present time, the R&D needs for an Experimental Test Reactor (ETR)-specific magnet system have not been fully assessed, and hence, the need to build and test prototype ETR coils remains to be determined. In this light, the use of the International Fusion Superconducting Magnet Test Facility for such testing will have to be evaluated relative to the development needs, and other available options for addressing these needs, at that time.

o Argonne National Laboratory -

- The Liquid Metal Test Facility is uncertain, but it is the type of facility that should continue to be considered as a candidate for future funding. This facility is required to advance fusion nuclear technology worldwide. However, only one such facility is required. Therefore, OFE funding for such a facility will be contingent upon specific U.S. responsibilities that evolve from the U.S. participation in the ETR design and R&D process. Until such responsibilities are further defined, ANL should defer more detailed planning for the subject facility.


John F. Clarke
Associate Director
for Fusion Energy
Office of Energy Research

0021252

INSTRUCTIONS FOR PREPARING THE WORK-FOR-OTHERS REPORT
(Report on Non-DOE Funded Work)

.....
Preparation Instructions

I. Management Summary

This section summarizes the WFO program within the subject facility. It explains briefly the trends in the levels of WFO, any anomalies which may have occurred in the past year or two, and the contractor's future plans for WFO.

A discussion should be provided that addresses possible issues and problems in WFO, whether they concern the contractor or arise within the Operations Office. (Problems or issues may relate to the administrative processes by which WFO is reviewed and approved, or to the nature and level of WFO projects.) Corrective measures that have been taken during the past year and areas that need attention in the coming year should be noted in the discussion. The specific recommendation of the Operations Office should be provided for each issue or problem that requires action. A concluding statement should outline the Operations Office's overall perception of the WFO activities. How does the Operations Office rate the general appropriateness of the work, the contractor's management process, and their responsiveness to DOE guidelines?

II. Program Descriptions

This section describes concisely the program effort for major non-DOE sponsors of WFO. The section should be divided into two subsections, Work for Other Federal Agencies and Work for All Others. Projects should be grouped by the sponsoring agency with largest sponsor first. Each project estimated to expend \$1.0 million, or more, in the current year should be listed and its content briefly defined. Lesser projects may be lumped into "miscellaneous" groups and described in general terms. Work for agencies that will provide less than \$1.0 million in the current year may be discussed as a miscellaneous group. However, the agencies involved should be identified and the general nature of the work outlined. The second subsection should provide a similar listing for all other WFO. Information on classified projects should be provided only in a manner and to the extent proper for inclusion in an unclassified public document. Laboratory effort on joint ventures should only be included to the extent that the laboratory is funded by sources outside of the DOE. That is, only those portions of a joint venture for which laboratory effort is paid for by non-DOE partners should be included as WFO. This does not include the value of direct contributions to the project by outside entities.

00212531

The intent of this section is to provide enough definition of the WFO to assure the reviewer that the projects are in general conformance with the provisions of DOE Order 4300.2A, and that they are appropriate to the mission of the laboratory. The project titles used in this section should correspond to those used in the tables. The project descriptions in Table II and Section II are complementary. The table descriptions, although concise, may be sufficient to describe the content of the project. This section may be used to expand the descriptions when necessary and to provide more complete explanations of the nature of miscellaneous groups of small projects.

III. WFO Management Process

The overall WFO management process should be addressed in two parts: the laboratory's review and approval process and the Operations Office review and approval process. A brief discussion of the two processes and their interrelation, with flow charts of the detailed administrative processes, is an excellent way to present this information.

A. The Laboratory System

A step-by-step chart which explains the laboratory's development and management review of WFO proposals should be provided, with any necessary clarifying discussion. The chart should graphically answer the following questions: What level of management review is performed prior to a proposal being submitted to DOE? Is there a central office which controls all aspects of WFO? At what stage is a proposal submitted officially to the sponsor?

B. The Operations Office System

The Operations Office overview should provide a "cradle to grave" explanation of the review and approval of proposals, and the administration of interagency agreements and contracts. An accompanying chart should graphically answer the following questions: Who within the organization reviews the work, and who officially approves the work? Does the Operations Office, or the laboratory execute WFO contracts and interagency agreements? Each of the discussions above should make clear the manner of ensuring that provisions of DOE Order 4300.2A are complied with, and who in each organization provides final authorization to proceed with a proposed WFO project.

C. General

When no significant changes to the WFO management process are made during the year, the descriptive material in this section should ordinarily be supplied as an appendix to the Work for Others report. When changes are made, the section should clearly identify the changes and the reasons for them. If changes are substantial, the section should be moved to the body of the report.

IV. Work for Others Tables

The following tables are required:

- Table 1. Trends in WFO.
- Table 2. Summary of Work-for-Others. This is the information required by DOE Order 4300.2A.
- Table 3. Human or Animal Subjects Research. Identify all ongoing projects involving research on human or animal subjects.
- Table 4. Projects with DOE Added Factor or Depreciation Waived. Identify current projects for which full cost recovery has been waived.

V. Table Formats

TABLE 1
TRENDS IN WORK FOR OTHERS
(\$ in Millions - Estimated Expenditure)
All Values in Operating Dollars

FY 1985 FY 1986 FY 1987 FY 1988 FY 1989

Work for DOE
WFO Federal Agencies
Work for All Others
Subtotal
Work for NRC

Total WFO

Total Laboratory

Procurements % (% of Total WFO \$ used for subcontracts or other procurements)

WFO % (% of total operating \$) - Including NRC Work

WFO % (% of total operating \$) - Excluding NRC Work

TABLE 2
SUMMARY OF WORK FOR OTHERS
(\$ in Millions - Estimated Expenditures)

Facility: Contractor:
Responsible Operations Office:
FY 1985 FY 1986 FY 1987 FY 1988 FY 1989

Total Laboratory WFO

Federal Sponsors:

- Agency #1 (in order of current year estimated expenditure)
 - Project #1 (project name, if \$1.0 M this year)
 - Procurement (amount of procurement if over \$1.0 M any year)
(an Operations Office may elect to use a % of project funding as the criterion for including this item - e.g., over 70% of project funding)
 - Construction (amount of construction if over \$1.2 M any year)
 - Description: ("bullet" description of work content, procurement if listed, construction if listed)
 - Project #2 (same as for #1)
 - Misc. Projects (group of agency #1 projects, each under \$1.0 M in any year)
 - Agency Total (sum of agency expenditures by same categories as for each project)
 - Agency #2 (same as for agency #1, etc.)
- All Other Sponsors:
Organization (provide listing parallel in format to above list)

TABLE 3
HUMAN OR ANIMAL SUBJECTS RESEARCH

SPONSOR PROJECT TITLE FY 1987 EXPENDITURE DURATION
 For all projects currently active, or planned in projected years, that involve human or animal subjects, list sponsoring agency or organization, project title as in WFO descriptions or other tables, funding for FY 1987, and fiscal year of project initiation and planned completion. List all individual projects qualifying regardless of funding level.

0021256

*Forward pg. attached to a file
m... 1/18/87*

TABLE 4
FULL-COST RECOVERY WAIVERS

<u>SPONSOR</u>	<u>PROJECT TITLE</u>	<u>FY 1987 EXPENDITURE</u>	<u>APPROX % WAIVED</u>
<p>List all projects currently active, or planned in projected years, for which full-cost recovery has been <u>waived</u> in full or in part. (Do not include programs or projects which are not normally required to provide full-cost recovery.) Use same project titles as in descriptions or tables. List all individual projects qualifying regardless of funding level. If waiver is partial, specify the approximate percent of cost waived.</p>			

0021257

TABLE #3
HUMAN OR ANIMAL SUBJECT RESEARCH
FUNDED WORK

04/24/87

SPONSOR	PROJECT TITLE	PROPOSAL	FY 1987 FUNDING	PROJECT PERIOD	- SUBJECTS -	
					ANIMAL	HUMAN
HHS	National Toxicology Study	82-09-01	\$565,000.00	09/29/82 - 09/30/87	y	n
HHS	Radiotracer R&D in Nuclear Medicine and Neuroscience	86-02-04	\$415,085.00	12/01/86 - 11/30/87	Y	N
HHS	Radiotracer R&D in Nuclear Medicine and Neuroscience	81-01-05	\$137,000.00	12/01/81 - 11/30/86	Y	-
HHS	Positron Emitters and PETT in Metabolism and Neurology	83-05-12	\$1,682,310.00	09/01/84 - 08/31/87	N	Y
HHS	In vitro radiosensitivity and DNA repair in genetic syndromes and families in high risk of malignancy.	84-12-05	\$310,950.00	10/01/85 - 09/30/87	n	y
HHS	Protocol for mouse bone marrow cytogenetic assay of chemicals	NIH-FY81	\$363,000.00	09/23/81 - 09/30/87	y	n
HHS	Maintenance of DAHL salt-sensitive & salt-resistant rats.	82-12-07	\$276,000.00	05/30/84 - 09/30/87	y	n
American Petroleum Institute	Myelotoxicity of Benzene and Its Metabolites	84-02-13	0-	05/14/85 - 11/14/85	Y	Y

*First WFO Reports
on Human Subjects -
as required by
Institutional Plan*

0021258

TABLE #3
HUMAN OR ANIMAL SUBJECT RESEARCH
UNFUNDED WORK

04/24/87

SPONSOR	PROJECT TITLE	PROPOSAL	PROPOSED FUNDING	PROJECT PERIOD	- SUBJECTS -	
					ANIMAL	HUMAN
Electric Power Research Institute	Are Electric/Magnetic (E/M) Fields Carcinogenic in Mice?	87-01-05	\$1,396,240.00	FY87-FY90	Y	N
HHS	UV Transformation, DNA Repair in Human Cells and Skin	87-02-06	\$1,351,411.00	01/88-12/92	N	Y
HHS	Peptide-Induced Thrombocytopenia and Pulmonary Thrombosis	87-02-05	\$865,500.00	12/87-11/92	Y	N
Winthrop-University Hospital	Prevention of Postmenopausal Bone Loss	87-01-03	\$339,720.00	10/87-09/92	N	Y
North Shore University Hospital	Regional Ventilation/Perfusion Studies in Premature Lambs	87-01-02	\$246,850.00	FY88-FY90	Y	N
SUNY - Stony Brook	Neuroendocrine Systems, PET, Dopamine and Schizophrenia	86-10-01	\$343,943.00	FY88-FY92	N	Y
University of Pennsylvania	Therapeutic Potential of Radiolabeled Monoclonal Antibodies	87-01-04	\$840,850.00	FY88-FY92	Y	N

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